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*Bill Analysis*  
*Legislative Service Commission*

## **H.B. 81**

127th General Assembly  
(As Introduced)

**Reps. Brown, Evans, Combs, Strahorn, Yuko, Otterman, Redfern, Chandler, Fende, B. Williams, Ujvagi**

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### **BILL SUMMARY**

- Subject to certain exceptions, requires each female pupil beginning sixth grade at a school subject to the State Board of Education's minimum standards during or after the 2008-2009 school year to be immunized by a Department of Health-approved method of immunization against human papillomavirus (HPV).
- Requires boards of health, municipal corporations, and townships, on application of a local school board, to provide the means of immunization against HPV to female pupils who are not provided the immunizations by their parents or guardians.
- Creates the HPV Immunization Advisory Committee in the Department of Health and imposes certain requirements on the Committee, including a requirement that the Committee approve or disapprove materials identified by the Department that contain information regarding the risks associated with HPV and cervical cancer and the availability, effectiveness, and potential risks of the HPV vaccine.
- Requires that both houses of the General Assembly, after the health committees of each house of the General Assembly hold a hearing to consider the materials identified by the Department on HPV, approve or disapprove the materials by passing a concurrent resolution not later than 45 days after the first day that both houses convene for a voting session following the delivery of materials to the committee chairpersons.

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## CONTENT AND OPERATION

### Background

#### Current immunization requirement and provisions for immunizations

(R.C. 3313.67, 3313.671, and 3701.134)

Under current law, a public school district board of education is authorized to make and enforce rules to secure the immunization of, and to prevent the spread of communicable diseases among, the children attending or eligible to attend the schools of the district, as in its opinion the safety and interest of the public require. Current law, subject to certain exceptions, also requires that children attending public schools<sup>1</sup> or nonpublic schools that meet state educational requirements be immunized against certain diseases at certain times. The following table summarizes these requirements and the applicable exemptions:

#### **Summary of Immunization Requirements Under Current Law**

Type of immunization	To whom the requirement applies	Exemptions
Mumps, poliomyelitis, diphtheria, pertussis, tetanus, rubeola, and rubella	Each pupil at the time of initial entry or at the beginning of each school year must have the immunization. A pupil is not permitted to remain in school for more than 14 days without having had the immunization or being in the process of being immunized, <sup>2</sup> unless an exemption applies.	(1) The pupil has had natural mumps or rubeola and presents a signed statement from the pupil's parent, guardian, or physician to that effect.  (2) The pupil presents a written statement of the pupil's parent or guardian in which the parent or guardian declines to have the pupil immunized for reasons of conscience, including religious convictions.

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<sup>1</sup> Public schools include community schools (commonly referred to as "charter schools").

<sup>2</sup> Current law defines "in the process of being immunized" to mean either of the following: (1) with respect to mumps, rubeola, rubella, and chicken pox, the pupil has been immunized, (2) with respect to poliomyelitis, diphtheria, pertussis, tetanus, or hepatitis B, the pupil has received at least the first dose of the immunization sequence and presents written evidence to the pupil's building principal or chief administrative officer of each subsequent dose required to obtain immunization at the intervals prescribed by the Director of Health (R.C. 3313.671(A)(3)).

Type of immunization	To whom the requirement applies	Exemptions
		(3) A physician certifies in writing that immunization is medically contraindicated for the pupil.
Hepatitis B	Each pupil beginning kindergarten during or after the 1999 school year must have the immunization. A pupil is not permitted to remain in school for more than 14 days without having had the immunization or being in the process of being immunized, unless an exemption applies.	<p>(1) The pupil presents a written statement of the pupil's parent or guardian in which the parent or guardian declines to have the pupil immunized for reasons of conscience, including religious convictions.</p> <p>(2) A physician certifies in writing that immunization is medically contraindicated for the pupil.</p>
Chicken pox	Each pupil beginning kindergarten during or after the 2006 school year must have the immunization. A pupil is not permitted to remain in school for more than 14 days without having had the immunization or being in the process of being immunized, unless an exemption applies.	<p>(1) The pupil has had natural chicken pox and presents a signed statement from the pupil's parent, guardian, or physician to that effect.</p> <p>(2) The pupil presents a written statement of the pupil's parent or guardian in which the parent or guardian declines to have the pupil immunized for reasons of conscience, including religious convictions.</p> <p>(3) A physician certifies in writing that immunization is medically contraindicated for the pupil.</p> <p>However, despite an exemption, a school may deny admission to a pupil who is not immunized for chicken pox if the Director of Health notifies a school's principal or chief administrative officer that a chicken pox epidemic exists in the school's population.</p>

Current law requires boards of health, municipal corporations, and townships, on application of the local school board, to provide the means of immunization against mumps, poliomyelitis, rubeola, rubella, diphtheria, pertussis, tetanus, and hepatitis B to pupils who are not provided the immunizations by their parents or guardians. The immunizations must be provided without delay and at the public expense.

