

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 213 Immunization Registry  
**SPONSOR(S):** Health & Human Services Committee, Massullo  
**TIED BILLS:** IDEN./SIM. **BILLS:** SB 354

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	10 Y, 1 N	Mielke	Clark
3) Health & Human Services Committee	16 Y, 0 N, As CS	Siples	Calamas

### SUMMARY ANALYSIS

Florida law requires children to comply with an immunization schedule established by the Department of Health (DOH) as a condition of school attendance, or register a religious objection to immunization. A parent or guardian must provide a school or child care facility a form signed by an administering health care practitioner that shows compliance with the immunization requirements for admission or attendance.

Every child born in the state is entered into an electronic database maintained by DOH to record vaccines received; children not born in the state are entered as they are immunized in Florida. A health care practitioner may voluntarily enter immunization records into the database, and schools and child care facilities may obtain the immunization records of a student as authorized by a parent or guardian. Although all children are listed in the database, a parent or guardian may choose to not to have his or her child's immunization record maintained in the database.

CS/HB 213 requires physicians, physician assistants, and nurses who administer vaccines to children through age 17, or to certain college or university students, to report the vaccinations to the immunization registry. The bill authorizes college or university students to refuse to be included in the immunization registry. The bill requires a parent or college student to submit an opt-out form to the health care practitioner or entity providing the immunization or directly to DOH. DOH must remove any identifying records of a child or college student who has opted out of the immunization registry. The bill also authorizes automated data uploads to the immunization registry from existing electronic health record systems.

The bill eliminates DOH's specific rulemaking and replaces it with general authority to adopt rules as needed to administer the communicable disease prevention program.

Currently, a school district or private school may accept a child's immunization record on a DOH-approved form or obtain it by accessing the immunization registry. The bill requires school districts and private schools to have a policy that requires each student to have a certification of immunizations on file with the state's electronic immunization registry. However, the school must still accept the DOH-approved immunization form if the child's parent has opted out of the immunization registry.

The bill has no fiscal impact on state or local governments.

The bill has an effective date of January 1, 2021.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### Present Situation

##### Vaccinations

Current law requires the Department of Health (DOH) to implement a program to prevent and control vaccine-preventable diseases, including the immunization of all children in this state and to develop an automated, electronic, and centralized registry of immunizations.<sup>1</sup> For school admission or attendance, a child must obtain the following vaccinations:<sup>2</sup>

- Diphtheria, tetanus, and pertussis;
- Polio
- Measles, mumps, rubella (MMR);
- Haemophilus influenza type b (Hib);
- Hepatitis B; and
- Varicella (Chickenpox).

Meningococcal meningitis and hepatitis B vaccines are required for individuals residing in on-campus housing of a postsecondary educational institution and are recommended for every student.<sup>3</sup>

A parent of a child may register a religious objection to immunizations or a physician may exempt a child from immunizations based on medical reasons.<sup>4</sup> These are the only reasons a child may be exempted from obtaining the required vaccinations.

##### Florida SHOTS

The Florida State Health Online Tracking System (SHOTS) is the statewide, online immunization registry employed by DOH to track immunization records.<sup>5</sup> Only authorized health care practitioners, schools, childcare providers, and parents may access the system.<sup>6</sup> A health care practitioner voluntarily enrolls to access SHOTS, and once enrolled, may upload his or her patients' immunization history into the system.<sup>7</sup> A health care practitioner who provides an immunization that is required for school admission or attendance documents such immunization on a Florida Certification of Immunization Form (immunization form) or submits such information to SHOTS for electronic certification.<sup>8</sup> In 2018, 12,548 providers reported data to SHOTS.<sup>9</sup> The SHOTS record includes:<sup>10</sup>

---

<sup>1</sup> Section 381.003(1)(e), F.S.

<sup>2</sup> Department of Health, *Immunization Guidelines: Florida Schools, Childcare Facilities, and Family Daycare Homes*, (March 2013), incorporated by reference in r. 64D-3.046, F.A.C., available at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/documents/school-guide.pdf> (last visited February 16, 2019). The schedule and the number of doses required varies by age.

<sup>3</sup> Section 1006.69, F.S. A student or the parent of a minor who is required to have such vaccines, may refuse by signing a waiver for each vaccine.

<sup>4</sup> Section 1003.22 (5), F.S. The form a parent must submit to register a religious objection to vaccines may be found at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/immunization-exemptions/index.html> (last visited March 3, 2019).

<sup>5</sup> Department of Health, *Frequency Asked Questions*, available at <http://www.floridahealth.gov/programs-and-services/immunization/immunization-faq.html> (last visited February 16, 2019).

<sup>6</sup> Id.

<sup>7</sup> Id.

<sup>8</sup> Rule 64D-3.046, F.A.C.

<sup>9</sup> E-mail correspondence with DOH, dated February 18, 2019, (on file with the Health Quality Subcommittee).

<sup>10</sup> *Supra* note 1.

- The child’s name, date of birth, address, and other unique identifiers necessary;
- The immunization record, including the date, type of vaccine administered, and vaccine lot number; and
- The presence or absence of any adverse reaction or contraindication related to the immunization.

