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FISCAL IMPACT REPORT

ORIGINAL DATE 01/29/08
 SPONSOR Komadina LAST UPDATED 2/10/08 HB _____
 SHORT TITLE Cervical Cancer & HPV Vaccine Information SB 244/aSJC
 ANALYST Geisler

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY08	FY09		
	\$25.0	Recurring	General

(Parenthesis () Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From

Department of Health (DOH)
 Health Policy Commission (HPC)

SUMMARY

Synopsis of SJC Amendment

The Senate Judiciary Committee amendments to Senate Bill 244 strike the requirement that female students entering the sixth grade receive the HPV vaccine before being admitted to school or submit notice of electing not to receive the HPV vaccine.

Synopsis of Original Bill

Senate Bill 244 would provide for parents or guardians of female students ages nine to fourteen years of age to receive educational information about cervical cancer and the human papillomavirus (HPV) vaccine. SB 244 would task the Public Health Division of the Department of Health (DOH), after consultation with the Public Education Department, with prescribing the content and means of distribution of this educational information.

SB 244 would also make HPV vaccine a requirement for female students entering the sixth grade with an option for the parent or guardian to submit notice of electing not to receive the vaccine. SB244 would appropriate \$25,000 to DOH from the general fund for expenditure in FY09 and FY10 to defray the costs for the content and distribution of the educational information. Any unexpended balance remaining at the end of FY10 would revert to the general fund.

FISCAL IMPLICATIONS

The funding in SB 244 is not a part of the Executive Budget Request. SB 244 would appropriate \$25,000 to DOH to be expended in FY09 and FY10. DOH notes that the federal Vaccines for Children (VFC) program is an entitlement program that provides vaccines to children ages 0-18 years of age who are on Medicaid, uninsured, underinsured or Native American. Approximately 70% of New Mexican 6th grade girls would receive HPV vaccine funded by the federal VFC program (at an estimated cost of \$2.8 million per year). New Mexico is a "universal-vaccine" state, meaning HPV vaccine for the other 30% of New Mexican 6th grade girls would have to be funded through state and MCOs (at an estimated cost of \$1.5 million per year).

SIGNIFICANT ISSUES

Certain HPVs cause cancer of the uterine cervix and pre-cancerous changes called "cervical dysplasia". Until recently, there has been no prevention for this disease and "Pap smear" screening has been relied upon to detect the cellular abnormalities of cervical dysplasia and providing treatment before it deteriorates into cervical cancer. Recently, FDA has licensed a vaccine that is effective in preventing infection with HPV types 16, 18, 6 and 11 responsible for approximately 70 percent of cervical dysplasia and cancer. In the near future, a second HPV vaccine is expected to be licensed by FDA. Clinical trials data indicate that these vaccines are highly effective at preventing HPV infections and cervical dysplasia if they are administered before a young woman becomes infected with these HPVs. Most young women become infected with these HPVs within several months of initiating sexual activity. These vaccines have not been demonstrated to be effective in eliminating HPV infections or cervical dysplasia once a woman has acquired the infections that cause them. Therefore, it is important that the vaccine be administered before a woman first becomes sexually active. Even though a woman receives HPV vaccine, she should still receive regular, recommended Pap smears.

An educational brochure for parents on the HPV vaccine has already been developed by DOH clinicians and health educators, and distributed by DOH regional staff to girls ages 11 and 12 and their families throughout the state during the current school year.

Although SB 244 allows a written opt-out, DOH opposes a mandatory requirement to receive the HPV vaccine for girls entering the sixth grade.

School entry requirements place a strong state imprimatur upon vaccines. A state sanctioned school entry requirement communicates strongly that the state believes that the individual and public health benefits of the vaccine are so compelling, and that the risks of the vaccine are sufficiently understood, that the state should influence the individual's decision to be vaccinated or not. There are specific justifications for imposing school entry requirements. First, a vaccine that significantly decreases the risk of casual transmission of serious communicable diseases (i.e., whooping cough, measles, mumps) can be justified because the classroom is a setting in which these infections are efficiently transmitted. Second, the overwhelming individual and public health benefits of the vaccine, together with a record of vaccine safety in the post-marketing surveillance period, may have resulted in a consensus that the vaccine markedly improves the public health without a significant risk of serious adverse health outcomes. This was a major justification for requiring hepatitis B vaccine as a school entry requirement. Third, a vaccine could be required when there is an imminent threat of epidemic disease transmission, as in the case of a serious influenza pandemic. In all cases, state sanctioning of vaccines for the

sake of the public health should be balanced against the individual's right to make well informed decisions without undue duress.

