

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.)

Prepared By: The Professional Staff of the Policy and Steering Committee on Ways and Means

BILL: CS/SB 242

INTRODUCER: Children, Families, and Elder Affairs Committee

SUBJECT: Human Vaccinations

DATE: April 18, 2009

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Ray	Walsh	CF	Fav/1 amendment
2.	Bell/Munroe	Wilson	HR	Fav/1 amendment
3.	Ray	Walsh	CF	Fav/CS
4.	Peters	Kelly	WPSC	Pre-meeting
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

Please see Section VIII. for Additional Information:

- | | | |
|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes |
| B. AMENDMENTS..... | <input type="checkbox"/> | Technical amendments were recommended |
| | <input type="checkbox"/> | Amendments were recommended |
| | <input type="checkbox"/> | Significant amendments were recommended |

I. Summary:

The bill prohibits the sale, purchase, manufacturing, delivery, importation, administration, or distribution of any human vaccine used for children under the age of six or pregnant women that contains a specific amount of any organic or inorganic mercury compound.

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 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, legal guardian, or other legal representative 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, legal guardian, authorized person, or legal representative, 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 Department of Health reports that the bill may affect federal funding received through the Vaccine For Children Program (VFC) specifically related to the supply of vaccines.

The bill amends ss. 381.003, 499.005, 1002.42, and 1003.22, 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 or the department) 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..."¹ 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.²

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

¹ Section 1003.22(4), F.S.

² 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.

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.³ Florida law requires that “the manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice.”⁴

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

- 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.⁵

DOH rules establish the forms and procedures for invoking an exemption.⁶

Vaccine Information Statement

According to 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.⁷

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.⁸

³ 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 (Last Viewed April 9, 2009).

⁴ Section 1003.22(3), F.S.

⁵ Section 1003.22(5), F.S.

⁶ 64d-3.011, F.A.C. (2008)

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

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

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.

Thimerosal in Vaccines

Thimerosal is a mercury-containing compound that has been used as a preservative in a number of biological and drug products, including vaccines. Concerns regarding the use of thimerosal and other mercury-containing compounds in vaccines and other products have been raised recently, and the FDA has worked with, and continues to work with, vaccine manufacturers to reduce or eliminate thimerosal from vaccines. Thimerosal has been removed or reduced to trace amounts in all vaccines recommended for children six years of age and younger, with the exception of inactivated influenza vaccine.⁹

Recent estimates from the CDC's Autism and Developmental Disabilities Monitoring network found that about 1 in 150 children have an Autism Spectrum Disorder (ASD). This estimate is higher than estimates from the early 1990s. Some people believe increased exposure to thimerosal explains the higher prevalence in recent years. However, evidence from several studies examining trends in vaccine use and changes in autism frequency does not support such an association.¹⁰ Furthermore, a review by the Institute of Medicine (IOM) concluded that “the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.”¹¹

III. Effect of Proposed Changes:

The bill amends s. 499.005, F.S., providing that it is unlawful for a person to sell, purchase, manufacture, deliver, import, administer, or distribute any human vaccine used for children under the age of six or pregnant women that contains any organic or inorganic mercury compound in excess of 0.1 microgram per milliliter.

The bill 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, legal guardian, or other legal representative of a minor child with a copy of the current VIS published by the CDC before

⁹ U.S. Food and Drug Administration website, Thimerosal in Vaccines, available at: <http://www.fda.gov/CBER/vaccine/thimerosal.htm>.

¹⁰ Centers for Disease Control and Prevention, Mercury and Vaccines website, available at: <http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm>.

¹¹ Id.

administering any vaccine to the minor child that is required to be administered by section 1003.22, F.S.

The bill prohibits the administration of vaccines to minors without a statement, signed by the parent, legal guardian, authorized person, or other legal representative 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 lot number for each vaccine administered must be recorded on the signed statement or on a permanent office log. 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:

Section 627.6579, F.S., relating to insurance coverage for child health supervision services, provides that all group, blanket, or franchise health insurance policies that provide health insurance benefits applicable for children must include coverage for child health supervision services. Child health supervision services include appropriate immunizations. Paragraph (b) of s. 627.6579(2), F.S., allow benefits to be limited to one visit payable to one provider for all of the services provided.

By choosing an alternative immunization schedule, a parent may be required to pay for additional visits out of pocket if their insurance policy provides for this limitation.

C. Government Sector Impact:

The department reports that the bill may affect federal funding received through the Vaccine For Children Program (VFC) specifically related to the supply of vaccines. (See Related Issues)

VI. Technical Deficiencies:

None.

VII. Related Issues:

According to DOH, all vaccines for children age three and younger are thimerosal-free with the exception of some influenza vaccines and the DT vaccine. The latter is the vaccine given to children under the age of seven who have a contraindication to the pertussis component of the DTaP vaccine. Since the DT vaccine is used as a substitute for the DTaP vaccine for series completion, these children would not be able to complete the DTaP series required for entry into child care centers and school, and would not be protected from serious, life-threatening diseases.¹²

The department receives over \$160 million¹³ in federally-supplied vaccine through the VFC. This program provides free vaccines to children receiving Medicaid and to other low-income children through both public and private healthcare providers. The department reports that it orders vaccines through the CDC. While Florida can request thimerosal-free flu vaccines, the CDC is not required to honor that request. According to the department, some of Florida's low income children may be unable to receive flu vaccines because of the insufficient manufacturing capacity for thimerosal-free influenza vaccines.¹⁴

Currently, DOH and other healthcare providers adhere to the Advisory Committee on Immunization Practices (ACIP) recommendations as the standard for scientifically based

¹² Department of Health, Amendment Analysis, Economic Statement and Fiscal Note, SB 242 amendment 209710, April 13, 2009, page 6 (on file with the committee).

¹³ Department of Health, Amendment Analysis, Economic Statement and Fiscal Note, SB 242 amendment 209710, April 13, 2009, page 8 (on file with the committee).

¹⁴ Department of Health, Amendment Analysis, Economic Statement and Fiscal Note, SB 242 amendment 209710, April 13, 2009, page 3 (on file with the committee).

recommendations and administration of vaccines for all populations. Further, all VFC Program healthcare providers are required to follow ACIP recommendations for appropriately vaccinating children. The department reports that alternative immunization schedules could have a negative impact on federal grant funding provided by the CDC.¹⁵

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

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

CS by Children, Families, and Elder Affairs on April 15, 2009:

The Committee Substitute for Senate Bill 242 reflects the Proposed Committee Substitute with the following additions:

- Prohibits the sale, purchase, manufacturing, delivery, importation, administration, or distribution of any human vaccine used for children under the age of six or pregnant women that contains a specific amount of any organic or inorganic mercury compound.
- Allows an authorized person to sign a statement regarding a vaccine prior to the vaccine being administered.
- Requires that the lot number for each vaccine administered must be recorded on the signed statement or on a permanent office log.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

¹⁵ Department of Health, Amendment Analysis, Economic Statement and Fiscal Note, SB 242 amendment 209710, April 13, 2009, page 8 (on file with the committee).