DOH must maintain the confidentiality of the information stored in SHOTS, and any health care practitioner or other agency that obtains such information must maintain the confidentiality.<sup>11</sup>

Any child entering a preschool, school (K-12), licensed childcare facility, or family daycare home must present an immunization form.<sup>12</sup> An enrolled school or childcare facility may access the system to obtain certification of a child’s immunizations. Parents or guardians may access SHOTS to track their children’s immunizations.<sup>13</sup> Authorized users may access and use SHOTS at no charge.<sup>14</sup>

A parent or guardian to elect to exclude his or her child’s immunization record from SHOTS by submitting a DOH-approved opt-out form.<sup>15</sup> However, by rule, DOH does not allow a parent to exclude a child’s data from SHOTS.<sup>16</sup> Instead DOH prevents a child’s immunization record from being automatically shared with preschools, schools, childcare facilities, and family daycare homes.<sup>17</sup> Therefore, the opt-out only prevents the child’s immunization record from being accessed electronically by persons or entities other than the child’s physician; the child’s record is still maintained in SHOTS. However, on March 1, 2019, DOH removed the records of those children and individuals for whom an opt-out form was submitted.<sup>18</sup> A health care practitioner may not access any pre-existing immunization information in SHOTS and may not enter a new record for a child who has opted out of SHOTS.<sup>19</sup> If an individual has opted-out of SHOTS participation, SHOTS displays a message that the patient has requested non-participation in Florida SHOTS and that no immunization record is available.<sup>20</sup> The opt-out does not exempt a child from obtaining required immunizations.<sup>21</sup>

### DOH Rulemaking Authority

Current law authorizes DOH to adopt, repeal, and amend rules related to the prevention and control of communicable disease and the immunization registry (SHOTS).<sup>22</sup> Specifically, DOH may adopt rules that address:

- Procedures for investigating diseases;
- Timeframes for reporting diseases;
- Definitions;
- Procedures for managing specific diseases;
- Requirements for follow reports of known or suspected exposure to disease;
- Procedures for providing access to confidential information necessary for disease investigations;

<sup>11</sup> Id.

<sup>12</sup> *Supra* note 2. A parent who has a religious objection to the administration of vaccines may apply to DOH for an exemption. A child may also be exempted from immunizations based on medical reasons.

<sup>13</sup> *Supra* note 5. A parent must obtain the identification and certification PIN numbers of their child’s immunization record from the child’s health care practitioner to access the information.

<sup>14</sup> Florida SHOTS, *Frequently Asked Questions*, available at <http://flshotsusers.com/resources/frequently-asked-questions> (last visited February 16, 2019).

<sup>15</sup> Section 381.003(1)(e)2., F.S.

<sup>16</sup> Rule 64D-3.046(6), F.A.C. See also Department of Health, *Florida SHOTS Notification and Opt Out Form*, Form DH-1478, (Sept. 3, 2014), available at <https://flshotsusers.com/sites/default/files/docs/DH%201478ENGLISH0914.pdf> (last visited February 16, 2019).

<sup>17</sup> Id.

<sup>18</sup> Department of Health, *Florida SHOTS Notice to Providers*, available at <http://flshotsusers.com/blog/florida-shots-notice-providers> (last visited February 16, 2019).

<sup>19</sup> Id.

<sup>20</sup> Id.

<sup>21</sup> *Supra* note 16.

<sup>22</sup> Section 381.003, F.S.

- Procedures for a health care practitioner to obtain authorization to use SHOTS;
- Methods for a parent or guardian to elect not to participate in SHOTS; and
- Procedures for a health care practitioner to access and share electronic immunization records with other entities allowed by law to have access to records.

### School District Policies for Immunization Records

Each school district and the governing board of each private school must maintain and enforce a policy that requires each child who is admitted to or attends a private or public school, respectively, present or have on file a certification of immunizations for those immunizations required by DOH.<sup>23</sup> The certification must be made on the DOH-approved immunization form and becomes a part of the child's permanent record.<sup>24</sup>

### **Effect of Proposed Changes**

Currently, reporting to SHOTS is voluntary for health care practitioners. CS/HB 213 requires physicians, physician assistants, and nurses who administer vaccines to children through age 17, or to students aged 18 to 23 at a Florida college or university health care facility, to report the vaccination to SHOTS. Vaccination data for any other individuals receiving immunizations may be voluntarily submitted to SHOTS. Current law allows a parent to exclude a child's data from SHOTS. The bill retains this provision and extends it to students who receive vaccinations at a Florida college or university health center or clinic. The bill requires a parent or college student to submit an opt-out form to the health care practitioner or entity providing the immunization for submission to DOH or directly to DOH. DOH must remove any identifying records of a child or college student who has opted out of SHOTS. The bill authorizes automated data uploads to the immunization registry from existing electronic health record systems used by health care practitioners and health care facilities.

The bill requires school districts and private schools to have policies that require each student to have a certification of immunizations on file with SHOTS. However, the school must accept the certification of immunization on a form approved by DOH, if the child's data is excluded from SHOTS.

The bill removes DOH's specific rulemaking authority and replaces it with general authority to adopt rules to administer the program.

The bill provides an effective date of January 1, 2021.

#### **B. SECTION DIRECTORY:**

**Section 1:** Amends s. 381.003, F.S., relating to communicable diseases and AIDS prevention and control.

**Section 2:** Amends s. 1003.22, F.S., relating to school-entry health examinations; immunizations against communicable diseases; exemptions; duties of Department of Health.

**Section 3:** Provides an effective date of January 1, 2021.

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

#### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

##### **1. Revenues:**

None.

<sup>23</sup> Section 1003.22(4), F.S.

<sup>24</sup> Id.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners who choose to have their electronic health records interface with the SHOTS system may incur costs associated with facilitating such access.

D. FISCAL COMMENTS:

None.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides DOH with sufficient rulemaking authority to implement its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 28, 2019, the Health and Human Services Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Required a parent or college student to submit a form to the health care practitioner or entity providing the immunization or to DOH to opt-out of the immunization registry;
- Required DOH to remove all records and identifying information of the child or student who has opted out of the registry; and
- Clarified that a parent may request to opt out of the registry for a child from birth through age 17, and a college student, age 18 to 23, may request to opt out.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.