There is a significant risk, if the public does not agree with the justification for a vaccine school entry requirement, that this mistrust could undermine the credibility of the state in promoting and enforcing all vaccine school entry requirements. In an editorial in the Journal of the American Medical Association titled "Public Health vs. Private Wealth" (Gostin LO & DeAngelis CD, JAMA, v. 297: pp. 1921 – 1923; May 2, 2007), the authors state "making the HPV vaccine mandatory contributes to long-standing parental concerns about the safety of school-based vaccinations. The use of compulsion, therefore, could have the unintended consequence of heightening parental and public apprehensions about childhood vaccinations." The authors conclude: "Years from now, when additional data and experience better inform clinicians and policy makers about the risks and benefits, states might consider requiring HPV vaccination as a condition of school entry. But for now, it is preferable to take a deliberative approach and view routine, voluntary HPV vaccination as part of a comprehensive package for preventing sexually transmitted infections and cervical cancer". A detailed discussion of the ethics and policy considerations in establishing vaccine school entry requirements is presented in the article "Ethics and Immunization Policy: Promoting Dialogue to Sustain Consensus" (Feudtner C & Marcuse EK, Pediatrics v. 107, pp. 1158-1164; 2001).

ADMINISTRATIVE IMPLICATIONS

DOH notes that it is not clear where the girls entering the sixth grade would receive the vaccine in order to comply with the school entry requirement. It can be assumed that a high percentage of them would receive vaccine either through school health nurses or through public health offices. This would substantially increase the work load of those school health nurses and public health offices potentially requiring additional FTE to meet this requirement.

TECHNICAL ISSUES

DOH notes concern about timing of requirement for vaccination before entering sixth grade.

SB 244 states that sixth grade girls must be vaccinated prior to the start of school, but no date is indicated. It is unclear in SB244 whether the sixth grade entry requirement would commence in the same year (i.e., 2009) as the requirement for the distribution of educational materials to 9 to 14 year-old girls (i.e., July 1, 2009). It is logistically impossible to distribute the educational materials and complete the vaccination requirement for the 2009 school year.

A complete HPV vaccine series consists of three doses of vaccine given on a specific schedule over a 6 month period. SB244 does not clearly state how many vaccines doses would be required for school entry. If the entry requirement goes into place after a parent or guardian receives the educational information, which would be on or after July 1, 2009, this would provide insufficient time for a girl entering sixth grade to have completed the full HPV vaccine series by the time school commences in August 2009.

OTHER SUBSTANTIVE ISSUES

DOH notes that immunization requirements for school entry in NM are currently implemented through DOH administrative codes, in consultation with the Public Education Department (7.5.2

NMAC). This process is more flexible and responsive than legislative mandates, allowing for necessary changes to be implemented more quickly when a change in vaccine age recommendations or the identification of previously unrecognized adverse effect of the vaccine is identified. In order to comply with SB 244, DOH administrative codes governing school immunization requirements would need to be amended to include HPV vaccine.

HPC Provided Background on Recent HPV Related Activities

The 2007 session of the New Mexico Legislature adopted House Memorial 66 and House Joint Memorial 39 for a HPV Screening and Advisory Panel assigned to the Health Policy Commission (HPC). In the memorial, the Legislature confirms its support of the Department of Health's (DOH) efforts directed towards improving the delivery of recommended Papanicolaou and Human Papillomavirus (HPV) testing.

The HPV advisory panel recommended:

1. Request all New Mexico medical providers be able to access and retrieve accurate and current HPV vaccination data in their offices via the State Immunization Information System (SIIS) on a real time basis.
2. Increase the number of cervical cancer screenings and access to treatment.
3. Request New Mexico Department of Health to evaluate the cost and medical effectiveness of implementing newer technologies such as the "thin prep" and self-sampling technique.
4. Request the Governor's Women's Health Advisory Council to create an innovative and highly visible media/ educational campaign to decrease the number of New Mexico citizens with HPV, precancers or cervical cancer.
5. Reauthorize the HPV advisory panel as a group of experts in HPV, precancers and cervical cancer prevention and interventions and to report to the Legislature.

HPC provided that the Governor's Women's Health Advisory Council notes that New Mexico will only be ready for school mandates when the elements necessary for mandate are fully available as follows: necessary resources (such as computers to track vaccine administration, refrigerators to store vaccines and providers to administer the vaccines), education, broad public acceptance, no barriers to access, and prior good vaccine penetration/coverage should be in place first. The council also noted that HPV vaccine penetration through comprehensive registration (currently NM Statewide Immunization Information System) is voluntary and not extended well into OB/GYN practices, mostly pediatric practices. The duration of protective immunity and when and how booster immunizations will be recommended is unknown.

ALTERNATIVES

DOH suggest that the provisions of SB 244 related to parental educational information could be retained, or modified to apply only to parents of 11 and 12 year old girls (consistent with current DOH activities), while eliminating the requirement for school entry.

GG/mt