

**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 Committee on Rules

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BILL: CS/SB 354

INTRODUCER: Education Committee and Senator Montford

SUBJECT: Immunization Registry

DATE: April 9, 2019

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	<b>Favorable</b>
2.	Olenick	Sikes	ED	<b>Fav/CS</b>
3.	Rossitto-Van Winkle	Phelps	RC	<b>Pre-meeting</b>

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 354 directs certain health care practitioners to report vaccination administration data to the Department of Health (DOH) immunization registry when vaccinating children up to 18 years of age or college or university students at a college or university health center who are 19 to 23 years of age. The bill permits a parent or guardian of a child up to 18 years of age or a college or university student 19 to 23 years of age to opt out of being included in the immunization registry. Such a decision not to participate in the immunization registry must be provided to DOH and the healthcare practitioner and all records regarding the child or student must be removed from the registry.

The bill also directs school boards and private school governing bodies to establish and enforce a policy requiring that before a child may attend a public or private school, the child must have on file a Florida Certification of Immunization (FCI) with the DOH immunization registry. Any child who does not participate in the immunization registry must present or have on file with the school an FCI form, which will be a part of the student's permanent record and be transferred with the student if the student transfers.

The bill also provides that school boards and private school governing bodies must establish and enforce a policy requiring appropriate scoliosis screening at the proper age.

The effective date of the bill is January 1, 2021.

## II. Present Situation:

### Communicable Disease Prevention and Control

The DOH is responsible for the state's public health system, which must promote, protect, and improve the health of all people in the state.<sup>1</sup> As part of fulfilling this public health mission, the DOH is responsible for conducting a communicable disease prevention and control program. A communicable disease is any disease caused by the transmission of a specific infectious agent, or its toxic products, from an infected person, animal, or the environment to a susceptible host, either directly or indirectly.<sup>2</sup>

The DOH communicable disease program includes, but need not be limited to, programs for the prevention and control of:

- Tuberculosis;
- Human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS);
- Sexually transmissible diseases;
- Communicable diseases of public health significance; and
- Vaccine-preventable diseases<sup>3</sup>, including programs to immunize school children<sup>4</sup> and the development of an automated, electronic, and centralized database or registry for immunization records.<sup>5</sup>

The DOH may adopt rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for:

- Investigating disease;
- Timeframes for reporting disease;
- Definitions;
- Procedures for managing specific diseases;
- Requirements for follow-up reports on disease exposure; and
- Procedures for providing access to confidential information necessary for disease investigations.<sup>6</sup>

### The DOH Immunization Registry (Florida SHOTS)

The DOH must ensure that all children are immunized against vaccine-preventable diseases and be included in the immunization registry, for the purpose of enhancing the DOH's immunization

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<sup>1</sup> Section 381.001, F.S.

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

<sup>3</sup> Measles, mumps, rubella, pertussis, diphtheria, tetanus, polio, varicella, pneumococcal disease, hepatitis A, hepatitis B, influenza, meningococcal and Haemophilus influenza type b (Hib) are all preventable by vaccine. See Department of Health, *Vaccine Preventable Diseases*, <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Jan. 18, 2019).

<sup>4</sup> See s. 1003.22(3)-(11), F.S.

<sup>5</sup> Section 381.003(1), F.S.

<sup>6</sup> Section 381.003(2), F.S.

activities and improve immunization for all children. Florida's State Health Online Tracking System (SHOTS) is the free, statewide, centralized online immunization registry that assists healthcare providers, schools, and parents keep track of immunization records.<sup>7</sup> The program seeks to ensure a cause-and-effect response by monitoring immunization levels in vulnerable populations throughout the state, thereby contributing to strategies to attain and sustain high immunization levels. This has the effect of lowering vaccine-preventable disease rates.<sup>8</sup>

The DOH may make rules for the immunization registry, to include:

- Procedures for a health care practitioner to obtain authorization to use the registry;
- Methods for a parent or guardian to elect not to participate in the registry; and
- Procedures for health care practitioners licensed under chs. 458, 459, or 464, F.S., to access and share electronic immunization records with other entities allowed by law to have access to the records.<sup>9</sup>

The DOH includes all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics and then adds other children to the registry as immunizations are given. The DOH documents in the registry the child's:

