JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY

EVALUATION OF PROPOSED MANDATED HEALTH INSURANCE BENEFITS

Evaluation of House Bill 2877: Mandated Coverage of Human Papillomavirus (HPV) Vaccine

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Laura Lee O. Viergever

JLARC Staff for This Evaluation

Hal Greer, Division Chief
Kimberly A. Sarte, Principal Fiscal Analyst
Jason W. Powell, Principal Legislative Analyst

JLARC provides evaluations of proposed health insurance mandates in accordance with Sections 2.2-2503 and 30-58.1 of the *Code of Virginia*.

This evaluation is available on the JLARC website at http://jlarc.state.va.us

Evaluation of House Bill 2877: Mandated Coverage of Human Papillomavirus (HPV) Vaccine

JLARC SUMMARY

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States; an estimated 6.2 million persons are newly infected every year. Although the majority of infections cause no clinical symptoms, persistent infection with cancer causing types of the virus can result in cervical cancer in women. HPV infection also causes genital warts and is associated with other cancers in both males and females. Gardasil, a vaccine which protects against four strains of HPV, was licensed by the U.S. Food and Drug Administration in June 2006. House Bill 2877 would require health insurers, health care subscription plans, and health maintenance organizations to provide coverage for HPV vaccination for all women and girls aged nine to 26. Separate legislation enacted by the 2007 General Assembly requires that rising sixth grade girls in Virginia public schools receive the vaccine beginning in October 2008.

MEDICAL EFFICACY AND EFFECTIVENESS

The availability of a HPV vaccine offers an opportunity to decrease incidence of HPV infection, cervical and other related cancers, and genital warts in the United States. Several well-designed, clinically-controlled studies have illustrated high overall safety and efficacy in providing prophylactic protection against HPV infection. However, it will be decades before a reduction in cervical cancer incidence rates can be measured.

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SOCIAL IMPACT

Use of the HPV vaccine in Virginia started after FDA approval in 2006, and is expected to increase significantly when legislation goes into effect in 2008 requiring all sixth grade girls attending Virginia public schools to receive the vaccine. In addition, the incidence of cervical cancer has decreased as the availability and utilization of cervical cancer screening has increased. The vaccine is the most expensive of the vaccines currently recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices; however, both private insurance and public payer coverage is extensive. Given the wide availability of both the vaccine and provider coverage, many of the potential benefits of HPV vaccination will likely accrue in the absence of a mandate.

FINANCIAL IMPACT

Because coverage of the HPV vaccine is already widespread, the proposed mandate will not likely impact the overall cost of obtaining the vaccine. The proposed mandate is also not likely to significantly increase the number of females receiving the vaccine; public awareness campaigns and Virginia's vaccination requirement will likely have more of an impact. As a result of decisions by most insurance providers to cover the vaccination, it is anticipated that the impact on providers and total premium costs paid by Virginia's insured would be negligible, and have largely been incorporated into rates currently charged to customers.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

The proposed mandate is consistent with the role of health insurance, as evidenced by the wide availability of coverage through both private and public providers. Medical experts also indicate that the cost of HPV vaccination is far outweighed by the costs of treating cervical cancer. Given the existing availability of coverage, the cost of mandating coverage under HB 2877 would be low. Mandating coverage would also be consistent with current State requirements for vaccination and funding allocated to HPV vaccination programs. However, the wide level of existing coverage of the vaccine suggests that a mandate may not be needed at this time. Additionally, it is unclear if coverage of HPV vaccines other than Gardasil would be included under the current wording of the proposed mandate. While there does not currently appear to be a need for mandating the coverage proposed under HB 2877, it may be prudent to monitor insurance coverage levels and consider whether a mandate is needed should coverage levels decline.

Evaluation of House Bill 2877: Mandated Coverage of Human Papillomavirus (HPV) Vaccine

House Bill 2877 of the 2007 General Assembly would mandate health insurance coverage for the human papillomavirus (HPV) vaccination administered in accordance with recommendations of the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP).

BACKGROUND

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States; an estimated 6.2 million persons are newly infected every year. Although the majority of infections cause no clinical problems, persistent infection with cancer-causing types of the virus can lead to cervical cancer in women. HPV infection also causes genital warts and is associated with other anogenital cancers in both males and females. An HPV vaccine, which protects against four strains of the virus, was licensed by the U.S. Food and Drug Administration (FDA) on June 8, 2006. House Bill 2877 would require health insurers, health care subscription plans, and health maintenance organizations to provide coverage for the HPV vaccination for all women and girls aged nine to 26 in accordance with ACIP recommendations. Separate legislation enacted by the 2007 General Assembly requires rising sixth grade girls in Virginia public schools to receive the vaccine beginning in October 2008, subject to parental opt-out provisions.

a. Description of Medical Condition and Proposed Treatment

An estimated 20 million people in the United States, approximately 15 percent of the population, are currently infected with at least one type of HPV. Almost half of the initial infections occur in those aged 15 to 25. At least half of all sexually active men and women acquire HPV at some point in their lifetime, and research suggests that up to 80 percent of sexually active women will have become infected by age 50. The following section provides background information on HPV, cervical and other anogenital cancers, the HPV vaccine, and requirements for receiving the vaccination.

Human Papillomavirus. HPVs are DNA viruses in the family *Papillomaviridae*. The majority of HPV infection is transient and

asymptomatic and causes no clinical problems; 70 percent of new HPV infections clear within one year, and approximately 90 percent clear within two years. The median duration of new infections is eight months.

Approximately 100 HPV types have been identified, over 40 of which infect the genital area. Genital HPV types are categorized according to their epidemiologic association with cervical cancer. Infections with low-risk types (for example types 6 and 11) can cause benign or low-grade cervical cell changes, genital warts, and respiratory tumors. High-risk HPV types (for example types 16 and 18) can cause low-grade cervical cell abnormalities and act as carcinogens in the development of cervical and other anogenital cancers (Table 1). Persistent infection with high-risk types of HPV is the most important risk factor for cervical cancer precursors and invasive cervical cancer.

HPV infection is primarily transmitted by genital contact, usually through sexual intercourse. In virtually all studies of HPV prevalence and incidence, the most consistent predictors of infection have been measures of sexual activity, most importantly the number of sexual partners (lifetime and recent). The potential for infection increases with the number of lifetime partners. Condom use might reduce the risk for HPV and HPV-associated diseases, as several ongoing studies have demonstrated a protective effect of condoms on acquisition of genital HPV. However, abstaining from sexual activity is the most effective way to prevent genital HPV infection. For those who choose to be sexually active, a monogamous relationship with an uninfected partner is the strategy most likely to prevent HPV infections.

Cervical Cancer. Cervical cancers are abnormal cell growths present in the cervix (the lower, narrower part of the uterus that connects to the vagina) and are the largest category of cancers caused by HPV. It is estimated that more than 11,000 new cases of cervical cancer will be diagnosed in the United States in 2007, and an

Table 1: Cancers Associated with Human Papillomavirus (HPV)

Cancer Site	New U.S. Cases	Attributable to HPV
Cervix	11,820	100 %
Anus	4,187	90
Vulva	3,507	40
Vagina	1,070	40
Penis	1,059	40
Oral cavity and pharynx	29,627	< 12

Source: U.S. Cancer Statistics Working Group. *United States Cancer Statistics: 2003*. US Department of Health and Human Services, Centers for Disease Control and Prevention.

