

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

**BILL #:** HB 117

Childhood Vaccinations

**SPONSOR(S):** Ambler

**TIED BILLS:**

**IDEN./SIM. BILLS:** SB 222

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	<b>REFERENCE</b>	<b>ACTION</b>	<b>ANALYST</b>	<b>STAFF DIRECTOR</b>
1)	<u>Health Care Regulation Policy Committee</u>	<u></u>	<u>Calamas</u>	<u>Calamas</u>
2)	<u>PreK-12 Appropriations Committee</u>	<u></u>	<u></u>	<u></u>
3)	<u>Civil Justice &amp; Courts Policy Committee</u>	<u></u>	<u></u>	<u></u>
4)	<u>Health Care Appropriations Committee</u>	<u></u>	<u></u>	<u></u>
5)	<u></u>	<u></u>	<u></u>	<u></u>

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**SUMMARY ANALYSIS**

House Bill 117 requires health care practitioners to provide the U.S. Centers for Disease Control and Prevention Vaccination Information Statement (VIS) to the parent or legal guardian of a minor vaccine recipient for each vaccine administered. Currently, immunization against certain infectious diseases is required for admittance or attendance at Florida public and private schools. Federal law requires distribution of the VIS at the time of immunization for specific vaccines.

The bill also requires the parent of legal guardian of a minor vaccine recipient to sign a statement acknowledging receipt of the VIS and other vaccination information. This statement must be retained in the patient's permanent medical record. The health care practitioner must also record on the statement the batch and lot number of each vaccine administered.

The bill does not appear to have a fiscal impact on state government.

House Bill 117 provides an effective date of July 1, 2010.

## HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### Current Situation

##### **School-Age Immunization Requirements**

Section 1003.22, F.S., requires children to be immunized against communicable diseases prior to admittance and attendance at both public and private schools in Florida. Admittance is conditioned upon submitting proof of immunization to the school board.<sup>1</sup> The section gives authority to the Florida Department of Health (DOH) to determine qualifying exemptions. Exemptions to the immunization requirement include religious and permanent medical exemptions and temporary exemptions for homelessness, transfers between schools, entrance into the juvenile justice system, and temporary medical reasons.<sup>2</sup>

Absent a documented exemption, children must be immunized against the following diseases: diphtheria; tetanus; pertussis (whooping cough); polio; measles, mumps and rubella (MMR); hepatitis B; haemophilus influenzae type b (Hib); and varicella (chicken pox).<sup>3</sup> Although not required for school entry in Florida, the national Centers for Disease Control and Prevention (the "CDC") recommends additional childhood immunization for: hepatitis A; meningococcal conjugate; human papillomavirus (HPV); rotavirus; pneumococcal conjugate vaccine; trivalent inactivated influenza vaccine; and live attenuated influenza vaccine.<sup>4</sup>

Florida law requires proof of immunization recorded on the DH Form 680 and kept on file at the child's school. Immunization records are also transmitted to DOH. Most county health departments and schools transmit immunization records electronically.<sup>5</sup> And some private health care providers use electronic immunization records. SHOTS and FASTER are two electronic, paperless systems maintained by DOH that facilitate the transfer of up-to-date immunization information among these entities.

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<sup>1</sup> Rule 64D-3.046, F.A.C., prescribes the form, the DH Form 680, as the certification document for immunization records required for school admittance. This form is available in hard-copy and electronic formats.

<sup>2</sup> Rule 64D-3.046(2)(e), F.A.C., prescribes the form, the DH Form 681, to document a religious exemption.

<sup>3</sup> Rule 64D-3.046(1)(b)(2), F.A.C.

<sup>4</sup> Centers for Disease Control and Prevention, *Recommended Immunization Schedules For Persons Aged 0 Through 18 Years --- United States, 2009*, MMWR Weekly, January 2, 2009, see

[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 visited February 12, 2010).

<sup>5</sup> County health department participation is authorized by s. 1003.22(4), F.S.