- Name;
- Date of birth;
- Address;
- Other unique information to identify the child; and
- The immunization(s) administered, including:
  - Type of vaccine administered;
  - The date the vaccine was administered;
  - The vaccine lot number; and
  - The presence or absence of any adverse reaction or contraindication to the immunization.<sup>10</sup>

A parent or guardian may refuse to have a child included in the immunization registry. In such case, a parent or guardian must sign a DOH-approved form which indicates that the parent or guardian does not wish to have the child's immunization history included in the immunization registry. The decision to not participate in the registry must be noted in the registry.<sup>11</sup>

The DOH immunization registry allows for immunization records to be electronically transferred to entities that are required by law to have such records, including schools, licensed child care facilities, and any other entities required by law to obtain proof of a child's immunizations. Any health care practitioner licensed under chs. 458, 459, or 464, F.S., who complies with the DOH rules to access the immunization registry, may:

- Directly access a child's immunization records;

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<sup>7</sup> Department of Health, Providing Records to Patients, *Deliver Accurate, Timely Records*, <http://www.floridahealth.gov/programs-and-services/immunization/information-for-healthcare-providers/providing-records-to-patients/index.html> (last visited Jan. 18, 2019).

<sup>8</sup> See Department of Health, *Vaccine Preventable Diseases*, <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Jan. 18, 2019).

<sup>9</sup> Section 381.003(1)(e), F.S.

<sup>10</sup> Section 381.003(1)(e)4., F.S.

<sup>11</sup> Section 381.003 (1)(e)2., F.S.

- Update a child's immunization history; or
- Exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.<sup>12</sup>

The SHOTS also helps prevent needless revaccinations for entry into daycare and schools because of lost or unavailable paper records. Currently over 15,000 health care practitioners licensed under chs. 458, 459, or 464, F.S., voluntarily provide data to the registry; but because reporting is currently voluntary, some individuals' immunization records in the data base have been incomplete. As a result, the immunization program has received many complaints with respect to incomplete records. This has resulted in unnecessary revaccinations and difficulty for parents and schools to obtain a paper record.<sup>13</sup>

The information included in the DOH immunization registry retains its status as confidential medical information; and the DOH must maintain the confidentiality of that information as required by law. A health care practitioner or other agency that obtains information from the immunization registry must also maintain the confidentiality of the records as required by law.<sup>14</sup>

### Required Immunizations

Each school district board and non-public school governing body is required to ensure that every child entering school in kindergarten through grade 12 must present or have on file a Florida Certificate of Immunization (FCI) before entering or enrolling in school.<sup>15</sup> Children entering, attending or transferring to Florida public or non-public schools, kindergarten through grade 12, must have on file as part of their permanent school record<sup>16</sup> an FCI documenting that they have had the following immunizations:

- Four or five doses of DTaP (Diphtheria-tetanus-acellular pertussis);
- Four or five doses of IPV (Inactivated polio vaccine);
- Two doses of MMR (Measles-mumps-rubella);
- Three doses of Hep B (Hepatitis B);
- One Tdap (Tetanus-diphtheria-acellular pertussis);
- Two doses of Varicella (unless there is a history of varicella disease documented by a health care provider); and
- If entering a public or non-public school in seventh grade or later, an additional dose of Tdap (Tetanus-diphtheria-acellular pertussis).<sup>17</sup>

<sup>12</sup> Section 381.003(1)(e), F.S.

<sup>13</sup> Department of Health, *Florida Shots, keeping shots in check*. available at <http://flshotsusers.com/parents-guardians>, (last visited Feb. 14, 2019).

<sup>14</sup> Section 381.003(1)(e)4., F.S.

<sup>15</sup> Section 1003.22(4), F.S.

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

<sup>17</sup> See also Department of Health, *School Immunization Requirements* (last modified Aug. 19, 2016), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare> (last visited Jan. 18, 2019). See also the Dep't of Health, Form DH-680, Form for Florida Certification of Immunizations (Jul. 2010), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/documents/dh-680-sample.pdf> (last visited Jan. 18, 2019).