Local entities are not required to provide a means of immunization against chicken pox. The Department of Health is required, however, to the extent appropriations made by the General Assembly make this possible, to provide the means of immunization against chicken pox to the local boards of health, municipal corporations, and townships.

### **Genital human papillomavirus (HPV)**

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the U.S. There are about 40 types of HPV and about 20 million people in the U.S. are infected, with about another 6.2 million persons infected each year. More than 50% of sexually active men and women are infected with HPV at some time in their lives. HPV is spread through sexual contact.<sup>3</sup>

Most HPV infections do not cause any symptoms and go away on their own. But according to the U.S. Centers for Disease Control and Prevention, HPV is important mainly because it can cause cervical cancer in women. Each year in the U.S., approximately 10,000 women are afflicted with cervical cancer and 3,700 die from it. In addition, HPV is associated with several less common types of cancer in both men and women. It can also cause genital warts and warts in the upper respiratory tract.<sup>4</sup>

There is no treatment for HPV infection, but the conditions it causes can be treated.<sup>5</sup>

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<sup>3</sup> U.S. Centers for Disease Control and Prevention. *HPV Vaccine: What You Need to Know* (last visited Mar. 15, 2007), available at <<http://www.cdc.gov/nip/publications/VIS/vis-hpv.pdf>>.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

### *The HPV vaccine*

**Federal approval.** On June 8, 2006, the U.S. Food and Drug Administration (FDA) licensed the first vaccine developed to prevent cervical cancer and other diseases in females caused by certain types of genital HPV. The vaccine, Gardasil<sup>®</sup>, protects against four HPV types which are responsible for 70% of cervical cancers and 90% of genital warts. On June 29, 2006, the Advisory Committee on Immunization Practices (ACIP) voted to recommend use of this vaccine in females ages nine through 26 years.<sup>6</sup> The Committee found, through studies it reviewed, that the HPV vaccine was safe and caused no serious side effects. Adverse events were mainly mild injection site pain.<sup>7</sup>

**Vaccine delivery and duration of efficacy.** It is recommended that the vaccine be delivered through a series of three intramuscular injections over a six-month period. The second and third doses should be given two and six months after the first dose.<sup>8</sup>

The duration of vaccine protection is unclear. Current studies (with five-year follow-up) indicate that the vaccine is effective for at least five years. There is no evidence of waning immunity during that time period.<sup>9</sup>

**List price and availability of vaccine through the Vaccines for Children Program.** The private sector list price of the vaccine is \$119.75 per dose (about \$360 for the full series). The CDC states that some private insurance companies may cover the cost of the vaccine and administration, while others may not. It also states that the federal Vaccines for Children (VFC) Program provides free vaccines to children and adolescents under 19 years of age, who are uninsured, Medicaid-eligible, American Indian, or Alaska Native, and that over 45,000 sites nationwide provide VFC vaccines.<sup>10</sup> According to the legislative liaison at the Department of Health, the Department currently receives HPV vaccines free of

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<sup>6</sup> According to the U.S. Centers for Disease Control and Prevention, the vaccine should be administered before the onset of sexual activity. However, females who are already sexually active also may benefit from vaccination.

<sup>7</sup> U.S. Centers for Disease Control and Prevention. *HPV and the HPV Vaccine: Information for Healthcare Providers* (last visited Mar. 15, 2007), available at <<http://www.cdc.gov/std/hpv/hpv-vacc-hcp-3-pages.pdf>>.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

charge that it distributes without charge to local boards of health for administration to VFC-eligible children for whom the parents or guardians of such children desire to have their children immunized against genital HPV.<sup>11</sup>

**The bill**

**HPV immunization requirement**

(R.C. 3313.671(A)(3) and (B))

Subject to certain exceptions, the bill requires each female pupil beginning sixth grade at a school subject to the State Board of Education's minimum standards during or after the 2008-2009 school year to be immunized by a Department of Health-approved method of immunization against HPV. Under the bill, a female pupil is prohibited from being permitted to remain in school for more than 14 days unless the pupil presents written evidence satisfactory to the person in charge of admission that the pupil has been immunized or is in the process of being immunized against HPV by a method of immunization approved by the Department.

The bill provides that a female pupil is exempt from the HPV immunization requirement if at least one of the following apply: (1) she presents a written statement of her parent or guardian in which the parent or guardian declines to have her immunized for reasons of conscience, including religious convictions, (2) her physician certifies in writing that her immunization against HPV is medically contraindicated, or (3) she presents a written, signed statement from her parent or guardian in which the parent or guardian attests to having received the information on the connection between HPV and cervical cancer disseminated by the Department of Health as directed by the bill and in which the parent or guardian declines to have the pupil so immunized (see **Dissemination of informational materials**," below).