Cervical Cancer Reporting

In the United States, cases of cervical cancer are routinely reported to cancer registries such as the National Cancer Institute, the Virginia Cancer Registry, and the CDC-administered National Program of Cancer Registries.

estimated 3,700 women will die from this disease. Globally, cervical cancer is the second most common cause of cancer deaths in women, with an estimated 510,000 newly diagnosed cervical cancer cases and 288,000 deaths annually.

In 2003, cervical cancer incidence in the United States was 8.1 per 100,000 women, with approximately 11,820 new cases reported. High-risk HPV types are detected in 99 percent of cervical cancers; approximately 70 percent of cervical cancers worldwide are caused by HPV types 16 and 18. The risk for persistence and progression to precancerous lesions varies by HPV type, with HPV 16 being more associated with cervical cancer than other high-risk HPV types.

The time between initial HPV infection and development of cervical cancer is usually decades, with the median age of diagnosis being 47. Although infection with high-risk HPV types is considered necessary for the development of cervical cancer, the majority of women with high-risk HPV infection do not develop cervical cancer. Other factors associated with cervical cancer in epidemiologic studies include cigarette smoking, increased age, other sexually transmitted infections, immune suppression, and long-term oral contraceptive use.

Cervical Cancer Screening and Detection. Cervical cancer can usually be prevented through routine Papanicolaou (Pap) testing, which can detect precancerous lesions of the cervix before they develop into cancer. A Pap test can also show non-cancerous conditions, such as infection or inflammation.

Invasive cervical cancer can usually be cured if it is found early and treated promptly. Cervical cancer incidence rates have decreased approximately 75 percent and death rates approximately 70 percent since introduction of the Pap test in the 1950s. Each year, approximately 50 million women worldwide undergo Pap testing. Since 2003, an estimated 82 percent of women in the United States have had a Pap test. Of the women in the United States who develop cervical cancer, about half have never had a Pap test.

The American College of Obstetricians and Gynecologists and the American Cancer Society have developed guidelines stating that all women should have a Pap test for cervical cancer screening within three years of beginning sexual activity or by age 21, whichever occurs first. Routine follow-up testing is recommended every one to three years. The *Code of Virginia* currently requires insurers to provide coverage for annual Pap tests. Uninsured and underinsured women have access to screenings through the Virginia Breast and Cervical Cancer Early Detection program.

Other HPV-Associated Diseases. In addition to cervical cancer, HPV infection also is associated with anogenital cancers (such as cancer of the vulva, vagina, penis, and anus), anogenital warts, and respiratory papillomas (Table 1). Each of these is less common than cervical cancer. The association of genital types of HPV with non-genital cancer is less well established, but studies support a role in a subset of oral and pharyngeal cancers.

HPV is associated with vaginal and vulvar cancer; however, unlike cervical cancer, not all vaginal and vulvar cancers are associated with HPV. New vulvar cancers number about 3,870 annually (870 deaths), and at least 40 percent of these are HPV-related. HPV is also associated with approximately 90 percent of anal cancers. Anal cancer is diagnosed in about 4,000 people annually (620 deaths) in the United States, and approximately 80 to 90 percent of anal cancers are caused by either HPV16 or HPV18. Variable proportions of penile, vaginal, urethral, and oral cancers have also been found to contain carcinogenic HPV types.

Approximately 1.4 million people in the United States currently have genital warts, and over 500,000 new cases of anogenital warts are diagnosed annually. Anogenital warts are benign growths that often recur within the first six months of initial diagnosis and therefore require repeated treatment sessions. About 90 percent of anogenital warts are caused by HPV types 6 or 11. Approximately ten percent of men and women will develop anogenital warts at some point in their lives. In rare instances, anogenital warts become locally invasive and require extensive surgery for removal.

Infection with low-risk HPV types 6 or 11 can result in recurrent respiratory papillomatosis (RRP), a disease that is characterized by recurrent warts or papillomas in the upper respiratory tract, particularly the larynx. On the basis of age of onset, RRP is divided into juvenile onset (JORRP) and adult onset forms. JORRP, generally defined as onset before age 18, is believed to result from transmission of HPV from mother to baby during delivery. JORRP occurs in about one in 200,000 children under age 18, most before age four, and is characterized by recurrent benign tumors that may lead to respiratory obstruction. Because of the high recurrence rate, multiple surgeries are required to remove warts and maintain an open airway (the median number of surgeries is 13 over a lifetime). The prevalence and incidence of the adult onset form is less clear.

Human Papillomavirus Vaccine. Two HPV vaccines have been developed, although only one has currently received FDA approval. Gardasil (Merck & Co., Inc.) is quadrivalent and protects against HPV types 6, 11, 16, and 18. Cervarix (GlaxoSmithKline) is biva-

lent and protects against types 16 and 18, but offers no protection against the subtypes typically associated with genital warts. The goal of vaccination is to reduce the incidence of HPV-related genital disease, including cervical, penile, vulvar, vaginal, and anal cancers. Additionally, reduction in the incidence of genital warts is expected for those receiving the quadrivalent vaccine and reduction in respiratory papillomatosis is expected among their children.

Gardasil was licensed for use by the FDA on June 8, 2006 (the bivalent vaccine has not yet received FDA approval). The vaccine has no components that adversely impact the safety or efficacy of other vaccinations and can be administered at the same time as other childhood vaccines, such as the Tdap (diphtheria, pertussis, tetanus) and meningococcal conjugate vaccines. However, no data exists on administration of the vaccine with other vaccines except hepatitis B.

Both ACIP and the American Cancer Society have developed recommendations for HPV vaccination among females aged nine to 26 in the United States based on the FDA-approved Gardasil (Exhibit 1). The vaccine is administered by intramuscular injection in a three-dose series with the second and third doses administered at two and six months after the first dose. The minimum recommended interval between the second and third doses of vaccine is 12 weeks.

Exhibit 1: Summary of the American Cancer Society Recommendations for HPV Vaccine Use to Prevent Cervical Cancer

- Routine HPV vaccination is recommended for females aged 11 to 12 years.
- Females as young as age nine years may receive HPV vaccination.
- HPV vaccination is recommended for females aged 13 to 18 years to catch up missed doses or complete the vaccination series.
- Insufficient data currently exist to recommend for or against universal vaccination of females aged 19 to 26 years in the general population. A decision about whether a woman aged 19 to 26 years should receive the vaccine should be based on an informed discussion between the woman and her health care provider regarding her risk of previous HPV exposure and potential benefit from vaccination. Ideally, the vaccine should be administered prior to potential exposure to genital HPV through sexual intercourse because the potential benefit is likely to diminish with an increasing number of lifetime sexual partners.
- HPV vaccination is not currently recommended for women over age 26 years or for males.
- Screening for cervical intraepithelial neoplasia (precancerous growths) and cervical cancer should continue in both vaccinated and unvaccinated women according to current American Cancer Society early detection guidelines.

Source: American Cancer Society.

The 2002 National Survey of Family Growth indicated that 24 percent of females in the United States were sexually active by the age of 15. This percentage increased to 40 percent by age 16 and to 70 percent by age 18. Among sexually active females aged 15–19 and 20–24, the median number of lifetime male sex partners was 1.4 and 2.8, respectively.