Private health care providers may grant a temporary medical exemption (TME), documented on the FCI form,<sup>18</sup> for those who are in the process of completing any necessary immunizations. The TME incorporates an expiration date after which the exemption is no longer valid, and the immunizations must be completed before or at that time. A permanent medical exemption may be granted if a child cannot be fully immunized due to medical reasons. In such case, the child's physician must state in writing the reasons for the exemption based on valid clinical reasoning or evidence on the FCI form.<sup>19</sup>

A request for a religious exemption from immunizations requires the parent or guardian to provide the school or facility with a Religious Exemption Immunization form.<sup>20</sup> The form is issued only by county health departments and only for children who are not immunized because of the family's religious tenets or practices. Exemptions for personal or philosophical reasons are not permitted under Florida law.<sup>21</sup>

### Scoliosis Screening

The term "scoliosis" indicates lateral curvature and rotation of the spine. Although it can span all age groups, the deformity is most frequently seen in normal, rapidly-growing, preadolescent or adolescent children. Because most of the serious consequences of scoliosis can be prevented, it is particularly responsive to early diagnosis and proper treatment.<sup>22</sup>

Currently, the DOH School Health Services Program, a component of the public health system, provides basic health services to all public school students, including scoliosis screening. Scoliosis screening is required by the DOH, at a minimum, for all sixth grade students.<sup>23</sup> In addition, all 67 counties provide additional basic services through the DOH School Health Services Program, including:

- Health appraisals;
- Nursing assessments;
- Child-specific training;
- Preventative dental screenings and services;
- Vision, hearing, scoliosis, and growth and development screenings;

<sup>18</sup> Department of Health, Form DH-680, Form for Florida Certification of Immunizations (Jul. 2010), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/documents/dh-680-sample.pdf> (last visited Jan. 18, 2019).

<sup>19</sup> Department of Health, *Exemptions from Immunizations*, <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/immunization-exemptions/index.html> (last visited Jan. 18, 2019).

<sup>20</sup> Department of Health, Form DH-681, *Form for Religious Exemption From Immunization*, <http://www.floridahealth.gov/%5C/programs-and-services/immunization/documents/dh-681-sample.pdf> (last visited Jan. 18, 2019). The DH 681 Form, *Religious Exemption From Immunization* form, puts a parent or guardian on notice that any child not immunized against a communicable disease that has been declared a communicable disease emergency.

<sup>21</sup> Department of Health, Immunization Section, Bureau of Communicable Diseases, *Immunization Guidelines, Florida Schools, Childcare Facilities and Family Daycare Homes* (March 2013), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/schoolguide.pdf> (last visited Jan. 18, 2019).

<sup>22</sup> Barbara H. Dunn, Michael W. Hakala, & Mary E. McGee, PEDIATRICS: *Scoliosis Screening* (May 1978, VOLUME 61 / ISSUE 5 available at [http://pediatrics.aappublications.org/content/61/5/794?sso=1&sso\\_redirect\\_count=1&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token](http://pediatrics.aappublications.org/content/61/5/794?sso=1&sso_redirect_count=1&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token)

<sup>23</sup>Rule 64F-003, F.A.C.

- Health counseling;
- Referral and follow-up of suspected or confirmed health problems;
- First aid and emergency health services;
- Assistance with medication administration; and
- Health care procedures for students with chronic or acute health conditions.

The goal of the School Health Services Program is to ensure that students are healthy, in school, and ready to learn.<sup>24,25</sup> In cooperation with the Department of Education (DOE), the School Health Services Program provides funding for the services mandated by statute.<sup>26</sup>

A non-public school may request to participate in the School Health Services Program. A non-public school that voluntarily participates must:

- Cooperate with the county health department and district school board in the development of the cooperative health services plan;
- Make available adequate physical facilities for health services;
- Provide in-service health training to school personnel;
- Cooperate with public health personnel in the implementation of the school health services plan;
- Be subject to health service program reviews by the DOH and the DOE;
- At the beginning of each school year, provide parents and guardians with information concerning ways they can help their children to be physically active and to eat healthful foods; and
- At the beginning of each school year, inform parents or guardians in writing that their children who are students in the school will receive specified health services as provided for in the district health services plan. A student will be exempt out of these services if his or her parent or guardian requests such exemption in writing.<sup>27</sup>

### III. Effect of Proposed Changes:

The bill directs health care practitioners licensed under chs. 458, 459, or 464, F.S., who administer vaccinations, or cause vaccinations to be administered, to children up to 18 years of age, or to college or university students at a college or university student health center who are 19 to 23 years of age, to report the following patient vaccination administration information to the DOH immunization registry (SHOTS):

- Patient's name;
- Date of birth;
- Address;
- Other unique information to identify the child; and
- The immunization(s) administered, including:

<sup>24</sup> The Department of Health, School Health Services program, *School Health Services*, available at: <http://www.floridahealth.gov/programs-and-services/childrens-health/school-health/index.html> (last visited Feb. 14, 2019).

