



## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES:

This bill does not appear to have an impact on the House Principles.

#### B. EFFECT OF PROPOSED CHANGES:

This bill amends s. 402.305, F.S., regarding child care facility licensing standards. These standards are designed to address the health, sanitation, safety and adequate physical surroundings, health and nutrition, and child development needs of all children in child care. This bill amends s. 414.13 F. S., providing an immunization exemption for the child of an applicant for temporary family assistance and requiring the Department of Children and Families to provide immunization information to applicants and allowing immunization exemptions for children whose parents have provided written objection. Further, this bill amends s.1003.22, F.S., providing an exemption from immunization requirements for children entering or attending a K-12 public or private school whose parents have provided written objection to the immunization and strikes the religious exemption to immunization. Finally the bill reenacts s. 1002.20(3)(b), F.S., relating to K-12 student and parent rights, and provides that vaccine use for immunizing minors in this state may not contain thimerosal or mercury.

The changes in the bill will affect the way the Department of Health currently accepts documentation for medical and religious immunization exemptions. The provisions in this bill would cause a decrease in the childhood immunization coverage rate, if there is an increase in immunization exemption. These changes will allow an increased number of non-immunized children into daycare settings thereby increasing the number of children susceptible to vaccine-preventable diseases. According to the Department of Health, studies reveal that children enrolled in entitlement programs are at high risk for failure to complete the basic immunization series. If children are unprotected, they will be excluded from attending school during a communicable disease outbreak. Restricting the use of any vaccine that contains thimerosal or mercury would require that the Department of Health and all other health care providers administer only thimerosal or mercury-free vaccines or not administer vaccinations if a preservative-vaccine supply is not available.

Based on the Department of Health's Kindergarten and Seventh Grade Immunization Status Report data for 2003-04, there are over 1,405 documented religious exemptions to immunization in these two grades statewide. If passed as written, exemptions allowed for any reason could increase the number of immunization exemptions.

#### Background

##### Thimerosal in Vaccinations

Regulations adopted by the United States Food and Drug Administration (FDA) require the addition of a preservative to multi-dose vials of vaccines.<sup>1</sup> Thimerosal is a mercury-containing compound that has been used as a preservative in a number of biological and drug products, including vaccines. Thimerosal acts as a preservative and helps prevent potentially life threatening contamination with harmful microbes. 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 6 years of age and younger, with the exception of inactivated influenza vaccine. A preservative-free version of the inactivated influenza vaccine is available in a limited supply. Some vaccines, such as the vaccine for tetanus, are available in formulations that are free of thimerosal.

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<sup>1</sup> See 21 CFR 610.15(a)

The Institute of Medicine's Immunization Safety Review Committee, in its 2001 report, concluded that the evidence is inadequate to either accept or reject a causal relationship between thimerosal exposure from childhood vaccines and the neurodevelopmental disorders of autism, attention deficit hyperactivity disorder, and speech or language delay.<sup>2</sup> The committee report indicated that an effort to remove thimerosal from vaccines was a prudent course to reduce mercury exposure of infants and children as much as possible. Again, in 2004, the committee concluded that the scientific evidence favors rejection of a causal relationship between vaccines containing thimerosal and autism.

While the use of mercury-containing preservatives has declined in recent years with the development of new products formulated with alternative or no preservatives, thimerosal is still used in certain antivenins, skin test antigens, and ophthalmic and nasal products, in addition to certain vaccines recommended for adults or older children. The Food and Drug Administration is encouraging the reduction or removal of thimerosal from all existing vaccines. The FDA has been actively working with manufacturers, particularly those that manufacture childhood vaccines, to reach the goal of eliminating thimerosal from vaccines, and has been collaborating with other PHS agencies to further evaluate the potential health effects of thimerosal. Manufacturers are working to increase the supply of thimerosal-reduced and thimerosal-free vaccines used to vaccinate children and pregnant women against the influenza virus.

According to the Department of Health, vaccines which contain thimerosal or mercury that are administered to children include: Diphtheria-Tetanus (DT), Tetanus-Diphtheria (Td), Influenza, and Meningococcal vaccine. Currently, children who have a contraindication to the major vaccine series Diphtheria and tetanus toxoids and acellular pertussis (DTaP) due to the pertussis component are vaccinated with either DT or Td vaccine. Completion of this series is required for school and child care center attendance in Florida and is necessary for protection against diphtheria and tetanus. In addition, adolescents, prior to entering middle school, are required to receive a Td booster dose for increased protection. These children are currently vaccinated with a product that contains trace amounts of thimerosal or mercury. At this time, there is no product without thimerosal or mercury, however, the trace amount is considered to be an acceptable amount. The benefits of immunizing these children against vaccine-preventable diseases are considered to outweigh the risks according to medical recommendations. Changes to immunization requirements would be necessary to ensure that those children who have contraindications to the pertussis component of the DTaP series receive a special exemption from the requirements. These children would remain susceptible to tetanus, pertussis and diphtheria diseases.