According to ACIP and ACS guidelines, the recommended age for vaccination of females is between 11 and 12; however, the vaccine can be administered as young as age nine. Ideally, HPV vaccine should be administered before sexual activity begins, and the duration of protection should extend for many years, providing protection when exposure through sexual activity might occur. However, females under age 26 who might have already been exposed to HPV should also be vaccinated. Sexually active females who have not been infected with any of the HPV types would receive full benefit from vaccination.

For sexually active women who have been infected with HPV, vaccination would provide protection against infection from HPV types not already acquired. However, results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions. Therefore, vaccination is not a substitute for routine cervical cancer screening, and vaccinated females should continue to have cervical cancer screening as recommended.

b. History of Proposed Mandate

House Bill 2877, requiring health insurers, health care subscription plans, and health maintenance organizations to provide coverage for the HPV vaccine, was introduced during the 2007 General Assembly. There is concern, however, that coverage mandated under HB 2877 would not apply to other HPV vaccines approved by FDA without the express recommendation by ACIP. Currently, the bill only covers the quadrivalent vaccine Gardasil on which the ACIP recommendations were developed. Accordingly, the language of HB 2877 may need to be modified to include all drugs approved by FDA, regardless of specific CDC endorsement.

Separate legislation enacted during the 2007 Session and signed by the Governor in April 2007 (HB 2035) requires females attending Virginia public schools to initiate the course of HPV vaccination prior to the entering the sixth grade. The legislation contains a delayed effective date of October 1, 2008, and allows parents or guardians to elect that their child not receive the vaccine. Prior to introduction of this legislation, in 2005, the Governor's Task Force on Cervical Cancer was established to develop strategies for reducing the incidence of cervical cancer in the Commonwealth. The task force recommended that Virginia follow CDC guidelines if an HPV vaccine received FDA approval.

Many other states have some form of HPV legislation under consideration, ranging from educational programs to mandating insurance coverage of the vaccine. As of April 2007, legislation mandating HPV vaccination has been proposed in 24 states. Virginia

and Texas currently have requirements for vaccination before admittance to the sixth grade. The Texas requirement was issued as an executive order of the governor; the legality of this order has been contested by the state's attorney general and the legislature is also considering legislation to override the executive order. Four states (New Mexico, Mississippi, West Virginia, and Kentucky) have defeated bills requiring HPV mandates, and 16 states have current legislation pending. In addition, several other states have withdrawn bills requiring mandates. Each state's bill has a parental opt-out clause, which is similar to that which exists for other required vaccinations.

c. Proponents and Opponents of Proposed Mandate

Proponents and opponents of HB 2877 will have the opportunity to express their views at the Special Advisory Committee on Mandated Health Insurance Benefits public hearing on September 20, 2007. Proponents of the proposed mandate indicate that, even with insurers already providing coverage, mandatory coverage of this vaccine is critical to ensuring that those populations at the highest risk of contracting HPV have access to the vaccine. Organizations such as the American Cancer Society and Planned Parenthood have expressed their support for universal availability of HPV vaccines.

The main opposition to the proposed mandate appears to be from the health insurance industry. Industry representatives that oppose the bill indicate that Virginians already have access to the HPV vaccine because insurers already cover the vaccination. Additionally, advocacy groups have expressed concern that the perception of increased safety resulting from introduction of a HPV vaccine will lead to an increase in sexual activity among adolescents.

MEDICAL EFFICACY AND EFFECTIVENESS

The availability of a quadrivalent HPV vaccine offers an opportunity to decrease HPV infection, cervical and other anogenital cancers, and genital warts in the United States. JLARC staff reviewed the literature and identified several randomized, double-blind, placebo-controlled studies demonstrating the vaccine's safety and efficacy but found few studies of its long-term effectiveness. JLARC staff also contacted medical experts at university health systems in Virginia, who indicated that changes in policy may be expected after long-term effects are known.

a. Medical Efficacy of Benefit

Medical Efficacy

Assessments of medical efficacy are typically based on clinical research, particularly randomized clinical trials, demonstrating the success of a particular treatment compared to alternative treatments or no treatment at all.

Five-year medical efficacy and safety studies, conducted by the vaccine manufacturer, evaluating the success of the vaccine under controlled conditions were required for FDA approval. Historically, FDA approval required an additional five years of safety approval and efficacy studies. In this case, Gardasil was evaluated and approved in six months under FDA's priority review process.

Enrollment criteria for these trials restricted participants' ages (between 15 and 26), number of lifetime sexual partners (two or fewer), and incidence of past infection (none). The studies demonstrated 100 percent efficacy with follow-up data available for up to five years (Table 2). It is important to note that participants in these studies did not violate the protocol and had no previous evidence of infection.

Intention-to-treat (ITT) analyses (conducted by Merck & Co.) in which participants received only one supervised dose of the vaccine have also been conducted. Participants were not screened for previous infection and were not monitored for compliance with the complete three-dose protocol. The efficacy of the vaccine in these studies ranged from 93 to 99 percent for cervical cancer precursors and associated infections. The results of these ongoing analyses will be reported every two years through 2013.

Both Gardasil and Cervarix have had few safety issues during any of the trials. The most common side effects were redness, pain, and swelling at the injection site. The most common adverse experiences reported were fever, headache, and nausea. Serious adverse experiences included one case each of bronchospasm, gastroenteritis, headache with hypertension, joint movement impairment, and vaginal hemorrhage. There were no deaths in the trials considered to be related to the vaccine.

Table 2: Clinical Trials of HPV Vaccines Demonstrate High Efficacy

Study	Participants' Age	Protocol	Efficacy
Gardasil FUTURE II	15-26	Complete	100 %
Gardasil FUTURE I	16-23	Complete	100
Gardasil ITT	15-26	Incomplete[1]	93 - 99
Cervarix	15-25	Complete	100

[1] Incomplete protocols are used in Intention to Treat (ITT) studies in which women were given only one monitored injection of the vaccine and follow-up courses were not monitored.

Sources: U.S. Food and Drug Administration, Centers for Disease Control, American Cancer Society.

b. Medical Effectiveness of Benefit

There are at least two known shortcomings of the current vaccine:

- The vaccine does not protect against all carcinogenic HPV types.
- The vaccine does not protect against pre-existing HPV infections.

Medical Effectiveness

Medical effectiveness refers to the success of a particular treatment in a normal clinical setting as opposed to ideal or laboratory conditions.

Also, additional research is ongoing or needed in several areas:

- duration of vaccine protection and the required length of protection to prevent HPV infection,
- efficacy for prevention of genital warts and anogenital cancers in males of any age,
- effectiveness in long-term reduction of cervical cancer rates; and
- access to, and use of, the vaccine among the medically underserved and uninsured.

Given the restrictions of the clinical populations, data assessing the benefit of HPV vaccination is only available for the targeted population of females aged 15 to 26 and having two or fewer lifetime sexual partners. While studies did not include girls younger than 15, in order to provide vaccination prior to beginning sexual activity the vaccine is recommended for girls as young as nine. This is an important area of research given the recommendation by ACIP and many provider groups for catch-up vaccination of all females aged 13 to 18, the manufacturers' emphasis on vaccinating this age group, and the potential cost of vaccinating such a large cohort. It will be important to review data (beyond the five-year data currently available) from the vaccine trials to assess the impact on younger age cohorts, as well as the impact on the general population of young women that will potentially have had more than an average of two lifetime sex partners. Because the goal of prophylactic immunization is to protect against infection prior to infection occurring, universal vaccination is not warranted for the general population of sexually active women.