<sup>25</sup> Philip, Celeste, M.D., M.P.H., State Surgeon General and Secretary, the Department of Health, School Health Administrative Resource Manual (revised 2017) at p. 8, available at <http://www.floridahealth.gov/programs-and-services/childrens-health/school-health/documents/2017-school-health-resource-manual1.pdf>

<sup>26</sup> See ss. 381.0056, 381.0057, and 402.3026, F.S.

<sup>27</sup> Section 381.0056(5), F.S.

- Type of vaccine administered;
- The date the vaccine was administered;
- The vaccine lot number; and
- The presence or absence of any adverse reaction or contraindication to the immunization.

The bill permits a parent or guardian of a child up to 18 years of age or a college or university student 19 to 23 years of age to opt out of being included in the immunization registry. The opt-out must be provided to the Florida Department of Health (DOH) and to the healthcare practitioner upon the administration of the vaccination. All records and references regarding a child or college or university student who has opted out must be removed from the immunization registry.

The bill directs school boards and private school governing bodies to establish and enforce a policy requiring that before a child may attend a public or non-public school, the child must have on file a Florida Certificate of Immunization (FCI) with the DOH immunization registry. Any child who does not participate in the immunization registry must present or have on file with the school an FCI form, which will be a part of the student's permanent record and be transferred with the student if the student transfers.

The bill also directs school boards and private school governing bodies to establish and enforce a policy requiring appropriate scoliosis screening at the proper age.

The bill specifies that the reporting of the vaccination administration data to the DOH immunization registry for other persons is permitted but not required. Health care practitioners may use an existing automated data system for updating immunization information in the immunization registry.

The bill directs that the immunization registry must make electronically available the immunization records to entities required by law to have such records, including, but not limited to, schools and licensed child care facilities.

The bill directs that detailed rulemaking authority relating to the DOH's responsibilities to conduct a communicable disease prevention and control program be condensed into a general granting of rulemaking authority.

The bill takes effect January 1, 2021.

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

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

None.

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

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Housing vaccination data in the registry may allow individuals to avoid the cost of needless revaccinations.

The bill may create a negative fiscal impact on private school governing bodies to cover the costs associated with establishing and enforcing a policy requiring appropriate scoliosis screening at the proper age.

C. Government Sector Impact:

It is unclear the extent to which school district technology systems will be able to handle the transfer and storage of student's immunization data from the state registry of immunizations, Florida SHOTS, to become a part of each student's permanent record.<sup>28</sup> If a school district's technology system requires modification to meet the requirements of the bill, there could be a fiscal impact on that school district.

**VI. Technical Deficiencies:**

The title of the bill is "An act relating to immunization registry." That title could be interpreted as failing to address the bill's requirements relating to public and private school scoliosis screening.

**VII. Related Issues:**

The DOH, in cooperation with the DOE, already has responsibility for the administration, supervision, and periodic review of the School Health Services Program, which includes mandatory scoliosis screening in public schools and in non-public schools that request to participate in the School Health Services Program.

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<sup>28</sup> Staff of the Florida Department of Education, *Legislative Bill Analysis for SB 354* (2019).



**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 381.003 and 1003.22.

**IX. Additional Information:****A. Committee Substitute – Statement of Changes:****CS by Education on March 26, 2019:**

The Committee Substitute provides an opt-out provision for parents or guardians to refuse to include their child on the immunization registry. It also specifies that a college or university student, from 19 years of age to 23 years of age, who obtains a vaccination from a Florida college or university student health center may also opt out from the immunization registry. The opt-out must be provided to the Florida Department of Health and to the healthcare practitioner upon the administration of the vaccination. All records and references regarding a child or college or university student who has opted out must be removed from the immunization registry.

**B. Amendments:**

None.