

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 Committee on Health Policy

BILL: CS/SB 1680

INTRODUCER: Health Policy Committee and Senator Montford

SUBJECT: Immunization Registry

DATE: January 23, 2018

REVISED: 1/23/18

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	Fav/CS
2.			ED	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1680 requires certain health care practitioners to report vaccination administration data to the Department of Health (DOH) immunization registry when vaccinating children, or college or university students, 18 to 23 years of age, at a college or university student health care facility. Mandatory reporting to the registry will eliminate the use of a paper-based certification of immunization. The bill removes a parent's or guardian's ability to opt a child out of the immunization registry.

The reporting of the vaccination data to the registry for other persons is permitted, but not required.

The bill also requires 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. Currently the policy allows submission of an FCI in paper form.

The effective date of the bill is January 1, 2020.

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.¹ 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.²

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 diseases³, including programs to immunize school children⁴ and the development of an automated, electronic, and centralized database or registry for immunization records.⁵

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.⁶

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, to enhance the department's current immunization activities and improve immunization for all children. The Florida State Health Online Tracking System (SHOTS) is the free, statewide, centralized online immunization registry that assists

¹ Section 381.001, F.S.

² Section 381.003(1), F.S.

³ 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, 2018).

⁴ See s. 1003.22(3)-(11), F.S.

⁵ Section 381.003(1), F.S.

⁶ Section 381.003(2), F.S.

healthcare providers, schools, and parents with keeping track of immunization records.⁷ The program ensures 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 increasing herd immunity and lowering vaccine-preventable disease rates.⁸

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.⁹

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;
- The immunization 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.¹⁰

A parent or guardian may refuse to have a child included in the immunization registry. In that 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 included in the immunization registry. The decision to not participate in the registry must also be noted in the registry.¹¹

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;
- Update a child's immunization history; or

⁷ 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, 2018).

⁸ See Department of Health, *Vaccine Preventable Diseases*, <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Jan. 18, 2018).

⁹ Section 381.003(1)(e), F.S.

¹⁰ Section 381.003(1)(e)4., F.S.

¹¹ Section 381.003 (1)(e)2., F.S.

- Exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.¹²

The SHOTS also helps prevent needless revaccinations for entry into daycare and schools because of lost or unavailable paper vaccination and medical 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 the scrambling of parents and schools to obtain a paper record.¹³

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.¹⁴

DOH Required Immunizations

Each school district board, and private school governing body, is required to ensure that every child entering school in kindergarten through grade 12, present, or have on file, an FCI before entering or enrolling in school.¹⁵ Children entering, attending or transferring to Florida public or private schools, kindergarten through grade 12, must have on file as part of their permanent school record¹⁶ 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 private school in seventh grade or later, an additional dose of Tdap (Tetanus-diphtheria-acellular pertussis).¹⁷

Private healthcare providers may grant a temporary medical exemption (TME), documented on the FCI form,¹⁸ for those who are in the process of completing any necessary immunizations. The TME requires an expiration date after which the exemption is no longer valid, and the

¹² Section 381.003(1)(e), F.S.

¹³ Department of Health, *Senate Bill 1680 Analysis* (Dec. 20, 2017) (on file with the Senate Committee on Health Policy).

¹⁴ Section 381.003(1)(e)4., F.S.

¹⁵ Section 1003.22(4), F.S.

¹⁶ *Id.*

¹⁷ See also Department of Health, *School Immunization Requirements* <http://www.floridahealth.gov/%5C/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare> (last visited Jan. 18, 2018). See also the DOH Form DH 680, 07/2010, <http://www.floridahealth.gov/%5C/programs-and-services/immunization/ documents/dh-680-sample.pdf> (last visited Jan. 18, 2018).

¹⁸ Department of Health, Form DH 680, 07/2010, <http://www.floridahealth.gov/%5C/programs-and-services/immunization/ documents/dh-680-sample.pdf> (last visited Jan. 18, 2018).

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 this case, the child's physician must state in writing, the reasons for exemption based on valid clinical reasoning or evidence on the ECI form.¹⁹

A request for a religious exemption from immunizations requires the parent or guardian to provide the school or facility with a *Religious Exemption From Immunization* form.²⁰ 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.²¹

III. Effect of Proposed Changes:

The bill requires health care practitioners licensed under chs. 458, 459, or 464, F.S., who administer vaccinations, or cause vaccinations to be administered, to children, or to college or university students, 18 to 23 years of age, at a college or university student health care facility, 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;
- The immunization 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.

Mandatory reporting to the registry will eliminate the use of a paper-based certificate of immunization.

The bill specifies that the reporting of the above vaccination administration data to the DOH 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 removes a parent's or guardian's ability to opt a child out of the immunization registry.

¹⁹ 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, 2018).

²⁰ Department of Health, *Religious Exemption From Immunization, DH 681 Form*, <http://www.floridahealth.gov/%5C/programs-and-services/immunization/ documents/dh-681-sample.pdf> (last visited Jan. 18, 2018). 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.

²¹ Department of Health, Immunization Section, Bureau of Communicable Diseases, *Immunization Guidelines, Florida Schools, Childcare Facilities and Family Daycare Homes* (March 2013), <http://www.floridahealth.gov/%5C/programs-and-services/immunization/schoolguide.pdf> (last visited Jan. 18, 2018).

The bill requires that the immunization registry 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.

Detailed rulemaking authority relating to the DOH's responsibilities to conduct a communicable disease prevention and control program is condensed into a general grant of rulemaking authority.

The bill requires 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 an FCI with the DOH immunization registry. The FCI becomes a part of each student's permanent school record.

The bill takes effect January 1, 2020.

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:

The mandatory registry for children and college students' immunization data records may reduce a parent's or individual's cost in locating and obtaining lost, destroyed or misplaced immunization records. Housing the vaccination data in the registry may also avoid the cost of needless revaccination.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

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

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS by Health Policy on January 23, 2018:**

Sets an age limit of up to 23 for required reporting on college or university students who are vaccinated at a student health center.

- Removes the delayed effective date of July 1, 2021, for updating the district school board and private school governing authority policies.
- Changes the effective date of the entire bill to January 1, 2020.

B. Amendments:

None.