Medical experts consulted at two Virginia medical schools indicated that it is important for girls to have access to the HPV vaccine prior to the beginning of sexual activity. According to Virginia public health officials, testing was the same as with other vaccines that have been approved, and it is not practicable to wait 20 years to measure the long-term effect of the drug in reducing the number of cervical cancer cases reported. Moreover, it is reasonable to ex-

pect some change in policy after long-term effects and effectiveness are monitored.

SOCIAL IMPACT

Use of the HPV vaccine in Virginia began with FDA approval in 2006, and is expected to increase significantly when legislation requiring all sixth grade girls attending Virginia public schools to receive the vaccine goes into effect in October 2008. At the same time, the incidence of cervical cancer has decreased as the availability and utilization of cervical cancer screening has increased. The vaccine is the most expensive vaccine currently recommended by ACIP; however both private insurance and public payer coverage is extensive. Given the wide availability of both the vaccine and provider coverage, many of the potential benefits of vaccination will likely accrue. Nonetheless, it is not guaranteed that all fully-insured females seeking vaccination will have insurance coverage for the vaccine.

a. Utilization of Treatment

Provision of the HPV vaccine is coordinated through the Virginia Department of Health's (VDH) Division of Immunization. The vaccine is available both through private providers of pediatric and gynecological services, as well as at local departments of public health and Virginia's community and rural health centers. Through May 2007, local departments of public health in Virginia had ordered 2,610 doses of Gardasil, of which 1,398 have been administered. In addition, 4,900 doses of the vaccine have been provided under the federal Vaccines for Children program to Virginia's rural and community health centers. (Differences between federal and State vaccination programs are explained later in the report.) Moreover, 24,280 doses of the vaccine had been requested and shipped to private physicians during the same period, but data on administration of these doses across the State is limited. Analysis of individuals covered under the State employee health plan indicates that more than 1,300 females between nine and 26 have initiated treatment, and almost 100 have been fully vaccinated.

With the requirement that rising sixth grade girls receive the vaccine, potential short-term demand can be estimated using Virginia Department of Education (DOE) 2006-2007 middle-school enrollment data. Based on DOE enrollment data, there are more than 320,000 girls currently enrolled in Virginia public school grades 6 through 12. For purposes of projecting usage in determining State vaccine supplies, VDH uses only the cohort of girls which will be rising sixth graders in the 2009 school year, estimated to be approximately 43,000.

This data provides a useful basis for estimating the demand for the vaccine, but several factors will affect the actual number of girls seeking vaccination. These factors include the rate at which parents opt out of having their daughters receive the vaccine and the number of girls educated outside of the public school system. Moreover, because this vaccine is recommended for females through age 26 to protect against HPV types to which sexually active women have not been previously exposed, actual demand will likely be higher. Medical experts in Virginia indicated that DOE data would be an acceptable lower threshold for analyzing potential future use of the vaccine, but cautioned that actual usage should be higher.

b. Availability of Coverage

While there are already requirements in the *Code of Virginia* and the State Corporation Commission's Rules Governing Health Maintenance Organizations for coverage of childhood immunizations, HPV vaccination coverage is not currently mandated by statute. However, large health insurance providers in Virginia, including Aetna, Anthem, Cigna, and Southern Health, as well as 30 providers responding to a 2007 survey by the Bureau of Insurance (BOI), currently provide, or intend to provide, some level of coverage for the vaccine. Some providers restrict coverage to females age 11 or older; in accordance with ACIP recommendations, none offer coverage after age 26.

Twenty-four respondents to the BOI survey of the top 50 providers in Virginia indicated that they currently offer coverage of the vaccination as part of their standard benefits package. Of the seven providers indicating that coverage was not available as part of their standard benefits package, five insurers indicated that this coverage was available as an optional benefit, and one provider indicated that they did not currently provide this coverage but intend to make it available prior to January 2008. In addition, one provider does not offer this coverage and one provider intends to reduce the reimbursement level for coverage. Nine respondents indicated that they did not offer coverage options in Virginia to which this mandate would apply and 10 companies (20 percent) did not respond to the BOI survey.

Health care practitioners contacted by JLARC staff could not provide specific examples of individuals who were not able to receive the vaccine. However, while most individuals with private insurance have coverage for the vaccine, some portion of the privately insured do not currently have coverage of through their health insurance carrier.

c. Availability of Treatment/ Benefit

The vaccine has been approved for sale since 2006 and more than 30,000 doses have been distributed in Virginia. The vaccine is currently available through both private physicians and local departments of public health, and there has been no concern over the availability of HPV vaccine. However, there has been no analysis of availability of the vaccine to meet projected needs resulting from the mandate that girls initiate the course of the vaccine prior to entering the sixth grade. JLARC staff did not identify any incidents in which individuals seeking to receive the vaccine were unable to receive it. Therefore, it is not expected that mandated insurance coverage required by HB 2877 would impact the availability of the vaccine.

d. Availability of Treatment Without Coverage

As previously discussed, both the vaccine and coverage of vaccination are widely available, and the primary barrier to receiving the vaccine is social acceptance. While JLARC staff identified one insurance provider not currently providing or intending to provide this benefit, individuals and parents that wish to receive the vaccine may also pay for the vaccine out-of-pocket if desired. As will be discussed, the cost of the vaccine may prove a barrier to some individuals; however, there have been extensive public health efforts at making the vaccine widely available in Virginia.

e. Financial Hardship

The cost of the vaccine may be problematic for some patients, physicians, and insurers. However, the cost of the vaccine is relatively modest compared to other health care costs. The current cost to physicians for stocking the vaccine is approximately $120 per dose ($360 for a full three-dose course) while the actual cost to the consumer is closer to $180 per dose ($540 for a full three-dose course). The cost of the HPV vaccine exceeds the cost of most childhood vaccinations by as much as $100 or more (Table 3).

Because of the high cost, it has been argued that some private physicians may not stock the vaccine; private pediatricians are the most affected by these potential cost constraints given the large stock of vaccines in which they are required to invest prior to reimbursement. Some private physicians may refer children to local departments of public health for HPV vaccination. However, as evidenced by VDH data on vaccine distribution it does not appear that private physicians are resistant to stocking the vaccine. Moreover, 72 percent of providers responding to a May 2007 survey of Virginia obstetricians, gynecologists, and family practitioners conducted by the University of Virginia Medical Center repor-

Table 3: HPV Vaccine Exceeds Cost of Other Childhood Vaccinations

Vaccine	Diseases Targeted	Doses Per Course	Estimated Cost Per Course for Private Physicians
HPV	Cervical Cancer, Genital Warts	3	$ 360
PCV7	Meningitis, Pneumonia	4	277
Rotavirus	Diarrheal Disease	3	190
Influenza	Influenza	5-6	120
DTaP/DTwP	Diphtheria, Pertussis, Tetanus	5	105
Varicella	Chickenpox	2	104
Polio	Polio	4	91
Hib	Haemophilus Influenzae Type B	4	90
MCV4	Meningitis	1	82
MMR	Measles, Mumps, Rubella	1-2	81
Hepatitis B	Hepatitis B	3	64
Hepatitis A	Hepatitis A	2	61
Td/Tdap	Diphtheria, Pertussis, Tetanus	1-2	36

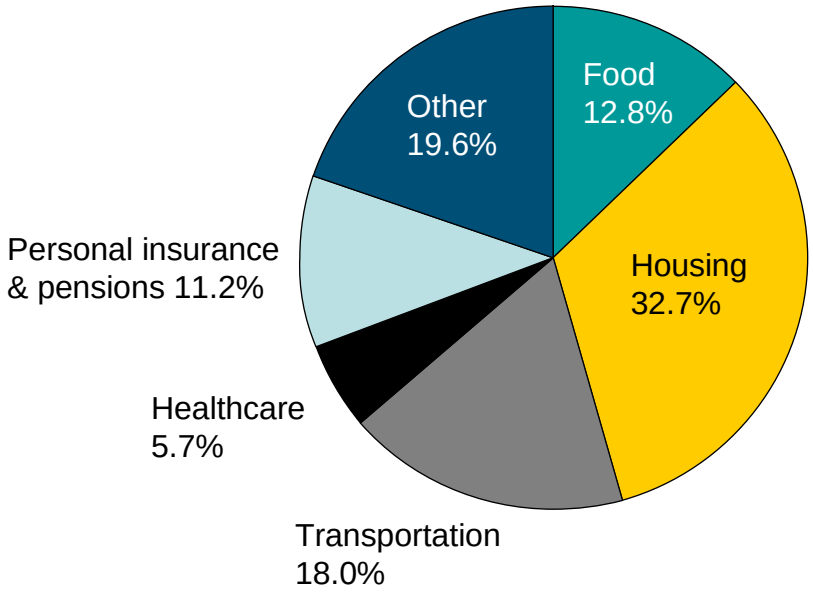
Source: *New York Times*, University of Wisconsin School of Medicine and Public Health, 2006.

ted that they currently offer the vaccine in their practices, and 84 percent of respondents believed that the vaccine should be stocked and provided despite its high cost.

The financial hardship for individuals seeking HPV vaccine would be greatest for those that do not currently have coverage and elect to pay for the vaccine out-of-pocket as opposed to receiving free vaccination at a local public health clinic. These individuals would be responsible for the full amount of charges for the vaccine. Based on a median household income of $56,859 in Virginia in 2007, the cost of obtaining the full three-dose course of the vaccination (estimated at $540) without insurance coverage is approximately 0.9 percent of median household income. However, the cost for a family with more than one eligible child could be substantially higher.

While the cost of the vaccine is higher than other childhood vaccinations, its cost is relatively modest compared to other medical expenses. As shown in Figure 1, annual individual health care costs are estimated to be approximately 5.7 percent of median household income (approximately $3,241 in Virginia). Therefore, the cost of the vaccine would equal approximately 17 percent of annual individual health care expenditures.

Figure 1: Distribution of Total Annual U.S. Household Expenditures by Major Category, 2005



Source: Bureau of Labor Statistics, Consumer Expenditure Survey, 2005.

f. Prevalence/ Incidence of Condition

The occurrence of HPV is not routinely reported in the United States. Information on HPV prevalence and incidence has been obtained primarily from evaluations of clinic-based populations, such as patients of family planning and sexually transmitted disease or university health clinics. These evaluations have documented the prevalence of HPV in clinical settings as ranging from 14 to 90 percent. Prevalence was highest among sexually active females under 25 and decreased with increasing age. Data from one multi-site, clinic-based study of sexually active women in the United States indicated that prevalence was highest among those aged 14 to 19. Overall in the United States, an estimated 6.2 million new HPV infections occur every year among persons aged 14 to 44. Of these, 74 percent occur among those aged 15 to 24. Statistical analysis suggests that more than 80 percent of sexually active women will have acquired genital HPV by age 50.

Major challenges in tracking the occurrence of HPV in Virginia are underreporting due to the relatively mild symptoms of the infection and limited information collected on the prevalence of some sexually transmittable diseases, such as genital warts. Given the lack of reporting of most HPV cases and the wide range of infection

rates in clinical observations, it is not practical to generalize from available Virginia data about the prevalence of HPV among individuals in Virginia.

There is, however, information available on the prevalence of cervical cancer across Virginia communities. The cervical cancer incidence rate in Virginia is relatively low compared to the national average. Nationwide, the cervical cancer incidence rate between 2000 and 2003 was 8.8 per 100,000. The cervical cancer incidence rate in Virginia between the years 2000-2004 was 7.1 per 100,000.

A report on the differences in cervical cancer incidence rates for minorities in Virginia is being presented to the Joint Commission on Health Care at its meeting on September 19, 2007.

In addition, medical experts in Virginia emphasize that the occurrence of cervical cancer in Virginia is region- and population-specific with higher incidence rates occurring in minority populations. Based on national data, there are substantial differences in cervical cancer incidence and mortality rates among different populations. Incidence and mortality rates are 1.5 to 2 times higher for minority women than white women. National mortality rates for cervical cancer are 2.5 per 100,000 for all women. Geographic differences exist in incidence and mortality, with notably higher incidence and mortality in Southern states and the Appalachian region.

The development of invasive cervical cancer (HPV acquisition, HPV persistence, development of cancer precursors, and invasion) takes 20 years on average, with the longest amount of time from development of high-grade cervical lesions to invasive cancer, although there are cases that develop more rapidly. Because of the extended length of time between HPV infection and development of cervical cancer, it will be many years before it will be possible to observe a reduction in cancer incidence within the vaccinated population. Since no single empirical study can address all policy questions involving vaccination and screening, mathematical models that simulate the natural history of disease and that integrate the best available clinical and economic data can be used to estimate the potential cost-effectiveness of different strategies.

g. Demand for Coverage

As JLARC the majority of insurance providers in Virginia are providing, or intending to provide, coverage of HPV vaccination, and the vaccine is readily available through local public health departments, the need for a mandated coverage requirement appears to be low. However, as previously discussed, demand for the vaccine will likely increase as the result of Virginia's requirement that rising sixth grade girls receive the vaccine. Indeed, mandating HPV vaccination statewide has likely influenced insurers' decisions to provide coverage as part of their basic benefits package, similar to coverage of the hepatitis B vaccination.

h. Labor Union Coverage

Labor unions do not appear to have advocated specifically for the inclusion of this benefit in their health benefit packages. Typically, labor unions advocate for broader benefits, rather than a benefit as specific as the proposed mandate.

i. State Agency Findings

In January 2005, the Governor issued Executive Directive 5 which established the Governor's Task Force on Cervical Cancer with responsibility for identifying cervical cancer incidence, mortality, and epidemiology in Virginia. The task force evaluated information related to HPV transmission and vaccinations. Among other findings, the task force recommended that Virginia develop a program for actively promoting cervical cancer awareness and follow-up reporting on cervical cancer incidence, and encouraged Virginia to develop strategies to adopt recommendations of the CDC once they were available.

The Virginia Department of Health intends to provide a status report on HPV vaccine usage to the Joint Commission on Health Care at its meeting on October, 17, 2007.

j. Public Payer Coverage

The federal Vaccines for Children (VFC) program supplies vaccines to all states, territories, and the District of Columbia for uninsured, underinsured, and Medicaid-enrolled children through age 19. All routine childhood vaccines recommended by ACIP are available through this program, including the HPV vaccine, without cost to the patients or the provider. The program saves patients and providers out-of-pocket expenses for vaccine purchases and provides cost savings to states through CDC vaccine contracts.

In Virginia, the VFC program is funded through grants, with direct federal funding used for the purchase of vaccines. Local departments of public health, as well as participating private physicians, request vaccine supplies through VDH, which reviews the orders and obtains the vaccine through the CDC contract. To receive a free vaccination under the VFC program, the vaccine must be administered at a community health center; there are approximately 60 of these facilities in Virginia, mainly in rural areas. VDH staff estimate that 40 percent of children in Virginia are eligible for the free VFC program. Of the children receiving the vaccination at public health centers, approximately 70 percent are VFC eligible.

The 2007 General Assembly included $1.4 million in general funding in the 2006-2008 Appropriation Act to expand the availability of free HPV vaccinations and supply local public health departments with the vaccine for girls and women who are ineligible for the federally funded program and not expected to receive the vaccine from private health insurance. VDH staff estimate that expanding the program to cover all girls mandated to receive the vaccine would require approximately $12 to $13 million annually. VDH is currently developing a policy for distributing available funding. One option being considered is to charge those who have some insurance coverage (currently it will be provided free of charge); however, VDH does not want to compete with the private sector. Additionally, women aged 20 to 26 with incomes up to 133 percent of the federal poverty level are eligible for coverage through Virginia's Medicaid program if a prescription for the vaccine is provided.

k. Public Health Impact

Although cervical cancer is not highly prevalent or a leading cause of mortality in Virginia when compared to other conditions, the proposed mandate could have an impact on public health. However, many of the benefits of the HPV vaccine may accrue even in the absence of the mandate due to both the general availability of the vaccine and coverage through private and public providers. As new iterations of the vaccine are developed to address different HPV types, the reduction of cervical cancer risk by 70 percent or more becomes a possibility depending on the number of carcinogenic HPV types eventually included in the HPV vaccine and on the percent of the population vaccinated. In addition, the vaccine could help reduce incidence and mortality rates across racial and ethnic groups.

There are factors that may limit the public health impact, at least in the short term. As evidenced by experience in introducing the hepatitis B vaccine, many adolescents do not receive annual health exams. Under the best circumstances, it will be decades before vaccinating girls will have a measurable impact on cervical cancer rates.

FINANCIAL IMPACT

Because health insurance coverage of the HPV vaccine is already widespread, the proposed mandate will not likely impact the overall cost of obtaining the vaccine. The proposed mandate is also not likely to significantly increase the number of individuals receiving the vaccine; public awareness campaigns and Virginia's requirement that rising sixth grade girls receive the vaccine will likely

have more of an impact. As a result of decisions by most insurance providers to cover the vaccination, it is anticipated that the impact on providers and total premium costs paid by Virginia's insured will be negligible. However, as the vaccine has been demonstrated to provide protection against cervical cancer, it has been estimated that use of the vaccine could reduce the total cost of health care nationally for treatment of cervical and other anogenital cancers by as much as $530 million annually.

a. Effect on Cost of Treatment

As Gardasil has been approved for use by the FDA, recommended by ACIP, and already covered by most insurance providers, the proposed mandate is not anticipated to have an impact on the overall cost of vaccination. There is the potential that FDA approval of Cervarix could decrease costs to physicians by introducing market competition. However, both vaccines would be under patent restrictions for several years, limiting the effect of market competition from generic drug manufacturers.

b. Change in Utilization

There may be a slight increase in the number of patients seeking HPV vaccination as a result of this mandate. However, extensive public awareness campaigns by VDH, public health organizations, and the drug manufacturer will likely have a more substantial impact on HPV vaccine usage in Virginia. Public health professionals in Virginia indicated that without mandated coverage, some individuals may have to pay for the vaccination out-of-pocket. Virginia public health officials believe that without mandated coverage, there is the potential that local public health clinics could become the primary providers of the vaccination for privately insured individuals, although insurance providers currently cover HPV vaccination.

c. Serves as an Alternative

Given the effectiveness of the vaccine in preventing the most oncogenic types of HPV, vaccination appears to be a viable method for preventing cervical cancer and other diseases related to HPV-infection which are more costly to treat. Studies have suggested that vaccination of an entire cohort of females aged 12 years could reduce the lifetime risk for cervical cancer by 20 to 66 percent in that cohort, depending on the efficacy of the vaccine and the duration of vaccine protection. Projections that incorporate HPV transmission dynamics suggest an even greater potential impact of HPV vaccination on cervical cancer and cervical cancer precursors. In the short term, vaccination will not replace routine cervical cancer

screening, and the most effective means to prevent contracting HPV is abstaining from sexual activity.

d. Effect on Providers

Mandating insurance coverage of the HPV vaccination is not expected to significantly increase the number of pediatricians, obstetricians, and gynecologists that currently offer the HPV vaccine. However, the high cost of stocking the vaccine would be offset by requirements for reimbursement by health insurance carriers. The increase in providers is expected to be minimal because the majority of Virginia's pediatricians, obstetricians, and gynecologists currently offer HPV vaccination, and insurance providers already offer coverage. Moreover, the impact of the mandate on providers would likely be reduced by the requirement that girls entering the sixth grade receive the vaccine beginning in 2008.

e. Administrative and Premium Costs

Administrative costs of the proposed mandate would likely be similar to other mandates. The impact on premiums would probably be less than most existing mandates. However, as mentioned previously, most insurance companies already provide coverage for the vaccine. If coverage is already provided, there should be little if any increase in premiums as a result of the mandate.

Administrative Expenses of Insurance Companies. The administrative expenses for insurance companies would likely be similar to other mandates. Insurance companies do not provide estimates on the administrative expenses separately in their responses to the BOI survey.

Premium and Administrative Expenses of Policyholders. BOI annually surveys a sample of Virginia health insurers on the premium impact of proposed mandates. In 2007, the top 50 health insurance providers in Virginia were surveyed. While an overall response rate to the survey of 80 percent (40 companies) was achieved, a relatively small number of insurance companies provided estimated monthly premium costs for HB 2877, which may limit the usefulness of the estimates. In addition, the estimates varied widely with considerable differences between individual and group policyholders (Table 4). If coverage is already provided, there should be minimal or no increase in individual premium costs as a result of the mandate.

Among the 30 insurance companies indicating that coverage was available as part of either standard or optional packages, not all provided an estimate of monthly premium costs. Nine companies

Table 4: Estimated Monthly Premium Impact of HB 2877

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Individual (standard)	9	$ 1.00	$ 6.21	$ 0.15
Individual (optional)	3	$ 0.68	$ 5.00	$ 0.68
Group (standard)	15	$ 2.20	$ 5.41	$ 0.01
Group (optional)	3	$ 0.61	$ 2.68	$ 0.61

Source: Bureau of Insurance Survey of Insurance Providers, 2007.

provided an estimate for individual policyholders and fifteen companies provided an estimate for group certificate-holders (Table 4). Contributing to the low response rate for individual coverage are those companies that do not serve the individual market, companies that no longer provide services in Virginia, and those unable to separate the costs of the proposed mandate because the benefit is already provided.

The median monthly premium estimates for coverage as part of a standard individual coverage option is around $1.00 per month and the estimate for standard group coverage is approximately $2.20. As only six providers indicated that this coverage is available as optional, data on the median costs for coverage under this option is limited. Optional individual coverage is estimated to cost $0.68 per month and optional group coverage is estimated at $0.61.