**Provisions for HPV immunizations**

(R.C. 3313.671(D))

Like immunizations against mumps, poliomyelitis, rubeola, rubella, diphtheria, pertussis, tetanus, and hepatitis B, the bill requires boards of health, municipal corporations, and townships, on application of a local school board, to provide the means of immunization against HPV to female pupils who are not

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<sup>11</sup> Telephone interview with Zach Holzapfel, Legislative Liaison, Ohio Department of Health (Mar. 16, 2007).

provided the immunizations by their parents or guardians. The bill does not contain an appropriation for the Department of Health to provide the means of immunization against HPV to the local boards of health, municipal corporations, and townships.

**HPV Immunization Advisory Committee**

(R.C. 3701.36)

**Membership.** The bill creates the HPV Immunization Advisory Committee in the Department of Health. The Committee must consist of the following members:

- (1) Two individuals appointed by the President of the Senate.
- (2) Two individuals appointed by the Speaker of the House of Representatives.
- (3) Three individuals appointed by the Governor.

Members of the Committee serve at the pleasure of the appointing authority and without compensation. Vacancies on the Committee must be filled in the manner provided for original appointments.

**Meetings.** The bill requires the Committee to meet as it determines necessary to carry out its duties. The Committee must:

- (1) Assist the Department in identifying materials that contain information regarding the risks associated with HPV and cervical cancer and the availability, effectiveness, and potential risks of the HPV vaccine.
- (2) Approve or disapprove materials identified by the Department.
- (3) Advise in the marketing and dissemination of the approved materials.

**Approval, and delivery of, informational materials.** The bill requires the Committee, once it approves the materials described above, to deliver a copy of the approved materials to the Columbus offices of the chairpersons of the standing committees of the House of Representatives and the Senate that consider issues pertaining to public health.

**Responsibilities of Health Committee chairpersons**

(R.C. 3701.361)

The bill provides that, after the Department of Health delivers a copy of informational materials, each committee chairperson to whom the materials were delivered must convene at least one hearing of the standing committee to consider the materials and recommendations to the General Assembly.

**Responsibilities of the General Assembly as a whole**

(R.C. 3701.361)

The bill requires that both houses of the General Assembly approve or disapprove the materials by passing a concurrent resolution not later than 45 days after the first day that both houses of the General Assembly convene for a voting session following the delivery of materials to the committee chairpersons. If the materials are delivered to either chairperson less than 45 days before the General Assembly adjourns sine die, the 45-day period commences on the first day the next General Assembly is in session.

If the General Assembly passes a concurrent resolution disapproving the proposed materials, the concurrent resolution must state specific objections to those materials. The HPV Immunization Advisory Committee must revise the proposed materials based on the General Assembly's objections, and the Department must resubmit them for the General Assembly's approval, as described above under "**Approval, and delivery of, informational materials.**"

If the General Assembly passes a concurrent resolution approving of the proposed materials, the Department must disseminate those materials as described under "**Dissemination of approved materials,**" below.

If the General Assembly does not pass a concurrent resolution with respect to the proposed materials within the 45-day period, those materials are deemed approved and the Department of Health must disseminate those materials as described under "**Dissemination of approved materials,**" below.

**Dissemination of approved materials**

(R.C. 3701.362)

The bill requires that the Department of Health, once the informational materials have been approved by the General Assembly, notify each school in Ohio that includes fifth and sixth grade of the availability of the materials, direct



the annual dissemination of the approved materials to all female students in the fifth grade in Ohio, and post the materials on the Department's web site.

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## COMMENT

### Constitutionality of immunization requirements

The law is well established that a state may compel immunization under its police powers (the broad power of a state to regulate matters relating to the health, safety, and welfare of the public).<sup>12</sup> The constitutionality of requiring immunization for school attendance has been upheld by the United States Supreme Court.<sup>13</sup> Many courts have rejected challenges to compulsory immunization laws on the basis of personal liberty, illegal search and seizure, due process, equal protection, and freedom of religion.<sup>14</sup>

A court may find, however, that the grounds for upholding the constitutionality of state laws that require immunization for diseases that are transmitted through the air or non-sexual contact may not apply with respect to a genital HPV vaccination law since this disease is transmitted only through sexual contact.

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## HISTORY

ACTION	DATE
Introduced	02-28-07

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<sup>12</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>13</sup> *Zucht v. King*, 260 U.S. 174 (1922).

<sup>14</sup> See *Jacobson* at 25-27; see also *Zucht*, 260 U.S. at 176 (equal protection); *Prince v. Massachusetts* (1944), 321 U.S. 158, 169-170 (holding that the right to free exercise of religion does not include a right to place children in harm's way); *McSween v. Bd. of Sch. Trustees* (1910), 60 Tex. Civ. App. 270, 273 (illegal search and seizure); *Seubold v. Fort Smith Special Sch. Dist.* (Ark. 1951), 237 S.W.2d 884, 887 (liberty and due process interests).