

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Children, Families, and Elder Affairs Committee

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BILL: PCS/SB 242

INTRODUCER: Children, Families, and Elder Affairs Committee

SUBJECT: Childhood Vaccinations

DATE: April 13, 2009

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Ray	Walsh	CF	<b>Pre-meeting</b>
2.				
3.				
4.				
5.				
6.				

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**I. Summary:**

The Proposed Committee Substitute for Senate Bill 242 provides that a parent, legal guardian, or other authorized person has the right to choose an alternative immunization schedule to that recommended by the Centers for Disease Control and Prevention (CDC), as long as the child is immunized prior to the earlier of, kindergarten or initial entry into a public or private school.

The bill requires health care practitioners to provide the parent or legal guardian of a minor child with a copy of the current vaccine information statement (VIS) published by the CDC before administering any vaccine to the minor child.

The bill prohibits administration of vaccines to minors without a statement, signed by the parent or guardian, documenting that the vaccine information statement was provided. The bill provides specific language to be used for the signed statement.

The bill provides that the practitioner must include the signed statement in the minor's medical record.

The bill amends ss. 1003.22, 381.003, and 1002.42, F.S.

The bill provides an effective date of July 1, 2009.

## II. Present Situation:

### School-Age Vaccination Requirements

Florida law requires the Department of Health (DOH) to consult with the Florida Department of Education and adopt rules governing the immunization of children against preventable communicable diseases.

Further, each district school board and the governing authority of each private school must establish and enforce a policy that, prior to admittance to or attendance in school, each child have a “certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health...”<sup>1</sup> These provisions together effectively require children to receive certain vaccinations, as determined by DOH, before attending school in Florida.

In Florida, the following immunizations are required prior to entry into kindergarten.<sup>2</sup>

Immunizations required for preschool entry (age-appropriate doses as are medically indicated):

- Diphtheria-Tetanus-Pertussis Series;
- Haemophilus influenzae type b (Hib);
- Hepatitis B;
- Measles-Mumps-Rubella (MMR);
- Polio Series; and
- Varicella

Immunizations required for kindergarten entry:

- Diphtheria-Tetanus-Pertussis Series;
- Hepatitis B Series;
- Measles-Mumps-Rubella (two doses of Measles vaccine, preferably as MMR);
- Polio Series; and
- Varicella

Other childhood vaccines, although not required for school, are recommended, including: hepatitis A, meningococcal conjugate, human papillomavirus, rotavirus, pneumococcal conjugate vaccine, trivalent inactivated influenza vaccine, and live attenuated influenza vaccine.<sup>3</sup> Florida law requires that “the manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice.”<sup>4</sup>

Florida law provides several exemptions. The school-age immunization requirements do not apply if:

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<sup>1</sup> Section 1003.22(4), F.S.

<sup>2</sup> Immunization Guidelines, Florida Schools, Childcare Facilities and Family DayCare Homes, Effective July 2008, available at: [http://www.doh.state.fl.us/DISEASE\\_CTRL/immune/schoolguide.pdf](http://www.doh.state.fl.us/DISEASE_CTRL/immune/schoolguide.pdf).

<sup>3</sup> Centers For Disease Control, “Recommended Immunization Schedules For Persons Aged 0 Through 18 Years United States, 2009”, Mmwr Weekly, January 2, 2009, Available At [http://www.cdc.gov/mmwr/Preview/Mmwrhtml/Mm5751a5.Htm?S\\_Cid=Mm5751a5\\_E](http://www.cdc.gov/mmwr/Preview/Mmwrhtml/Mm5751a5.Htm?S_Cid=Mm5751a5_E) (Last Viewed April 9, 2009).

<sup>4</sup> Section 1003.22(3), F.S.

- A parent objects in writing that the administration of immunizing agents conflicts with his or her religious tenets or practices;
- A physician certifies in writing that the child should be permanently exempt from the required immunization for medical reasons stated in writing, based upon valid clinical reasoning or evidence;
- A physician certifies in writing that the child has received as many immunizations as are medically indicated at the time and is in the process of completing necessary immunizations;
- DOH determines that, according to recognized standards of medical practice, the required immunization is unnecessary or hazardous; or
- An authorized school official issues a temporary exemption for up to 30 days.<sup>5</sup>

DOH rules establish the forms and procedures for invoking an exemption.<sup>6</sup>

### **Vaccine Information Statement**

According to the DOH, the National Vaccine Injury Compensation Program (42 U.S.C. 300aa-26), requires all health care providers in the United States who administer, to any child or adult, vaccines for diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b, trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus, or varicella, shall provide a copy of the most recent and relevant edition of vaccine information materials that have been produced by the CDC. These vaccine information materials are entitled Vaccine Information Statements. This information is provided to parents, legal guardians or patients prior to administering any of the above-mentioned vaccines.<sup>7</sup>

Vaccine Information Statements do not include detailed information regarding the vaccine ingredients as listed on the package insert or vaccine efficacy, but do cover the potential side effects (adverse events) of the vaccine, risks associated with the disease that the vaccination is intended to prevent, contraindications to the vaccine, and options regarding the administration of the vaccination, including the timing or combination of multiple vaccinations.<sup>8</sup>

### **Informed Consent**

Section 765.101(9), F.S., defines the term “Informed consent” as consent voluntarily given by a person after a sufficient explanation and disclosure of the subject matter involved to enable that person to have a general understanding of the treatment or procedure and the medically acceptable alternatives, including the substantial risks and hazards inherent in the proposed treatment or procedures, and to make a knowing health care decision without coercion or undue influence.

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<sup>5</sup> Section 1003.22(5), F.S.

<sup>6</sup> 64d-3.011, F.A.C. (2008)

<sup>7</sup> U.S. Department of Health and Human Services National Vaccine Injury Compensation Program (VICP) website, available at: <http://www.hrsa.gov/vaccinecompensation/>.

<sup>8</sup> Department of Health Bill Analysis, Economic Statement and Fiscal Note, Senate Bill 308 (2009).

### **III. Effect of Proposed Changes:**

The Proposed Committee Substitute for Senate Bill 242 amends section 1003.22, F.S., relating to school entry health examinations and childhood immunizations against communicable diseases. The bill provides that a parent, legal guardian, or other authorized person has the right to choose an alternative immunization schedule to that recommended by the CDC, as long as the child is immunized prior to the earlier of, kindergarten or initial entry into a public or private school.

The bill requires health care practitioners to provide the parent or legal guardian of a minor child with a copy of the current VIS published by the CDC before administering any vaccine to the minor child that is required to be administered by section 1003.22, F.S.

The bill prohibits administration of vaccines to minors without a statement, signed by the parent or guardian, documenting that the vaccine information statement was provided. The bill provides specific language to be used for the signed statement, by which the parent or guardian represents that he or she:

- Has received a copy of the VIS;
- Has received information on the benefits and risks of the vaccine and how to report an adverse reaction;
- Has received information on the National Vaccine Injury Compensation Program; and
- How to get more information on childhood diseases and vaccines.

The signed statement must also include a notation of the batch and lot number for each vaccine administered to the child. The practitioner must include the signed statement in the minor's medical record.

The bill clarifies that the requirements apply to each VIS published by the CDC, regardless of whether the statement is covered by the federal National Vaccine Injury Compensation Program. The bill permits a practitioner to provide a single statement covering multiple vaccines, if the CDC has published a VIS that covers multiple vaccines.

The bill amends ss. 381.003 and 1002.42, F.S., conforming cross references.

The bill provides an effective date of July 1, 2009.

### **IV. Constitutional Issues:**

#### **A. Municipality/County Mandates Restrictions:**

None.

#### **B. Public Records/Open Meetings Issues:**

None.

C. Trust Funds Restrictions:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.