Average Individual Insurance Premiums

In October 2006, the State Corporation Commission's Bureau of Insurance reported average annual individual health insurance premiums with current mandated benefits of $2,573 - approximately $214 per month

A median individual premium increase of $0.68 to $1.00 would result in a monthly premium increase between 0.32 percent and 0.47 percent based on the estimated average monthly premium cost for a single coverage, individual contract, as defined in BOI's 2005 report on the financial impact of mandated health insurance benefits. This compares to the premium impacts of existing mandates, which range from 0.06 to 1.26 percent for single coverage individual contracts. Data is not available on the monthly premium estimate for group plans, so it is not possible to calculate the percent increase in premium costs resulting from this mandate. The BOI estimates that mandates currently contribute approximately $355 (13.8 percent) to average annual premium costs.

f. Total Cost of Health Care

The proposed mandate may have a slight impact on the total cost of health care in the short term because the vaccine is relatively expensive and is a new service available to patients. However, given that insurers already provide coverage for the vaccination

and the demonstrated efficacy of the vaccine, there is the potential to reduce the long-term epidemiologic consequences and overall health care costs for the treatment of cervical cancer and other related diseases. The CDC has found HPV vaccination to be cost effective because of the high prevalence of HPV, especially in the initial two to five years after onset of sexual activity, and the high cost incurred in the treatment of HPV-related conditions. In 2000, the Institute of Medicine found that with a 100 percent effective vaccine and with 100 percent coverage, the costs associated with cervical cancer, penile cancer, and genital warts could be reduced by as much as $530 million annually.

Limited information is available on the costs of HPV infection and related cervical cancer in Virginia. The 2005 *Report of the Governor's Task Force on Cervical Cancer* estimated that more than $3 billion was spent nationally on HPV-related treatments and $737 million on related cervical cancer treatments in 1994 (Table 5). Estimates of the cost of treatment for Virginia residents are not directly available; however, for State employees, more than $1.6 million has been spent since 2001 for treatment of cervical cancer in 180 individuals.

Table 5: Estimated National Costs of Selected Sexually Transmitted Infections, 1994

Sexually Transmitted Infections	Estimated Annual Cost ($ millions)
Sexually transmitted HIV	$ 6,683
Pelvic Inflammatory Disease	4,140
HPV	**3,826**
Chlamydia	2,013
Gonorrhea	1,051
Cervical Cancer	**737**
Herpes Simplex	237
Hepatitis B	156

Source: Report of the Governor's Task Force on Cervical Cancer. November, 2005.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

The proposed mandate is consistent with the role of health insurance, as evidenced by the wide availability of coverage through both private and public providers. Medical experts also indicate that the cost of HPV vaccination is far outweighed by the costs of treating cervical cancer. Given the existing availability of coverage, the cost of mandating coverage under HB 2877 would be low. Mandating coverage would also be consistent with current State requirements for vaccination and funding allocated to HPV vaccination programs. However, the wide level of existing coverage of

the vaccine (nearly all insurers responding to a BOI survey and all insurers represented by the Virginia Association of Health Plans) suggests that a mandate may not be needed at this time. Additionally, it is unclear if coverage of HPV vaccines other than Gardasil would be included under the current wording of the proposed mandate. While there does not currently appear to be a need for mandating the coverage proposed under HB 2877, it may be prudent to monitor insurance coverage levels and consider whether a mandate is needed should coverage levels decline.

a. Social Need/ Consistent With Role of Insurance

Based on the premise that the role of health insurance is to promote public health, encourage the use of preventive care, and provide protection from catastrophic financial expenses for unexpected illnesses, the proposed mandate appears consistent with the role of health insurance given the preventive nature of HPV vaccination. Consistency with the role of insurance is further illustrated by the decision of most insurers' responding to the BOI survey to provide coverage of the HPV vaccine, as well as extensive State and federal efforts at making the vaccine available to uninsured and underinsured individuals. There is, however, the potential that a small number of insurers not responding to the BOI survey may not offer this coverage.

b. Need Versus Cost

The cost of treating some HPV infections, as well as cervical cancer and other associated diseases are considerable, and the reduction in these costs is desirable. As evidenced by the substantial number of insurers currently electing to provide this coverage as part of their standard or optional coverage packages, it is likely that the short-term costs of providing HPV vaccination will eventually decrease the overall costs for treatment of cervical cancer and other related diseases, although long-term efficacy data is not available.

The costs of mandating coverage of HPV vaccination would be low because most insurers are already providing this coverage and have incorporated these costs into current premium rates. Additionally, mandating coverage under HB 2877 would be consistent with both the State's current requirements for vaccination and general funding allocated to HPV vaccination programs. Mandating this benefit has the potential to increase the proportion of vaccinations provided by private practitioners and reduce the number of individuals referred by private physicians to public health clinics for the vaccination in cases where individuals or their employer have not selected coverage of the benefit when provided as optional coverage. However, as indicated, the vaccine is already widely

available, and these benefits will likely accrue without mandated coverage.

The need for mandated coverage is largely reduced by the extensive availability of private coverage. Additionally, the availability of public coverage for the vaccine may also serve to limit the need for mandated coverage under HB 2877, as options for individuals to obtain this coverage are numerous. Given the current level of coverage, it does not appear necessary to impose a mandate at this time. However, given the value in making the HPV vaccine available to as many Virginians as possible, it may be prudent to monitor insurance coverage levels and reconsider the need for a mandate or a mandated offer should insurance companies reduce or eliminate vaccine coverage, as one provider has already announced its intention to do. If a mandate is to be further considered, then consideration should be given to modifying the language of the requirement in order to ensure that coverage of all HPV vaccines approved by the FDA is available.

Mandated Offer

A mandated offer requires health insurers to offer for purchase the coverage described in the mandate for an additional fee.

c. Mandated Offer

Because of the prevalence of the condition, a mandated offer would allow individuals in plans without coverage to purchase this coverage, but would not impose additional costs on individuals for which coverage is not necessary. However, based on the BOI survey, it appears that nearly all plans are already providing, or intend to provide, coverage as a standard or optional benefit. Additionally, requiring insurance providers to offer this benefit may have the potential of reducing the number of insurers that offer this benefit as part of their standard benefits package. As previously stated, it may be prudent to monitor current coverage levels and consider a mandated offer if coverage levels decrease.

ACKNOWLEDGMENTS

JLARC staff would like to acknowledge the expertise, assistance, and information provided by staff at Virginia Commonwealth University Medical Center and the University of Virginia Health System. JLARC would also like to thank Dr. Robert Valdez, President of Valdez and Associates, for his suggestions and expertise as a public health consultant. In addition, JLARC would like to thank the Virginia State Corporation Commission Bureau of Insurance, the Virginia Association of Health Plans, and the Department of Human Resources Management.

Appendix A

Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

§ 2.2-2503. Special Advisory Commission on Mandated Health Insurance Benefits; membership; terms; meetings; compensation and expenses; staff; chairman's executive summary.

A. The Special Advisory Commission on Mandated Health Insurance Benefits (the Commission) is established as an advisory commission within the meaning of § 2.2-2100, in the executive branch of state government. The purpose of the Commission shall be to advise the Governor and the General Assembly on the social and financial impact of current and proposed mandated benefits and providers, in the manner set forth in this article.

B. The Commission shall consist of 18 members that include six legislative members, 10 nonlegislative citizen members, and two ex officio members as follows: one member of the Senate Committee on Education and Health and one member of the Senate Committee on Commerce and Labor appointed by the Senate Committee on Rules; two members of the House Committee on Health, Welfare and Institutions and two members of the House Committee on Commerce and Labor appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; 10 nonlegislative citizen members appointed by the Governor that include one physician, one chief executive officer of a general acute care hospital, one allied health professional, one representative of small business, one representative of a major industry, one expert in the field of medical ethics, two representatives of the accident and health insurance industry, and two nonlegislative citizen members; and the State Commissioner of Health and the State Commissioner of Insurance, or their designees, who shall serve as ex officio nonvoting members.

C. All nonlegislative citizen members shall be appointed for terms of four years. Legislative and ex officio members shall serve terms coincident with their terms of office. All members may be reappointed. However, no House member shall serve more than four consecutive two-year terms, no Senate member shall serve more than two consecutive four-year terms, and no nonlegislative citizen member shall serve more than two consecutive four-year terms. Vacancies occurring other than by expiration of a term shall be filled for the unexpired term. Vacancies shall be filled in the manner as the original appointments. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment.

D. The Commission shall meet at the request of the chairman, the majority of the voting members or the Governor. The Commission shall elect a chairman and a vice-chairman, as determined by the membership. A majority of the members of the Commission shall constitute a quorum.

E. Legislative members of the Commission shall receive such compensation as provided in § 30-19.12, and nonlegislative citizen members shall receive such compensation for the performance of their duties as provided in § 2.2-2813. All members shall be reimbursed for all reasonable and

necessary expenses incurred in the performance of their duties as provided in §§ 2.2-2813 and 2.2-2825. Funding for the compensation and costs of expenses of the members shall be provided by the State Corporation Commission.

F. The Bureau of Insurance, the State Health Department, and the Joint Legislative Audit and Review Commission and such other state agencies as may be considered appropriate by the Commission shall provide staff assistance to the Commission. The Joint Legislative Audit and Review Commission shall conduct assessments, analyses, and evaluations of proposed mandated health insurance benefits and mandated providers as provided in subsection D of § 30-58.1, and report its findings with respect to the proposed mandates to the Commission.

G. The chairman of the Commission shall submit to the Governor and the General Assembly an annual executive summary of the interim activity and work of the Commission no later than the first day of each regular session of the General Assembly. The executive summary shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

§ 30-58.1. Powers and duties of Commission.

The Commission shall have the following powers and duties:

A. Make performance reviews of operations of state agencies to ascertain that sums appropriated have been, or are being expended for the purposes for which such appropriations were made and to evaluate the effectiveness of programs in accomplishing legislative intent;

B. Study on a continuing basis the operations, practices and duties of state agencies, as they relate to efficiency in the utilization of space, personnel, equipment and facilities;

C. Make such special studies and reports of the operations and functions of state agencies as it deems appropriate and as may be requested by the General Assembly;

D. Assess, analyze, and evaluate the social and economic costs and benefits of any proposed mandated health insurance benefit or mandated provider, including, but not limited to, the mandate's predicted effect on health care coverage premiums and related costs, net costs or savings to the health care system, and other relevant issues, and report its findings with respect to the proposed mandate to the Special Advisory Commission on Mandated Health Insurance Benefits; and

E. Make such reports on its findings and recommendations at such time and in such manner as the Commission deems proper submitting same to the agencies concerned, to the Governor and to the General Assembly. Such reports as are submitted shall relate to the following matters:

1. Ways in which the agencies may operate more economically and efficiently;

2. Ways in which agencies can provide better services to the Commonwealth and to the people; and

3. Areas in which functions of state agencies are duplicative, overlapping, or failing to accomplish legislative objectives or for any other reason should be redefined or redistributed.

Appendix B

Proposed Mandated Benefit Requiring Coverage of the Human Papillomavirus (HPV) Vaccine

HOUSE BILL NO. 2877

Offered January 10, 2007

Prefiled January 10, 2007

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for the human papillomavirus vaccinations.

Patrons-- McEachin and McClellan; Senator: Lucas

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for human papillomavirus vaccinations.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a healthcare plan for healthcare services shall provide coverage for the cost of human papillomavirus vaccinations for women in accordance with recommendations of the Center for Disease Control's Advisory Committee on Immunization Practices.

B. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, fee, policy year or calendar year, or durational benefit limitation or maximum for benefits or services that is not equally imposed upon all individuals in the same benefit category.

C. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2008, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

D. This section shall not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, nor to policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.14~~ *38.2-3418.15*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.09:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13 through 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

Appendix C

Evaluation Topic Areas and Criteria for Assessing Proposed Mandated Health Insurance Benefits

Topic Area	Criteria
1. Medical Efficacy	
a. Medical Efficacy of Benefit	The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any clinical research, especially randomized clinical trials, demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.
b. Medical Effectiveness of Benefit *JLARC Criteria**	The contribution of the benefit to patient health based on how well the intervention works under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather a more flexible intervention that is often used in broader populations.
c. Medical Efficacy of Provider	If the legislation seeks to mandate coverage of an additional class of practitioners: 1) The results of any professionally acceptable research, especially randomized clinical trials, demonstrating the medical results achieved by the additional class of practitioners relative to those already covered. 2) The methods of the appropriate professional organization to assure clinical proficiency.
d. Medical Effectiveness of Provider *JLARC Criteria**	The contribution of the practitioner to patient health based on how well the practitioner's interventions work under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather more flexible interventions that are often used in broader populations.
2. Social Impact	
a. Utilization of Treatment	The extent to which the treatment or service is generally utilized by a significant portion of the population.
b. Availability of Coverage	The extent to which insurance coverage for the treatment or service is already generally available.
c. Availability of Treatment *JLARC Criteria**	The extent to which the treatment or service is generally available to residents throughout the state.
d. Availability of Treatment Without Coverage	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.
e. Financial Hardship	If the coverage is not generally available, the extent to which the lack of coverage result in unreasonable financial hardship on those persons needing treatment.
f. Prevalence/Incidence of Condition	The level of public demand for the treatment or service.
g. Demand for Coverage	The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

h. Labor Union Coverage	The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.
i. State Agency Findings	Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.
j. Public Payer Coverage *JLARC Criteria**	The extent to which the benefit is covered by public payers, in particular Medicaid and Medicare.
k. Public Health Impact *JLARC Criteria**	Potential public health impacts of mandating the benefit.
3. Financial Impact	
a. Effect on Cost of Treatment	The extent to which the proposed insurance coverage would increase or decrease the cost or treatment of service over the next five years.
b. Change in Utilization	The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.
c. Serves as an Alternative	The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.
d. Impact on Providers	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.
e. Administrative and Premium Costs	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.
f. Total Cost of Health Care	The impact of coverage on the total cost of health care.
4. Effects of Balancing Medical, Social, and Financial Considerations	
a. Social Need/Consistent with Role of Insurance	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.
b. Need Versus Cost	The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.
c. Mandated Option	The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policy holders.

*Denotes additional criteria added by JLARC staff to criteria adopted by the Special Advisory Commission on Mandated Health Insurance Benefits.

Source: Special Advisory Commission on Mandated Health Insurance Benefits and JLARC staff analysis.

Appendix D

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PEER-REVIEWED RESEARCH

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Joint Legislative Audit and Review Commission
Suite 1100
General Assembly Building
Capitol Square
Richmond, Virginia 23219
804-786-1258 Fax 804-371-0101
http://jlarc.state.va.us