Currently, parental signature is not required as a prerequisite to immunization. According to the DOH, there is no federal signature requirement, and DOH eliminated the state signature requirement in 2007.<sup>6</sup>

### **National Childhood Vaccine Injury Act**

Federal law requires health care providers to distribute information to a vaccine recipient at the time of immunization. Under the National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-26, a health care provider must give the recipient a Vaccine Information Statement (VIS) prior to the administration of each of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A and B, Haemophilus influenza type b, trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus; or varicella.<sup>7</sup> The CDC produces and distributes a VIS for each vaccine that details benefits, risks and adverse reaction symptoms of the vaccine.<sup>8</sup> A tool to inform the vaccine recipient or his guardian if the recipient is a minor, the VIS is designed to supplement the exchange of information between the health care provider and patient.<sup>9</sup>

The health care provider is required to record the VIS edition date and the date upon which it was provided to the patient in the patient's permanent medical record. There is no requirement that the patient's signature be captured at that time.<sup>10</sup> Further, the Act requires the health care provider to include the "...date of administration, vaccine manufacturer, and lot number as well as the name, address, and title of the health care provider..." in the patient's permanent record."<sup>11</sup>

Federal law also provides for the National Vaccine Injury Compensation Program, a no-fault fund (Fund) to compensate patients for vaccine injuries.<sup>12</sup> Claims against the Fund are heard in the U.S. Court of Federal Claims. Successful claims are limited to those included on the Vaccine Injury Table during prescribed time periods.<sup>13</sup> For example, injury from anaphylactic shock caused by the MMR vaccine must have occurred 0-4 hours from time of immunization to be eligible for compensation from the Fund.<sup>14</sup> If the alleged injury is not included on the table or did not occur within the specified time limit, then the petitioner must prove that the vaccine did in fact cause the injury or that the vaccine aggravated a pre-existing condition.

Whether or not the injury is included on the table or the petitioner is proving injury, the court is required to make a specific causal determination. Even if the injury is included on the table, the court must determine that there is no other cause for the injury.<sup>15</sup> Awards from the Fund may include past and future medical expenses, lost earnings and attorney's fees and costs. The Fund provides for a cap of \$250,000 on pain and suffering damages.<sup>16</sup>

### **Failure to Vaccinate or Delayed Vaccination**

In highly infectious diseases, greater than 90 percent of the population needs to be vaccinated to interrupt transmission and maintain elimination of the disease in populations.<sup>17</sup> Not all vaccinations are 100 percent effective for prevention of a targeted disease, thus the risk elevates when less than 90 percent of the population is vaccinated. For example, in Switzerland, a widespread outbreak of

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<sup>6</sup> Florida Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 117 (October 2, 2009).

<sup>7</sup> Florida Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 33 (January 12, 2009).

<sup>8</sup> Centers for Disease Control and Prevention, see <http://www.cdc.gov/vaccines/pubs/vis/default.htm> (last visited February 12, 2010).

<sup>9</sup> Immunization Action Coalition, *It's federal law! You must give your patients current Vaccine Information Statements (VISs)*, see <http://www.immunize.org/catg.d/p2027.pdf> (last visited February 15, 2010).

<sup>10</sup> Florida Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 33 (January 12, 2009).

<sup>11</sup> Florida Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 117 (October 2, 2009).

<sup>12</sup> Public Law 99-660, the National Childhood Vaccine Injury Act, National Vaccine Injury Compensation Program.

<sup>13</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, "Vaccine Injury Table," see <http://www.hrsa.gov/Vaccinecompensation/table.htm> (last visited February 15, 2010).

<sup>14</sup> *Id.*

<sup>15</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, "Filing a Claim with the VICP," see [http://www.hrsa.gov/vaccinecompensation/filing\\_claim.htm](http://www.hrsa.gov/vaccinecompensation/filing_claim.htm) (last visited February 13, 2010).

<sup>16</sup> *Id.*

<sup>17</sup> Centers for Disease Control and Prevention, *Outbreak of Measles – San Diego, California, January – February 2008*, MMWR Weekly, February 22, 2009, see <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm> (last visited February 13, 2010).

measles occurred in 2005 despite the fact that 86 percent of the population had received one dose of the vaccine and 70 percent of the population has received two doses of the vaccine.<sup>18</sup>

Last year, Sarasota County experienced a whooping cough outbreak, a documented 58 cases in 2009, compared to an average of 6.3 cases over the preceding three years. An investigation by the Sarasota County Public Health Department concluded that the outbreak “can be partially attributed to a large outbreak of 24 cases among a group of families that...had very poor pertussis vaccination coverage.”<sup>19</sup> This outbreak began with the infection of a child who received only one pertussis vaccine.<sup>20</sup> The state requirement is 4-5 doses.<sup>21</sup> Sixteen children out of the 24 total cases in this group had “incomplete vaccination coverage” or “no history of vaccine.”<sup>22</sup>

Public response to disease outbreak typically involves identification of cases, isolation of patients and vaccination, administration of immune globin, and voluntary quarantine of contacts who have no evidence of immunity.<sup>23</sup> The cost associated with controlling an outbreak can be substantial. Although a final cost estimate for last year’s Sarasota County whooping cough outbreak is not available, public health staff suggested that personnel cost alone was “tens of thousands [of dollars].”<sup>24</sup>

### **Express and Informed Consent**

Informed consent requires patient authorization, when practicable, for treatment of a specific diagnosis after consultation with the treating health care practitioner. Informed consent should be given prior to the initiation of treatment. Informed consent arises in the common law context generally and Florida law recognizes informed consent requirements for certain conditions.<sup>25</sup>

Chapter 766, F.S., prohibits recovery for claims against certain health care practitioners for lack of informed consent when treatment was in accordance with an accepted standard of care such that a reasonable person would have “a general understanding” of the treatment, associated risks and alternative treatments for his condition. In the absence of informed consent, s. 766.103(b), F.S., provides that recovery is prohibited when a patient would “reasonably, under all the surrounding circumstances” have consented to the treatment after having been advised by a health care practitioner.

A rebuttable presumption of valid informed consent arises under Chapter 766, F.S., when informed consent is expressed in writing and signed by the patient. However, to operate as a bar to recovery, informed consent expressed in writing is not required.

### **Vaccines and Autism Spectrum Disorder**

Autism spectrum disorder (ASD) is the term for a number of pervasive developmental disorders including autistic disorder, Asperger’s Syndrome, and Rhettt’s syndrome.<sup>26</sup> Generally detected by three years of age, the CDC estimates that ASD affects between two and six in every 1,000 children.<sup>27</sup> Common characteristics shared by children with ASD are varying degrees of deficits in social interaction, verbal and nonverbal communication, and repetitive behaviors or interest.

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<sup>18</sup> *Id.*

<sup>19</sup> Correspondence with Sarasota County Health Department, dated February 12, 2010 (on file with the Committee).

<sup>20</sup> *Id.*

<sup>21</sup> Florida Department of Health, Immunization *Guidelines: Florida Schools, Childcare Facilities and Family Daycare Home, Effective July 2008*, see <http://www.immunizeflorida.org/schoolguide.pdf> (last visited February 13, 2010).

<sup>22</sup> Correspondence with Sarasota County Health Department, dated February 12, 2010 (on file with the Committee).

<sup>23</sup> Centers for Disease Control and Prevention, *Outbreak of Measles – San Diego, California, January – February 2008*, MMWR Weekly, February 22, 2009, see <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm> (last visited February 13, 2010).

<sup>24</sup> Teleconference with Sarasota County Health Department, February 12, 2010 (notes on file with the Committee).

<sup>25</sup> See e.g., s. 394.459, F.S., relating to the mental health treatment for children; s. 390.0111, F.S., relating to termination of pregnancies; s. 381.004, F.S., HIV testing.

<sup>26</sup> National Institute of Mental Health, U.S. Department of Health and Human Services, *Autism Spectrum Disorders: Pervasive Developmental Disorders*, see <http://www.nimh.nih.gov/health/publications/autism/index.shtml> (last visited February 14, 2010).

<sup>27</sup> *Id.*

According to the National Institute of Mental Health, the rate of autism diagnosis is increasing - possibly due a change in the criteria to diagnose and "increased recognition of the disorder by professionals and the public."<sup>28</sup> Currently, there is no determinative cause of autism, but many theories have been suggested. A controversial theory attributed the cause of autism to the preservatives used in vaccines, in particular thimerosal. Use of thimerosal as a vaccine preservative ceased, with the exception of use in some influenza vaccines, due to recommendations by the American Academy of Pediatrics and other medical associations over ten years ago.<sup>29</sup>

A 1998 study of 12 children in the medical journal, *The Lancet*, documented a link between the MMR vaccine and autism. The study led to a debate in the medical community about the relationship between vaccination and autism and concern spread in the public health community that such speculation would cause a drop in vaccination rates. Subsequent to publication of the study, Britain sustained growing measles outbreaks leading to the first measles-related death in over a decade.<sup>30</sup> The country's vaccination rate has dropped 20% in the last fifteen years and is currently below 70% in some areas.<sup>31</sup> Ten of the 13 authors of the study in *The Lancet* partially retracted it.<sup>32</sup> In February 2010, *The Lancet* officially retracted the article based on its methodological flaws. *The Lancet* authorized the full retraction after it was discovered that the main researcher, Andrew Wakefield, "had been paid to conduct his study on children who were clients of lawyer ginning up a lawsuit."<sup>33</sup>

Numerous studies have concluded that no causal link exists between vaccination and autism. In repudiation of the study in *The Lancet*, a 2004 study by the Institute of Medicine concluded that there is no causal link between the MMR vaccine and autism.<sup>34</sup>

A number of lawsuits brought by parents of autistic children against vaccine manufactures have been filed since *The Lancet's* study was first published. Last year the U.S. Court of Federal Claims denied three families damages from the Vaccine Injury Compensation Program after they argued that vaccinations caused their children's autism. The Court found, "The numerous medical studies concerning these issues, performed by medical scientists worldwide, have come down strongly against the petitioners' contentions. . . . the petitioners failed to demonstrate that thimerosal-containing vaccines can contribute to causing...autism..."<sup>35</sup> A total of 5,613 autism-related petitions have been filed with the Fund; zero qualified for compensation.<sup>36</sup>

### **Effect of Proposed Changes**

House Bill 117 requires that prior to immunization required for Florida school admittance or attendance, a health care practitioner must provide the current CDC VIS to the parent or legal guardian of the minor vaccine recipient. When available, the bill authorizes practitioners to use a single VIS that covers multiple vaccines.

The bill provides that the parent or legal guardian of a minor vaccine recipient must also sign a "statement" which acknowledges recipient of:

- the applicable VIS;
- vaccine-specific information including risks and benefits;
- adverse reaction reporting information;

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<sup>28</sup> *Id.*

<sup>29</sup> The Centers for Disease Control and Prevention, Frequently Asked Questions about Thimerosal, see [http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal\\_faqs.html](http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal_faqs.html) (last visited February 14, 2010).

<sup>30</sup> The Wall Street Journal, "The Lancet's Vaccination Retraction: A medical journal's role in the autism scare," February 3, 2010, see <http://online.wsj.com/article/SB10001424052748704022804575041544115791952.html> (last visited February 14, 2010).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> The Wall Street Journal, "Lance Retracts Study Tying Vaccine to Autism," February 3, 2010, see <http://online.wsj.com/article/SB10001424052748704022804575041212437364420.html> (last visited February 14, 2010).

<sup>35</sup> *Cedillo v. Sec'y of U.S. Dept. of Health and Humans Svcs.*, No. 98-916v, 2009 WL 331968 (Fed. Cl.) (Feb. 12, 2009).

<sup>36</sup> National Vaccine Injury Compensation Program, "Statistics Reports," see [http://www.hrsa.gov/Vaccinecompensation/statistics\\_report.htm](http://www.hrsa.gov/Vaccinecompensation/statistics_report.htm) (last visited February 14, 2010).

- awareness of the National Vaccine Injury Compensation Program; and
- general childhood disease and vaccine information.

The signed statement must be retained in the patient's permanent medical record. The bill requires a VIS to be distributed for each vaccine administered whether or not the statement is required under federal law. The health care practitioner must also record the batch and lot number of each vaccine administered on the signed statement.

**B. SECTION DIRECTORY:**

Section 1: Amends s. 1003.22, F.S., relating to school-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.

Section 2: Amends s. 381.003, F.S., relating to communicable diseases and AIDS prevention and control.

Section 3: Amends s. 1002.42, F.S., relating to private schools.

Section 4: Provides an effective date of July 1, 2010.

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

**A. FISCAL IMPACT ON STATE GOVERNMENT**

1. Revenues:

None.

2. Expenditures:

None.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

**C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

According to DOH, there may be some cost to private health care providers for producing and storing the hardcopy required statements, particularly if the private provider utilizes electronic medical records.

**D. FISCAL COMMENTS:**

None.

**III. COMMENTS**

**A. CONSTITUTIONAL ISSUES:**

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

None.

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

According to DOH, the term “batch number” is no longer used to identify vaccines and is not readily available to health care practitioners as it is not included on vaccine packaging. Due to the obsolete nature of the term “batch number,” compliance with this requirement may be difficult.

Most county health departments utilize electronic means for immunization records. The bill does not expressly provide for an electronic signature on the statement.

DOH vaccination and immunization policy is to remove barriers to vaccination for parents and legal guardians to encourage timely immunization. As there is no federal or state law requiring parental signature, this additional requirement may lead to less compliance with immunization requirements.<sup>37</sup> The bill does not provide for an alternative means of immunization upon a parent’s refusal to sign the statement.<sup>38</sup>

**IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES**

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<sup>37</sup> Teleconference with Florida Department of Health Staff, dated February 10, 2010 (notes on file with the Committee).

<sup>38</sup> Florida Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 117 (October 2, 2009).