#### Florida Law

Section 402.305, F.S., regarding child care facility licensing standards. These standards are designed to address the health, sanitation, safety and adequate physical surroundings, health and nutrition, and child development needs of all children in child care. The standards require compliance with the applicable immunizations for children.

Section 414.13, F.S., requires each applicant for cash assistance programs who has a preschool child to begin and complete appropriate childhood immunizations for the child as a condition of eligibility.

Section 1003.22, F.S., authorizes the Department of Health, after consultation with the Department of Education, to adopt administrative rules governing the immunization of children against, the testing for and the control of preventable communicable diseases. The rules must include procedures for exempting a child from immunization requirements. Immunizations must be required for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by rules of the Department of Health.<sup>3</sup> The manner and frequency of administration of the immunization or testing must conform to recognized standards of medical practice. The Department of Health must supervise and secure the enforcement of the required immunization. Required immunizations must be available at no cost from county health departments.

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<sup>2</sup> See "Thimerosal in Vaccines" at <<http://www.fda.gov/cber/vaccine/thimerosal.htm>>.

<sup>3</sup> See Rule 64D-3.011, Florida Administrative Code.

C. SECTION DIRECTORY:

Section 1. Amends s. 402.305(9)(c), F.S., regarding child care facility licensing standards and provides for immunization exemptions based on written objection.

Section 2. Amends s. 414.13, F.S., regarding childhood immunizations as a condition of participating in cash assistance programs and provides for immunization exemption based in receipt of related information and a written objection.

Section 3. Amends s. 1003.22 (5) (a) (d), F. S., regarding school-entry health examinations; immunization against communicable diseases' exemptions; duties of the Department of Health and provides broad immunization exemptions and prohibits the Department of Health from using an immunization agent that contains thimerosal or mercury.

Section 4. Reenacts s. 1002.20 (3) (b), F. S., regarding K-12 student and parent rights. This section is reenacted for the purpose of incorporating section 3 of this bill.

Section 5. Creates new language to direct that a vaccine used for immunizing a minor in this state may not contain thimerosal or mercury.

Section 6. Provides an effective date of upon becoming law.

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

2. Expenditures:

The Department of Health estimates the following expenses:

- 2004/05 federal contract cost for Aventis-Pasteur preservative-free influenza is \$10.00 per dose.
- 2004/05 federal contract cost for Aventis-Pasteur preservative-containing vaccine is \$6.80 per dose.
- Increased administrative and operations costs related to increased exemption referrals impacting the County Health Departments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

The assumed costs to school districts, private and other school governing boards for the required documentation and acceptance of expanded immunization exemptions on existing forms and in automated immunization information systems are undetermined.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The potential increased morbidity and mortality from vaccine-preventable disease due to the number of immunization exemption could increase health care costs associated with the disease. These costs could be passed on to parents, families, insurers, etc. There may also be some increased cost associated with the purchase of preservative-free formulations, where available.

**D. FISCAL COMMENTS:**

In the event of a vaccine-preventable disease outbreak, this bill may have a fiscal impact on the Department of Health. The pool of children susceptible to vaccine-preventable diseases rises when immunization exemptions increase. When vaccine-preventable diseases are introduced, unvaccinated children, children too young to be vaccinated, and children with contraindications to vaccinations are vulnerable to serious health consequences including death. Without routine vaccination, a resurgence of vaccine preventable diseases such as varicella (chicken pox) and measles quickly occurs, causing widespread harm. Public Health policy requires exclusion from school for unprotected persons during a communicable disease outbreak. Incubation periods for such diseases may result in exclusion for 21 days or longer. The costs for such disease outbreaks include reduction in school attendance for the child, potential loss of income and decreased work attendance for the parent/caregiver, and costs incurred to provide home-school instruction if necessary.

**III. COMMENTS**

**A. CONSTITUTIONAL ISSUES:**

**1. Applicability of Municipality/County Mandates Provision:**

This bill will have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

**2. Other:**

None

**B. RULE-MAKING AUTHORITY:**

No additional rule-making authority is required as a result of this bill. However, a rule change to Chapter 64D-3.011, F.A.C., is required to allow children to enter or attend child care or school without the required vaccinations if thimerosal/mercury free vaccine is not available.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

None

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES**