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 Rules

BILL:	SB 6-D
INTRODUCER:	Senator Yarborough
SUBJECT:	Medical Freedom
DATE:	April 24, 2026
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Kruse	RC	**Pre-meeting**

I. Summary:

SB 6-D creates a statutory nonmedical exemption from immunization requirements for a child attending a K-12 school if the administration of a vaccine conflicts with the parent's conscience. Like the existing religious exemption, the conscience-based exemption would also be available to parents with children attending preschool or day care in a child care facility or family day care home facility who are subject to immunization requirements pursuant to existing rules. The bill requires the Department of Health to make the nonmedical exemption form available on its website.

Before a vaccine may be administered, the bill requires a health care practitioner or paramedic who administers a vaccine to a minor child to provide the child's parent or guardian with the appropriate Vaccine Information Statement published by the U.S. Centers for Disease Control and Prevention and materials relating to the role of immunization in communicable disease prevention, including risks, benefits, safety, and efficacy, as approved and adopted by joint rule of the Board of Medicine and the Board of Osteopathic Medicine. A parent's or guardian's signature must be obtained to document receipt of the information. When a parent or guardian accesses the nonmedical exemption form on the DOH website, the bill requires that the form and the materials approved and adopted by joint rule of the Boards are downloadable as a single document, ensuring that all parents and guardians have access to the same information.

The bill requires that when more than one vaccine is to be administered to a child, the practitioner must discuss the parent's or guardian's options for the timing of the vaccinations and may, at the parent's or guardian's request, administer the vaccines to the child over multiple encounters.

The bill also establishes that it is unlawful for a vaccine manufacturer to offer or pay, or for a health care practitioner to receive, a financial incentive, directly or indirectly, overtly or covertly, in cash or in kind, for the administration of a vaccine. Any such act is considered patient brokering and is punishable by existing law.

The bill authorizes pharmacists to provide ivermectin[1] as a behind-the-counter medication without a prescription to a person 18 years of age or older. Before such dispensing, the bill requires a pharmacist to provide the person with written information regarding indications and contraindications, dosage, and the need to seek follow-up care from the person's primary care physician. The bill grants immunity from civil or criminal liability or disciplinary action under Florida law for pharmacists acting in accordance with these provisions.

Additionally, the bill grants immunity from civil or criminal liability or disciplinary action under Florida law to health care practitioners licensed under chs. 458, 459, or 464, F.S., whose license includes prescribing authority, for prescribing or administering ivermectin to an adult, in good faith, in accordance with the applicable standard of care, and in accordance with the applicable practice act and pertinent rules.

The bill preserves the statutory definition of "messenger ribonucleic acid vaccine" by deleting the definition's scheduled repeal. In practice, this maintains existing prohibitions against mandates by governmental entities, business establishments, and educational institutions that a person must be vaccinated with an mRNA-based vaccine. Finally, the bill clarifies that during a declared public health emergency, the State Surgeon General may not order an individual to be vaccinated.

The bill provides an effective date of July 1, 2026, except as otherwise provided.

II. Present Situation:

Florida Department of Health Immunization[2] Guidelines

Duty to Immunize All Children in Florida

The Florida Department of Health (DOH) is directed by law to ensure that all children in this state are immunized against vaccine-preventable diseases.[3] This requirement is integral to the department's duty to conduct a communicable disease prevention and control program as part of fulfilling its public health mission. The Florida Statutes provide that a communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly.[4]

The DOH is responsible for adopting rules governing the immunization of school children, as well as the testing for and control of preventable communicable diseases. The DOH establishes

[1] Prescription ivermectin tablets are approved for treating certain parasitic infections. Some topical forms of ivermectin are approved to treat external parasitic infestations and rosacea. A topical lotion for head lice is available without a prescription. Ivermectin products are also used to prevent heartworm disease and to treat certain internal and external parasites in animals. *See:* U.S. Food and Drug Administration, *Ivermectin and COVID-19,* Apr. 5, 2024, https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19 (last visited Apr. 20, 2026).
[2] Immunization is defined as "The process of being made immune or resistant to an infectious disease, typically by the administration of a vaccine. It implies that a vaccine will trigger an immune response." *See:* U.S. Centers for Disease Control and Prevention, *Immunization Glossary of Terms*, available at https://www.cdc.gov/vaccines/glossary/index.html (last visited Apr. 20, 2026).
[3] Section 381.003(1)(e), F.S.
[4] Section 381.003(1), F.S.

and maintains its own immunization schedule through the *Immunization Guidelines for Florida Schools, Childcare Facilities, and Family Daycare Homes* ("DOH Immunization Guidelines"), which have remained unchanged since their adoption in 2013.[5]

Florida School-entry Vaccination Requirements

Section 1003.22, F.S., requires immunizations for certain preventable communicable diseases as a condition of admittance to or attendance in Florida public and private schools (K–12) and for initial entrance into a Florida school. The statute requires immunization against the following diseases, several of which are typically provided in combined vaccine formulations:

- DTaP: Diphtheria, Tetanus, and acellular Pertussis (whooping cough);[6]
- Polio;[7]
- MMR: Measles, mumps, and rubella.[8]

The statute authorizes the DOH to determine additional communicable diseases for which immunization is required.[9] Pursuant to this authority, the DOH currently requires vaccinations against the following diseases by rule:

- Haemophilus influenzae type b (Hib);[10]
- Hepatitis B (Hep B);[11]
- Varicella (chickenpox);[12] and
- Pneumococcal conjugate.[13]

Immunizations required under s. 1003.22, F.S., and related DOH rule are available at no cost from county health departments.[14]

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[5] Florida Administrative Code & Florida Administrative Register, Reference: Ref-02342 (adopting Fla. Admin. Code R. 64D-3.046, *Immunization Requirements: Public and Nonpublic Schools, Grades Preschool, Kindergarten Through 12, and Adult Education Classes*; Form DH 150-615, *Revised Form 150-615*), available at https://flrules.org/Gateway/reference.asp?No=Ref-02342 (last visited Apr. 20, 2026).

[6] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: DTaP Vaccine*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/dtap.pdf (last visited Apr. 20, 2026).

[7] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: IPV Vaccine*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/ipv.pdf (last visited Apr. 20, 2026).

[8] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: MMR Vaccine*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/mmr.pdf (last visited Apr. 20, 2026).

[9] Section 1003.22(3), F.S.

[10] Unrelated to the influenza viruses that cause seasonal flu, Hib is a bacterium that can cause severe respiratory infections (including pneumonia), otitis, and diseases such as meningitis. *Supra* note 2. *See also:* U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: Hib Vaccine*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/hib.pdf (last visited Apr. 20, 2026).

[11] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: Hepatitis B Vaccine (Interim)*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/hep-b.pdf (last visited Apr. 20, 2026).

[12] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: Varicella (Chickenpox) Vaccine*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/varicella.pdf (last visited Apr. 20, 2026).

[13] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statement: Pneumococcal Conjugate (PCV) Vaccine*, available at https://www.cdc.gov/vaccines/hcp/current-vis/downloads/pcv.pdf (last visited Apr. 20, 2026).

[14] Section 1003.22(3), F.S.

Eliminating Rule-based Vaccine Mandates

The DOH held a rule workshop on December 12, 2025, in Panama City Beach.[15] At the workshop, draft Proposed Revisions to Rule 64D-3.046 were distributed to attendees. The draft proposed rule eliminated the four vaccinations required only by rule.[16] At this time, no proposed rule has been formally published, and those four vaccinations are still required.

Florida Requirements Versus Federal Vaccination Recommendations

The vaccine recommendations issued by the U.S. Centers for Disease Control and Prevention (CDC) include every vaccine required under Florida law and current DOH rule for K-12 school entry.[17] On January 5, 2026, the CDC announced changes to its Recommended Child and Adolescent Immunization Schedule, which would have reduced the number of recommended vaccinations. Those changes have been stayed by the U.S. District Court for the District of Massachusetts and are not in effect at this time.[18] Under the stayed schedule, the Hep B vaccination would be recommended only for certain high-risk groups or populations.[19]

Florida School-entry Immunization Requirements; Exemptions

To attend a public or private K-12 school, each child must present to the school either a Florida Certificate of Immunization Form[20] or a Religious Exemption from Immunization Form,[21] both of which are adopted under DOH rule. Child care facilities[22] and family day care homes[23] are

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[15] Fla. Dept. of Health, *Notice of Workshop re: Proposed Revisions to Rule 64D-3.046, Immunization Requirements: Public and Nonpublic Schools, Grades Preschool, Kindergarten Through 12, and Adult Education Classes*, Fla. Admin. Reg., Dec. 12, 2025 (notice filed in Vol. 51/230). *See:* Rule 64D-3.046, Fla. Admin. Code.

[16] Proposed Revisions to Rule 64D-3.046 as presented at the Dec 12, 2025 workshop (on file with Senate Committee on Health Policy).

[17] U.S. Centers for Disease Control and Prevention, *Child and Adolescent Immunization Schedule by Age (Addendum updated July 2, 2025)*, available at https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (last visited Apr. 20, 2026).

[18] *American Academy of Pediatrics, et al. v. Robert F. Kennedy, Jr., et al.*, Civil Action No. 25-11916-BEM, (D. Mass., Mar. 16, 2026), Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction, available at https://litigationtracker.law.georgetown.edu/wp-content/uploads/2025/07/American-Academy-of-Pediatrics_2026.03.16_ORDER-ON-MOTION-FOR-PRELIMINARY-INJUNCTION.pdf (last visited Apr. 20, 2026).

[19] The high-risk groups or populations would include infants born to women who tested positive for the hepatitis B virus or whose status is unknown, if the proposed changes were to take effect.

[20] Florida Administrative Code & Florida Administrative Register, Reference Material, Ref-02410 (*64D-3.046, DH Form 680—Florida Certification of Immunization*), available at https://flrules.org/Gateway/reference.asp?No=Ref-02410 (last visited Apr. 20, 2026).

[21] Florida Administrative Code & Florida Administrative Register, Reference Material, Ref-02341 (*64D-3.046; DH Form 681—Religious Exemption from Immunization*), available at https://flrules.org/Gateway/reference.asp?No=Ref-02341 (last visited Apr. 20, 2026).

[22] Section 402.305, F.S., requires the Dept. of Children and Families to establish licensing standards that all licensed child care facilities must meet, including minimum standards relating to immunizations and the maintenance of emergency and health records for all children. Department rule 65C-22, F.A.C., incorporates the *Child Care Facility Handbook*, which in turn references the DOH Immunization Guidelines. The handbook requires child care facilities to obtain a Certificate of Immunization (Form DH 680) or a Religious Exemption from Immunization (Form DH 681) for each child within 30 days of enrollment. See Fla. Admin. Code R. 65C-22.001(8); Fla. Dept. of Children & Families., *Child Care Facility Handbook*, available at https://flrules.org/Gateway/reference.asp?No=Ref-13928 (last visited Apr. 20, 2026).

[23] Section 402.313, F.S., directs the Department of Children and Families to adopt rules establishing minimum standards for family day care homes. These standards must include health and safety requirements, including provisions for the maintenance of immunization records. Department rule 65C-20, F.A.C., incorporates the *Family Day Care Home and Large Family Child Care Home Handbook*, which references the DOH Immunization Guidelines. The handbook requires the

also required, by rule of the Florida Department of Children and Families (DCF), to collect one of these forms for each child they serve.

The Certificate of Immunization Form is prepared by a physician's office or clinic and provides:

- Part A: Completion of immunizations in accordance with DOH Immunization Guidelines;
- Part B: A temporary medical exemption for children[24] who have commenced a schedule to complete the required immunizations;[25] or
- Part C: A permanent medical exemption for medically contraindicated immunizations. Only a licensed allopathic or osteopathic physician may certify a permanent medical exemption.[26]

Aside from a 30-day temporary exemption applicable to transferring students, homeless students, dependent children, or students entering the juvenile justice system, the only nonmedical exemption authorized in the Florida Statutes is a religious exemption. The DOH Religious Exemption from Immunization Form must be signed by a parent or guardian who declares that immunizations conflict with his or her "religious tenets or practices."[27]

The DOH Immunization Guidelines currently state the following regarding the unlawfulness of exemptions that might be sought for other reasons:[28]

> D. Consistency With Florida Law:
>
> Requests for religious exemption from immunizations should be consistent with section 1003.22, *Florida Statutes*. **Exemptions for personal or philosophical reasons are not permitted under Florida law.**

However, the DOH's draft Proposed Revisions to Rule 64D-3.046 delete "Exemptions for personal or philosophical reasons are not permitted under Florida law."[29] from the DOH Immunization Guidelines and amend the Religious Exemption from Immunization form to allow

operator to obtain a Certificate of Immunization (Form DH 680) or a Religious Exemption from Immunization (Form DH 681) for each child within 30 days of enrollment. See Fla. Admin. Code R. 65C-20.010(1)(a); Fla. Dept. of Children & Families., *Family Day Care Home and Large Family Child Care Home Handbook*, available at https://flrules.org/Gateway/reference.asp?No=Ref-13928 (last visited Apr. 20, 2026).

[24] Children under age four are generally granted a temporary medical exemption because they have not received all required vaccine doses required of a kindergartener by that age.

[25] An allopathic, osteopathic, or chiropractic physician can certify a temporary medical exemption pursuant to s. 1003.22(5)(c), F.S. The DOH has indicated that it is not within a chiropractic physician's scope of practice to administer a vaccine to a minor child. *See:* Fla. Dept. of Health, *Legislative Bill Analysis: SB 1756,* Jan. 22, 2026 (on file with Senate Committee on Health Policy).

[26] Florida Administrative Code & Florida Administrative Register, *supra* note 20.

[27] The immunization requirements do not apply if "the parent of the child objects in writing that the administration of immunizing agents conflicts with his or her religious tenets or practices." *See:* s. 1003.22(5)(a), F.S.

[28] Florida Administrative Code & Florida Administrative Register, Reference: Ref-02342 (adopting Fla. Admin. Code R. 64D-3.046, *Immunization Requirements: Public and Nonpublic Schools, Grades Preschool, Kindergarten Through 12, and Adult Education Classes; Form DH 150-615, Revised Form 150-615*), available at https://flrules.org/Gateway/reference.asp?No=Ref-02342 (last visited Apr. 20, 2026).

[29] Proposed Revisions to Rule 64D-3.046 as presented at the Dec 12, 2025, workshop (on file with Senate Committee on Health Policy).

a parent to attest that "Immunizations are in conflict with my religious tenets or practices*, which may include a sincerely held moral or ethical belief*." (Emphasis added.) The current exemption form does not contain this reference to "a sincerely held moral or ethical belief," nor does Florida law. As of this writing, no proposed rules have been formally published.

Religious Exemption Form

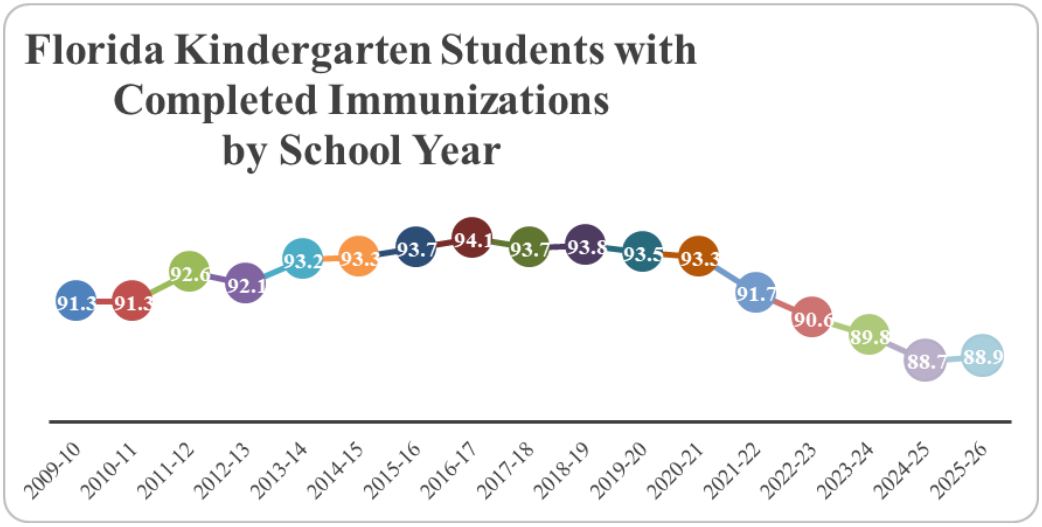
The DOH Immunization Guidelines require county health department staff to issue the Religious Exemption from Immunization form, which is available electronically in the Florida SHOTS registry. (See "Florida SHOTS Immunization Registry" on page 11 of this analysis.) No other information should be solicited from the parent or guardian.[30] The form requires the electronic signature of the county health department director or administrator.[31] The exemption form must be presented to the school, preschool, child care facility, or family day care home where it is to be kept on file in order to identify unimmunized children needing exclusion during an outbreak of a vaccine-preventable disease.

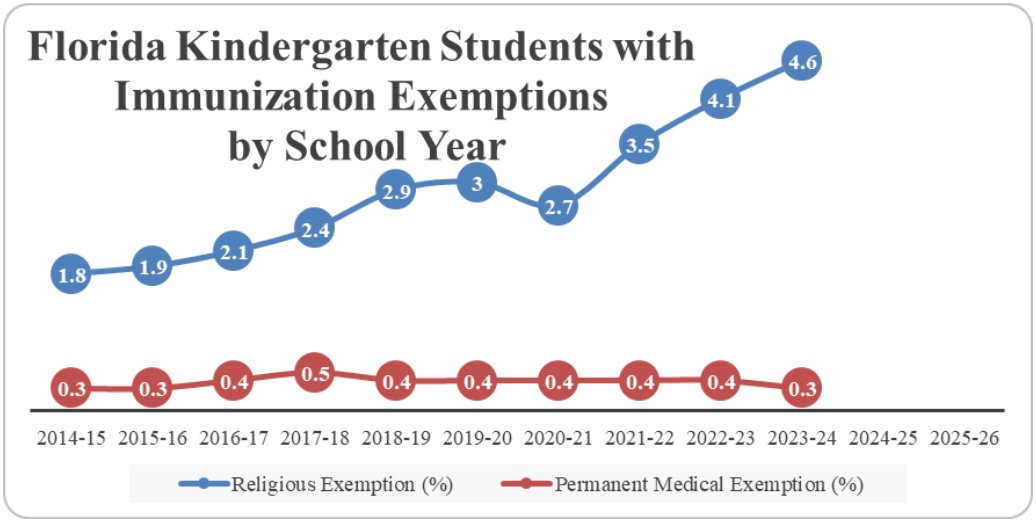
Each public school and private school, including kindergarten, is required to provide to the county health department director or administrator annual reports of compliance with immunization requirements.[32] Those reports are generally compiled into statewide data.

Florida Statewide Immunization Completion for Kindergarten with Exemption Data

The following charts show immunization completion,[33] and religious and permanent medical exemption status,[34] among children enrolled in public and private kindergarten by school year using the DOH data.

[30] Florida Administrative Code & Florida Administrative Register, Reference: Ref-02342 (adopting Fla. Admin. Code R. 64D-3.046, *Immunization Requirements: Public and Nonpublic Schools, Grades Preschool, Kindergarten Through 12, and Adult Education Classes; Form DH 150-615, Revised Form 150-615*), available at https://flrules.org/Gateway/reference.asp?No=Ref-02342 (last visited Apr. 20, 2026).
[31] Florida Administrative Code & Florida Administrative Register, Reference Material, Ref-02341 (64D-3.046; DH Form 681—Religious Exemption from Immunization), available at https://flrules.org/Gateway/reference.asp?No=Ref-02341 (last visited Apr. 20, 2026).
[32] Section 1003.22(8), F.S.
[33] Fla. Dept. of Health, Florida CHARTS: Community Health Assessment Resource Tool Set, *Immunization Levels in Kindergarten*, available at https://www.flhealthcharts.gov/charts/ (last visited Apr. 20, 2026).
[34] Fla. Dept. of Health, *Kindergarten and Seventh Grade Immunization Status Report, 2023–24 School Year,* memorandum from Carina Blackmore, DVM, PhD, to County Health Department Health Officers, Aug. 12, 2024 (on file with Senate Committee on Health Policy). Exemption data were requested multiple times for the 2024-25 and 2025-26 school years but were not provided by the DOH.



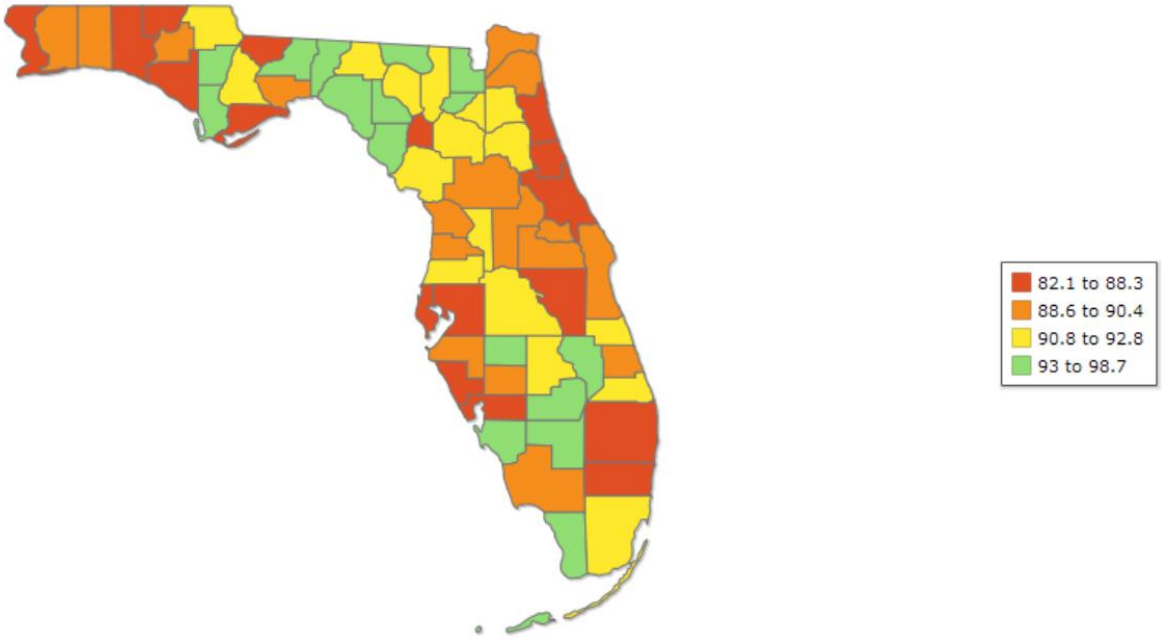


Immunization Levels in Kindergarten by Florida County

The following map[35] and data reflect percentages of students who have documented completion of their immunizations on the Certificate of Immunization form. Note that this reflects *all* immunizations, so the percentages may be lower than if it were to reflect each vaccination one by one.

[35] Fla. Dept. of Health, *supra* note 33.

Immunization Levels in Kindergarten, Percent of Kindergarten Students Enrolled, 2026



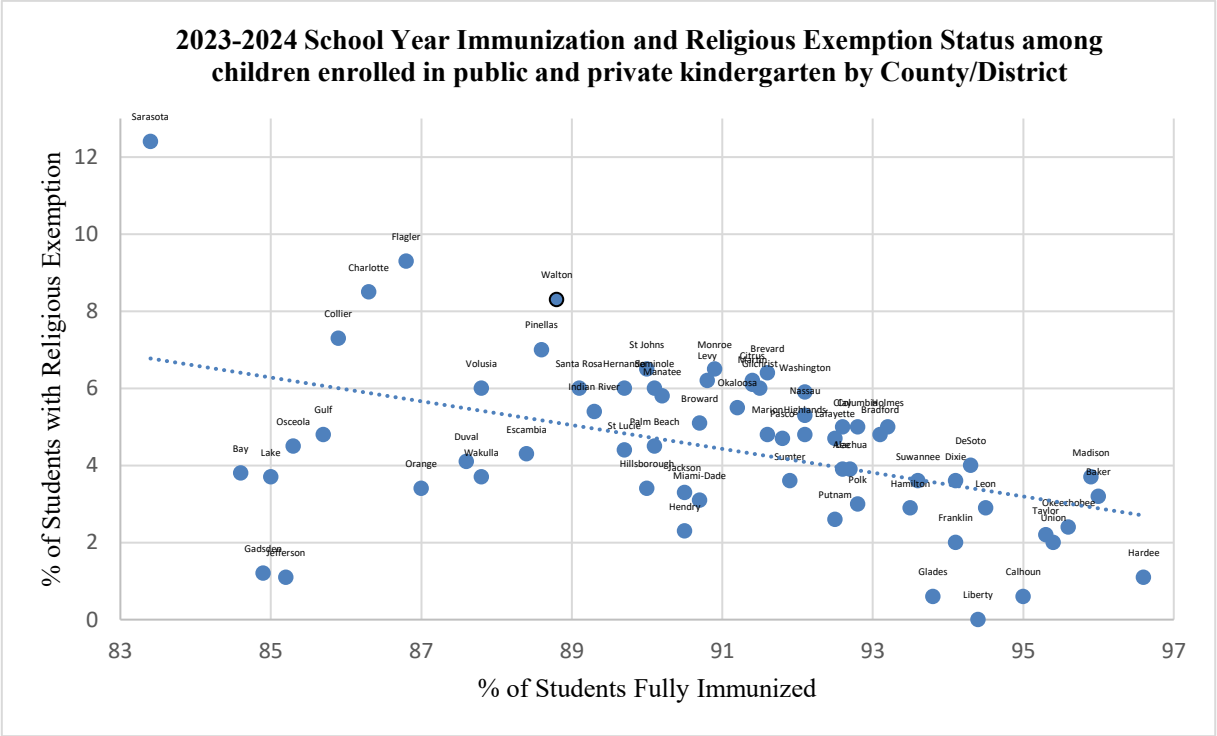
Immunization and Religious Exemption Status among Students enrolled in Public and Private kindergarten					
	2023-2024 School Year[36]			2025-2026 School Year[37]	
County	Students Enrolled	% Fully Immunized	% Religious exemption	Students Enrolled	% Fully Immunized
Alachua	2,484	92.7	3.9	2,498	91.1
Baker	349	96	3.2	363	93.1
Bay	2,252	84.6	3.8	2,237	86.4
Bradford	334	93.1	4.8	292	92.8
Brevard	5,811	91.6	6.4	5,404	89.6
Broward	19,964	90.7	5.1	17,793	84.7
Calhoun	161	95	0.6	153	98.7
Charlotte	1,178	86.3	8.5	1,187	85.7
Citrus	1,233	91.4	6.2	1,134	89.5
Clay	2,847	92.6	5	2,638	92.2
Collier	3,695	85.9	7.3	3,367	89.1
Columbia	941	92.8	5	871	90.9
DeSoto	352	94.3	4	345	90.4
Dixie	169	94.1	3.6	164	93.3

[36] Fla. Dept. of Health, *supra* note 34.
[37] Fla. Dept. of Health, *supra* note 33. Note that these data have been updated since Jan. 20, 2026, when they were originally included in the Senate Bill Analysis for SB 1756 during the 2026 Regular Legislative Session.

Immunization and Religious Exemption Status among Students enrolled in Public and Private kindergarten					
	2023-2024 School Year[36]			2025-2026 School Year[37]	
County	Students Enrolled	% Fully Immunized	% Religious exemption	Students Enrolled	% Fully Immunized
Duval	12,468	87.6	4.1	11,779	89.5
Escambia	3,628	88.4	4.3	3,494	87.3
Flagler	1,034	86.8	9.3	990	86.0
Franklin	101	94.1	2	98	87.8
Gadsden	405	84.9	1.2	351	83.2
Gilchrist	282	91.5	6	245	86.5
Glades	160	93.8	0.6	143	93.0
Gulf	126	85.7	4.8	147	95.2
Hamilton	139	93.5	2.9	145	95.9
Hardee	354	96.6	1.1	334	97.0
Hendry	610	90.5	2.3	553	94.0
Hernando	1,934	89.7	6	1,871	88.7
Highlands	1,031	92.1	4.8	987	91.3
Hillsborough	16,211	90	3.4	15,182	85.4
Holmes	221	93.2	5	209	87.1
Indian River	1,401	89.3	5.4	1,363	90.9
Jackson	568	90.5	3.3	491	91.0
Jefferson	88	85.2	1.1	85	97.6
Lafayette	106	92.5	4.7	81	93.8
Lake	3,855	85	3.7	3,807	89.3
Lee	6,981	92.6	3.9	7,410	93.1
Leon	2,894	94.5	2.9	2,926	93.7
Levy	437	90.8	6.2	456	91.9
Liberty	90	94.4	0	88	92.0
Madison	217	95.9	3.7	230	91.3
Manatee	3,971	90.2	5.8	3,925	89.1
Marion	3,659	91.6	4.8	3,552	89.8
Martin	1,334	91.4	6.1	1,400	91.5
Miami-Dade	27,296	90.7	3.1	26,315	90.8
Monroe	725	90.9	6.5	645	93.0
Nassau	1,028	92.1	5.3	981	89.2
Okaloosa	2,454	91.2	5.5	2,292	89.5
Okeechobee	505	95.6	2.4	446	93.5
Orange	14,743	87	3.4	14,378	88.6
Osceola	5,551	85.3	4.5	5,393	87.8
Palm Beach	15,692	90.1	4.5	14,603	88.3

Immunization and Religious Exemption Status among Students enrolled in Public and Private kindergarten					
	2023-2024 School Year[36]			2025-2026 School Year[37]	
County	Students Enrolled	% Fully Immunized	% Religious exemption	Students Enrolled	% Fully Immunized
Pasco	6,385	91.8	4.7	6,104	91.0
Pinellas	7,354	88.6	7	6,626	87.4
Polk	9,181	92.8	3	8,962	91.6
Putnam	832	92.5	2.6	786	91.5
St. Johns	2,151	89.1	6	3,486	88.2
St. Lucie	3,405	83.4	12.4	3,576	89.9
Santa Rosa	4,803	90.1	6	2,017	89.3
Sarasota	3,573	90	6.5	3,211	82.1
Seminole	3,567	89.7	4.4	4,808	90.1
Sumter	666	91.9	3.6	805	90.8
Suwannee	470	93.6	3.6	425	91.1
Taylor	275	95.3	2.2	238	93.7
Union	196	95.4	2	161	95.7
Volusia	4,887	87.8	6	4,642	87.5
Wakulla	403	87.8	3.7	376	88.8
Walton	964	88.8	8.3	945	87.1
Washington	304	92.1	5.9	307	88.9

The following chart reflects the same 2023-2024 school year data above in an attempt to show the inherent correlation between religious exemptions and completion of vaccinations by Florida County. Generally, the more religious exemptions, the fewer students with completed Certificates of Immunization.



Florida SHOTS Immunization Registry

The DOH maintains a secure statewide electronic immunization registry, Florida SHOTS (State Health Online Tracking System), which consolidates immunization histories and facilitates access to immunization documentation for clinical care and school recordkeeping.[38] A parent or guardian, or a certain eligible student, may decline participation in the registry by submitting an opt-out form.[39] A parent or guardian who opts out generally assumes responsibility for maintaining and providing documentation of their child's immunization status.[40]

During an outbreak, Florida SHOTS enables the DOH and county health departments to rapidly verify immunization status, identify individuals who may be susceptible to disease, and support response activities such as contact investigations, targeted vaccination outreach, and, when authorized, school exclusion decisions.[41]

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[38] Section 381.003(1)(e), F.S. Florida SHOTS (State Health Online Tracking System), *About Florida SHOTS*, available at https://flshotsusers.com/about (last visited Apr. 20, 2026).
[39] Section 381.003(1)(e)2.-3., F.S.
[40] Florida SHOTS Notification and Opt-Out Form, (Fla. Dept. of Health, Immunization Section, Sept. 2019), available at https://flshotsusers.com/sites/default/files/Opt-OutForm.pdf (last visited Apr. 20, 2026).
[41] Florida SHOTS, "Using the Tools in Florida SHOTS" training page (Fla. Dept. of Health, Immunization Section), available at https://flshotsusers.com/training/using-the-tools-in-florida-shots (last visited Apr. 20, 2026).

Disease Outbreaks

The CDC defines a measles outbreak as three or more related cases.[42] The DOH rule defines an "outbreak" as "an increase in the number of cases of a disease or condition compared to the expected number in a particular period of time and geographical area. For diseases where the expected number is zero, a single case constitutes an outbreak."[43]

Measles Outbreak

Florida is currently experiencing a measles outbreak. The DOH reports 131 confirmed cases of measles between January 1 and April 11, 2026, as follows: [44]

Alachua	2
Broward	3
Collier	93
Duval	6
Escambia	5
Hillsborough	2
Lee	3
Manatee	3
Miami-Dade	1
Osceola	1
Pasco	3
Pinellas	6
St. Johns	3
TOTAL	131

Not included in this count are an additional 14 probable cases in Collier County[45] awaiting confirmation of test results.[46] These numbers reflect the reporting of each infection to the DOH.

Reporting Requirements

All practitioners, health care facilities, and laboratories in Florida are required to notify the DOH of diseases or conditions of public health significance.[47] DOH rules require reporting for each disease for which the DOH seeks to immunize children under its Immunization Guidelines. For those specified diseases, practitioners must report as follows:

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[42] U.S. Centers for Disease Control and Prevention, *Measles Cases and Outbreaks,* Apr. 17, 2026, available at https://www.cdc.gov/measles/data-research/index.html (last visited Apr. 20, 2026).
[43] Rule 64D-3.028, F.A.C.
[44] Fla. Dept. of Health, *Reportable Diseases Frequency Report* (select "Measles (rubeola)"), FLHealthCHARTS: Community Health Assessment Resource Tool Set, available at https://www.flhealthcharts.gov/ChartsReports/rdPage.aspx?rdReport=FrequencyMerlin.Frequency&FirstTime=True (last visited Apr. 20, 2026).
[45] *Id*.
[46] The Collier County Health Department is working closely with Ave Maria University officials to provide pre- and post-exposure resources on campus. Florida Department of Health, *Measles (Rubeola)*, available at https://www.floridahealth.gov/diseases-and-conditions/disease/measles/ (last visited Apr. 20, 2026).
[47] Section 381.0031, F.S.

- Immediately upon initial suspicion, or upon ordering a test: measles; rubella; diphtheria; *Haemophilus influenzae* type b (Hib); polio; and pneumococcal disease caused by *Streptococcus pneumoniae*.
- Immediately upon confirmatory test or diagnosis: pertussis (whooping cough).
- By the next business day: hepatitis B (Hep B); mumps; tetanus; and varicella (chickenpox).[48]

Emergencies and Advisories

While the Governor of this state has broad emergency management powers,[49] the statutes grant specified authority to the State Health Officer, commonly referred to as the State Surgeon General. In the State Surgeon General's discretion, he or she may issue a public health advisory[50] (a warning or report giving information to the public about a potential public health threat) or may declare a public health emergency[51] (for any occurrence which results or may result in substantial injury or harm to the public).

During a public health emergency, the State Surgeon General has statutory authority to order an individual to be examined, tested, treated, isolated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health.[52] In 2021, the Legislature amended the statute to remove the State Surgeon General's authority to order an individual to be vaccinated for such a disease.[53]

At the local level, a county health department director or administrator[54] may declare a communicable disease emergency if a communicable disease for which vaccination is required by the DOH is present in a public or private school.[55] Upon declaration of such an emergency, the district school board or the governing authority of a private school must identify all students in attendance who have not completed the required immunizations, as documented on the Certificate of Immunization form. Students identified as not immunized against the disease for which the emergency has been declared must be excluded from school until the county health department director or administrator specifies otherwise.[56] In 2024, when seven elementary school students contracted confirmed cases of measles, a communicable disease emergency was not declared. Instead, a public health advisory was issued.[57]

[48] Rule 64D-3.029, F.A.C.
[49] Section 252.36, F.S.
[50] Section 381.00315(1)(b), F.S.
[51] Section 381.00315(1)(a), F.S.
[52] Section 381.00315(2)(d)4., F.S.
[53] Chapter 2021-7B, Laws of Fla.
[54] A county health department director or administrator is appointed by and serves at the pleasure of the State Surgeon General. *See:* s. 154.04, F.S.
[55] Section 1003.22(9), F.S.
[56] *Id*.
[57] Fla. Dept. of Health in Broward County, *Measles Health Advisory,* Feb. 18, 2024, available at https://www.westonfl.org/home/showpublisheddocument/6597/638440458711170000 (last visited Apr. 20, 2026).

Measles and Community Immunity as Illustrated by the Manatee Bay Elementary Outbreak of 2024

According to the CDC website:

- "Some people think of measles as just a little rash and fever that clear up in a few days."[58]
- "Measles can cause serious health complications, especially in children younger than five years of age. Common complications are ear infections and diarrhea. Serious complications include pneumonia and encephalitis."[59]
- "Measles is highly contagious. If one person has it, up to 9 out of 10 people nearby will become infected if they are not protected."[60]
- "It spreads through the air when an infected person coughs or sneezes."[61]

The CDC further indicates that "The measles, mumps, and rubella (MMR) vaccine is very safe and effective. *When more than 95 percent of people in a community are vaccinated (coverage >95 percent), most people are protected through community immunity (herd immunity)*."[62]

The CDC defines "community immunity" as "a situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely. Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community. Also known as herd immunity."[63]

In 2024, seven children at Manatee Bay Elementary in Broward County contracted confirmed cases of measles.[64] Broward County experienced two additional cases of measles, and there were single cases of measles in Martin, Orange, and Polk Counties in 2024, bringing the state total up to 12 confirmed cases in 2024 according to the DOH data.[65]

The Broward County health department issued a public health advisory on February 18, 2024, in response to the outbreak of related measles cases at Manatee Bay Elementary.[66] Initially, the Broward County school district superintendent declared that the school was 92 percent

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[58] U.S. Centers for Disease Control and Prevention, *Measles (Rubeola): About Measles*, available at https://www.cdc.gov/measles/about/index.html (last visited Apr. 20, 2026).
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] U.S. Centers for Disease Control and Prevention, *Measles Data and Statistics*, available at https://www.cdc.gov/measles/data-research/index.html (last visited Apr. 20, 2026).
[63] Immunization is defined as "The process of being made immune or resistant to an infectious disease, typically by the administration of a vaccine. It implies that a vaccine will trigger an immune response." *See:* U.S. Centers for Disease Control and Prevention, *Immunization Glossary of Terms,* available at https://www.cdc.gov/vaccines/glossary/index.html (last visited Apr. 20, 2026).
[64] City of Weston, Florida, *Measles Cases in Weston,* Feb. 23, 2024, updated Mar. 5, 2024, available at https://www.westonfl.org/Home/Components/News/News/1249/18 (last visited Apr. 20, 2026).
[65] Fla. Dept. of Health, *Measles (Rubeola), 2024*, Florida CHARTS: Community Health Assessment Resource Tool Set, available at https://www.flhealthcharts.gov/charts/ (last visited Apr. 20, 2026).
[66] Fla. Dept. of Health in Broward County, *supra* note 57.

vaccinated against measles.[67] It is probable that the school district obtained initial data from the Florida SHOTS immunization registry to quickly assess the school's immunization rate. Children whose parents have opted them out of Florida SHOTS would not be counted in the initial data pull.

State Surgeon General Ladapo has reiterated that "people with a history of prior infection or vaccination of the full series of the Measles, Mumps, Rubella (MMR) immunization are 98 percent protected and are unlikely to contract measles."[68]

The county health department began offering MMR immunizations at the school.[69] The measles vaccination is typically given in a combined vaccine formulation also protecting against mumps and rubella. The Broward County school district superintendent later gave an update claiming that 33 of 1,067 Manatee Bay students were unimmunized against measles.[70] This mathematically suggests that 97 percent of students had at least one dose of the MMR vaccine, reflecting a 5 percent increase in immunization, with roughly 3 percent of students totally unprotected from the virus. The on-site vaccination efforts, together with the inclusion of students who acquired immunity through infection, appears to have increased the overall immunization rate.

According to both the CDC Child and Adolescent Immunization Schedule and the DOH Immunization Guidelines, the first dose of the MMR vaccine is recommended at one year of age, so infants under one year of age are unprotected and have no immunity from measles, mumps, and rubella. While some vaccines, such as Tdap[71], that are given during pregnancy can pass protective antibodies to the baby, the MMR vaccine should not be administered during pregnancy.[72] The second recommended dose of the MMR vaccine is recommended at four years of age. Because this outbreak occurred in an elementary school rather than a day care or preschool, the students had significantly higher immunity due to having received the second dose.

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[67] NBC 6 South Florida, Ari Odzer, *Doctors Worry Herd Immunity Against Measles Is Fading as Cases at Manatee Bay Rise to 6,* Feb. 20, 2024, available at https://www.nbcmiami.com/news/local/doctors-worry-herd-immunity-against-measles-is-fading-as-cases-at-manatee-bay-rise-to-6/3238882/ (last visited Apr. 20, 2026).

[68] Executive Office of the Governor and the Fla. Dept. of Health: "Leading the Nation Again, Florida Successfully Balances Personal Responsibility, Parents' Rights, and Public Health," Mar. 8, 2024, available at https://www.flgov.com/eog/news/press/2024/florida-department-health-leading-nation-again-florida-successfully-balances (last visited Apr. 20, 2026). *See also:* Fla. Dept. of Health, *Measles (Rubeola)*, available at https://www.floridahealth.gov/diseases-and-conditions/disease/measles/ (last visited Apr. 20, 2026).

[69] NBC 6 South Florida, *Florida Surgeon General Doesn't Urge Vaccinations Amid Measles Outbreak,* Feb. 21, 2024, available at https://www.nbcmiami.com/news/local/florida-surgeon-general-measles-vaccinations-outbreak/3239826/ (last visited Apr. 20, 2026).

[70] *Id*.

[71] U.S. Centers for Disease Control and Prevention, *Tdap Vaccination During Pregnancy*, available at https://www.cdc.gov/pertussis/vaccines/tdap-vaccination-during-pregnancy.html (last visited Apr. 20, 2026). The CDC Child and Adolescent Immunization Schedule recommends the first DTaP vaccine be given to infants at two months of age.

[72] American College of Obstetricians and Gynecologists, *Practice Advisory: Measles, Mumps, Rubella (MMR) Vaccination and Management of Obstetric–Gynecologic Patients During a Measles Outbreak,* Mar. 2024, available at https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2024/03/management-of-obstetric-gynecologic-patients-during-a-measles-outbreak (last visited Apr. 20, 2026).

It is likely that several of the Manatee Bay Elementary students had a permanent medical exemption in place. A medical doctor or osteopathic physician may advise against a measles vaccine if the child has a known life-threatening allergy to MMR ingredients such as gelatin or neomycin, has a serious immune system condition that makes live vaccines unsafe, or has a documented history of severe brain inflammation or injury that would make MMR vaccination dangerous. Certainly, some students had a temporary medical exemption in place with the intent of completing the second recommended dose.

A child may have a religious exemption in place while still receiving selected immunizations. For the 2023-2024 school year, Broward County reported that 5.1 percent of its kindergarten students in public and private schools had a religious exemption.[73] It is likely that the majority of the school's 33 unimmunized students had a religious exemption in place.

Assuming the superintendent's updated data are accurate, with roughly 97 percent of students immunized from measles, the CDC's 95 percent threshold was exceeded within the school, offering most students protection through community immunity.

The school remained open.[74] The DOH deferred to parents and guardians to make decisions about school attendance and provided virtual learning options for students whose parents or guardians chose to keep them at home.[75] On March 8, 2024, the DOH issued a press release entitled "Leading the Nation Again, Florida Successfully Balances Personal Responsibility, Parent's Rights, and Public Health."[76] The disease outbreak was contained due to the DOH and county health department's response measures which appear to have boosted the school's already high immunization rate, exceeding the threshold needed to achieve community immunity.

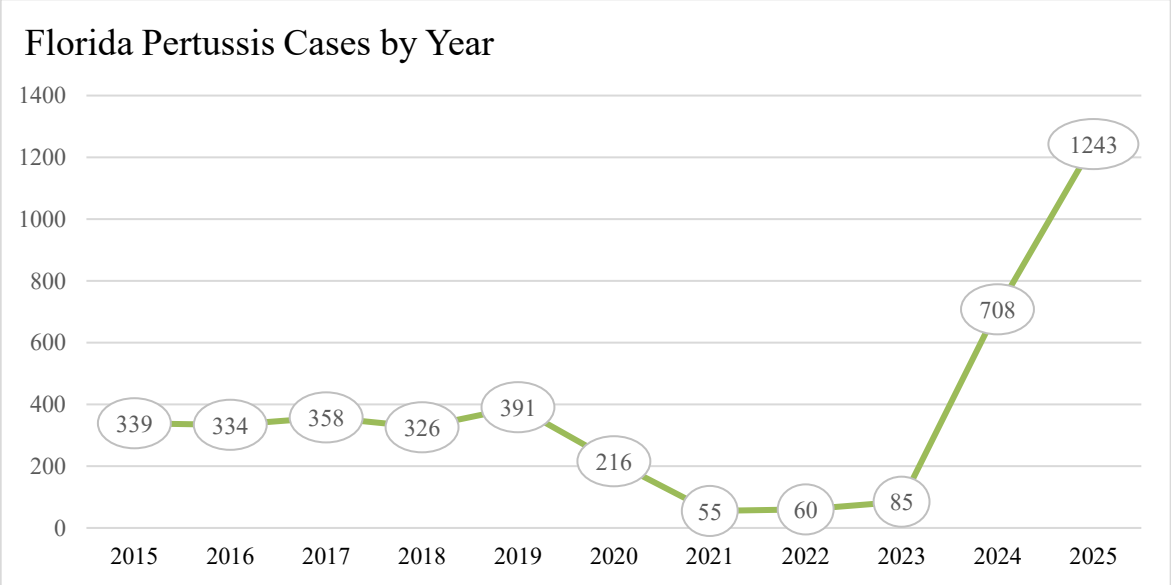
It should be noted that the percentage of kindergarten students fully immunized in Broward County has fallen dramatically from 90.7 percent during the 2023-2024 school year to 84.7 percent during the 2025-2026 school year, as reported in recently updated DOH data.[77] The DOH indicates that the Broward County immunization rate is statistically significantly different from the statewide rate.

Community immunity thresholds vary from disease to disease. Pertussis (whooping cough), which most commonly affects infants and young children, also requires a relatively high vaccination rate to achieve community immunity, estimated to be between 92-94 percent.[78] The

[73] Fla. Dept. of Health, *supra* note 34.
[74] Letter from Joseph A. Ladapo, M.D., Ph.D., State Surgeon Gen., to Parents and Guardians of Students Attending Manatee Bay Elementary School, Feb. 20, 2024, available at https://www.westonfl.org/home/showpublisheddocument/6609/638917115733530000 (last visited Apr. 20, 2026).
[75] *Id*.
[76] Executive Office of the Governor and the Fla. Dept. of Health, *supra* note 68.
[77] Fla. Dept. of Health, *supra* note 34. The 2024–2025 data point for completed immunizations was obtained from *Immunization Levels in Kindergarten,* Florida CHARTS: Community Health Assessment Resource Tool Set, available at https://www.flhealthcharts.gov/charts/ (last visited Apr. 20, 2026). Exemption data were requested multiple times for the 2024-25 and 2025 26 school years but were not provided.
[78] Laura Helft & Emily Willingham, "What Is Herd Immunity?," *NOVA,* Sept. 5, 2014, available at https://www.pbs.org/wgbh/nova/article/herd-immunity/ (last visited Apr. 20, 2026).

pertussis vaccine is typically provided in a combined vaccine formulation along with diphtheria and tetanus, known as DTaP or Tdap.[79]

The chart below shows the total number of confirmed pertussis cases in Florida according to DOH data.[80]



Spartanburg, South Carolina Measles Outbreak and Localized Data

Assessing local outbreak risk based on statewide data is of limited utility. The South Carolina Department of Public Health recently reported 997 measles cases associated with a single outbreak, with no new reported cases since March 17, 2026.[81] If no new cases are reported, the last day of the outbreak will be April 26, 2026.[82] At this time, no people are in quarantine or isolation, though both methods were used to widely control the outbreak. On January 27, 2026, 557 people in South Carolina (including students in 23 different schools) were in quarantine and 20 were in isolation to control the spread.[83]

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[79] DTaP is recommended for children under seven years of age. Tdap is recommended for older children and adults. Different dosages are recommended for different age groups. *See:* U.S. Centers for Disease Control & Prevention, *Whooping Cough Vaccination,* Dec. 2, 2025, available at https://www.cdc.gov/pertussis/vaccines/index.html (last visited Apr. 20, 2026).
[80] Fla. Dept. of Health, *Pertussis: 10 Year Report,* Florida CHARTS: Community Health Assessment Resource Tool Set, available at https://www.flhealthcharts.gov/charts/ (last visited Apr. 20, 2026). *See also:* Fla. Dept. of Health, *Reportable Diseases Frequency Report* (select all counties, "pertussis," "confirmed" "all ages" and Jan. 1, 2025-Dec. 31, 2025), FLHealthCHARTS: Community Health Assessment Resource Tool Set, available at https://www.flhealthcharts.gov/ChartsReports/rdPage.aspx?rdReport=FrequencyMerlin.Frequency&FirstTime=True (last visited Apr. 20, 2026).
[81] South Carolina Dept. of Public Health, "TUESDAY MEASLES UPDATE: DPH Reports No New Measles Cases, Outbreak Total Remains 997," Apr. 14, 2026, available at https://dph.sc.gov/news/tuesday-measles-update-dph-reports-no-new-measles-cases-outbreak-total-remains-997 (last visited Apr. 20, 2026).
[82] *Id*. A period of 42 days with no new cases is required to declare an end to a measles outbreak. This is double the number of days for an incubation period (21 days) and a clear indicator of a broken transmission chain.
[83] South Carolina Dept. of Public Health, "TUESDAY MEASLES UPDATE: DPH Reports 89 New Measles Cases in Upstate, Bringing Outbreak Total to 789, Additional School and Public Exposures," Jan. 27, 2026, available at https://dph.sc.gov/news/tuesday-measles-update-dph-reports-89-new-measles-cases-upstate-bringing-outbreak-total-789 (last visited Apr. 20, 2026).

Age Breakdown of 997 Cases[84]	
Under 5	253
5-11	460
12-17	186
18-29	53
30-49	32
50+	6
Unknown	7

Of the confirmed cases, 932 were unvaccinated, 25 were fully vaccinated, 21 were partially vaccinated with one of the recommended two-dose MMR sequence, and 19 are unknown.[85]

The epicenter of the South Carolina outbreak was Spartanburg County, where the majority of cases were concentrated. Although approximately 90 percent of students in Spartanburg County met school immunization requirements, significant variation exists at a more granular level.[86] Some schools in the county reportedly had vaccination rates as low as 20 percent.[87] When assessing outbreak risk, county- and school-level immunization data provide more meaningful insight than statewide averages.

Approximately eight percent of students in Spartanburg County had a nonmedical religious exemption from immunization requirements, reflecting a jump from three percent in 2020.[88] An eight-percent figure suggests that the county as a whole will not achieve the CDC community immunity threshold for measles of at least 95 percent. The religious exemption is the only nonmedical exemption available under South Carolina law.[89] The South Carolina Department of Public Health has made the religious exemption form available on its website, warning parents that unvaccinated children are more likely to get sick.[90]

Consistent with the Spartanburg outbreak, a recent study concluded that nonmedical vaccine exemptions tend to be geographically concentrated in a fraction of counties, creating localized pockets of increased vulnerability.[91]

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[84] South Carolina Dept. of Public Health, Measles Dashboard (updated Apr. 1, 2026) available at https://dph.sc.gov/diseases-conditions/infectious-diseases/measles-rubeola/measles-dashboard (last visited Apr. 20, 2026).
[85] *Id*.
[86] Maria Godoy, "Measles Outbreak in South Carolina Has Some Parents Rethinking Vaccines as Cases Spread Among Children," *All Things Considered,* Jan. 16, 2026, available at https://www.npr.org/2026/01/16/nx-s1-5677299/measles-outbreak-vaccines-kids-health (last visited Apr. 20, 2026).
[87] *Id*.
[88] *Id*.
[89] South Carolina Dept. of Public Health, *Exemptions from School Vaccine Requirements*, available at https://dph.sc.gov/health-wellness/child-teen-health/vaccine-requirements-info/school-vaccination-coverage-data-0 (last visited Apr. 20, 2026).
[90] *Id*.
[91] Fattah *et al.*, *Trends in County-Level Childhood Vaccination Exemptions in the U.S.,* JAMA, Jan. 14, 2026, available at https://jamanetwork.com/journals/jama/article-abstract/2843870 (last visited Apr. 20, 2026).

Nonmedical Exemptions in Other States[92]

Nationally, all 50 states and the District of Columbia require specified immunizations for K–12 school attendance and allow medical exemptions. For nonmedical exemptions, state statutes fall into four nonmedical exemption categories.

- Religious-only (and no personal/philosophical): Alabama, Alaska, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Massachusetts, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, and Wyoming. (Washington, D.C., is also religious-only.)
- Both religious and personal/philosophical exemptions: Arizona, Arkansas, Colorado, Idaho, Michigan, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Washington, and Wisconsin.
- Nonmedical allowed but not specified as religious or personal: Louisiana and Minnesota.
- Medical exemptions only: California, Connecticut, Maine, New York, and West Virginia.

Conditions for Nonmedical Exemptions

States that allow nonmedical exemptions generally require a parent or guardian (or adult student) to submit a state-required form (sometimes vaccine-specific), a signed statement or affidavit attesting to the basis for the exemption, and depending on the jurisdiction, renewal at defined grade levels or annually, with explicit notice that an exempt child may be excluded from school attendance during outbreaks. Some states also narrow the scope of personal/philosophical exemptions. For example, D.C. and Virginia allow a personal-belief exemption only for HPV, and Washington state removed the personal/philosophical option for MMR. In a smaller subset, the exemption is not merely filed with the school; it is processed through a health agency workflow (e.g., state or county health department intake), or it must be notarized.

Consultation and Parental Education Requirements for Nonmedical Exemptions

Several states require parents seeking a nonmedical vaccine exemption to complete an education or counseling step rather than simply filing a form. Colorado and Oregon allow two routes, either completing an online education module or obtaining documentation after a health care provider consultation. Michigan requires education through the county health department before issuing the waiver form, and Utah similarly requires either an online module or an in-person local health department consultation. Mississippi requires an in-person county health department appointment that includes watching an education video and discussing vaccine information, while Vermont requires an annual religious-exemption statement confirming the parent has reviewed evidence-based educational materials. Washington state generally requires a health care practitioner signature on the exemption certificate to document that the required information was provided (with separate limits on certain personal/philosophical exemptions, such as for MMR).

[92] National Conf. of State Legislatures, Letter to Senior Attorney, Florida Senate Committee on Health Policy, Oct. 22, 2025 (on file with Senate Committee on Health Policy).

Legal Challenges

The U.S. Supreme Court has long recognized that compulsory vaccination falls within a state's police powers for the protection of public health.[93] However, disputes over nonmedical exemptions have given rise to recent challenges.

West Virginia state law provides for compulsory school immunization with medical exemptions and does not codify a nonmedical exemption. On January 14, 2025, West Virginia Governor Morrisey issued Executive Order 7-25, directing an exemption process for families asserting religious objections in K–12 schools and state-regulated child care.[94] On March 24, 2025, West Virginia Senate Bill 460, which would have established a religious exemption and related changes, was defeated on the House floor (42–56).[95] On December 2, 2025, the West Virginia Supreme Court granted a stay of a ruling that would have allowed students to attend school with the religious exemption.[96] Litigation is ongoing.

New York removed its religious exemption from the state's school-immunization law in 2019, after a significant measles outbreak that was at least partly attributed to high numbers of religious exemptions in certain schools and childcare centers,[97] leaving medical exemptions as the only statutory basis for attending school without the required vaccines. That change brought forth litigation in *Miller v. McDonald*.[98] In that case, Old Order Amish parents and Amish schools challenged the 2019 repeal on federal constitutional grounds (principally the Free Exercise Clause), arguing that eliminating the religious exemption while retaining a medical exemption unlawfully burdened their religious exercise. In a decision issued March 3, 2025, the U.S. Court of Appeals for the Second Circuit upheld dismissal of the challenge, concluding that New York's post-2019 scheme is neutral and generally applicable for Free Exercise purposes despite the continued availability of medical exemptions. The U.S. Supreme Court intervened, vacating the Second Circuit's judgment and remanding the case for further consideration on December 8, 2025.[99]

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[93] *Zucht v. King,* 260 U.S. 174, 176–77 (1922) ("Jacobson v. Massachusetts … had settled that it is within the police power of a State to provide for compulsory vaccination."), and id. at 177 ("[T]hese ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health."); *see* also *Jacobson v. Massachusetts,* 197 U.S. 11, 25-27 (1905) (upholding a state's authority to mandate smallpox vaccination as a valid exercise of its police power to protect public health).

[94] State of West Virginia, Exec. Order No. 7-25, Jan. 14, 2025, available at https://apps.sos.wv.gov/adlaw/executivejournal/readpdf.aspx?DocID=97525 (last visited Apr. 20, 2026).

[95] West Virginia Legislature, "House Rejects Senate Vaccine Bill," *Blog of the West Virginia Legislature,* Mar. 24, 2025, available at https://blog.wvlegislature.gov/house-floor-session/2025/03/24/house-rejects-senate-vaccine-bill/ (last visited Apr. 20, 2026).

[96] John Raby, "West Virginia again bans religious reasons for school vaccine exemptions after state Supreme Court pauses injunction," Associated Press, Dec. 3, 2025, available at https://apnews.com/article/e61c5814de407a1aa280ce3916f82cc6 (last visited Apr. 20, 2026).

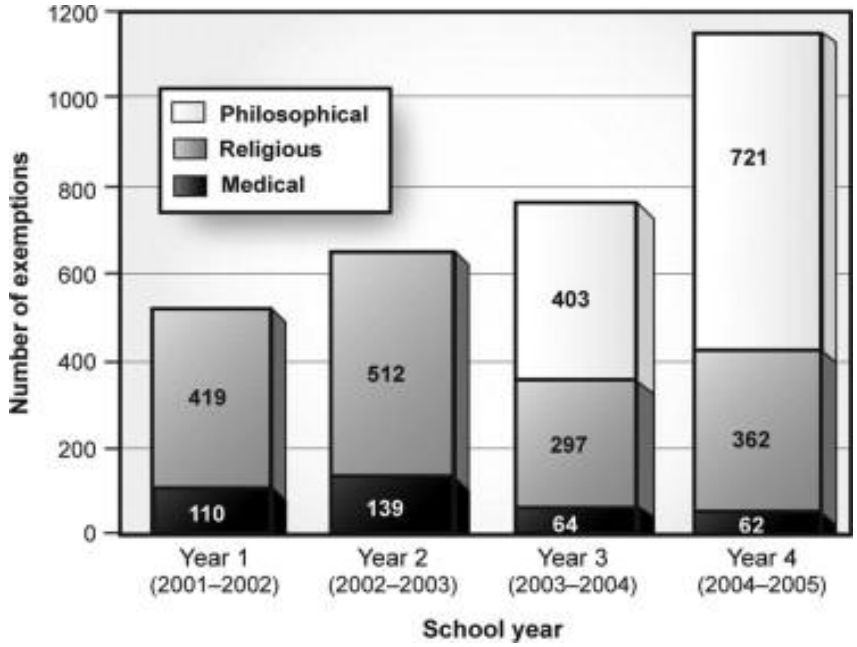
[97] Jane R. Zucker, M.D., et al., "Consequences of Undervaccination — Measles Outbreak, New York City, 2018–2019," The New England Journal of Medicine, March 11, 2020, available at https://www.nejm.org/doi/full/10.1056/NEJMoa1912514 (last visited April 21, 2026).

[98] *Miller v. McDonald*, No. 24-681 (2d Cir. Mar. 3, 2025).

[99] *Joseph Miller, et al. v. James V. McDonald, Commissioner, New York State Department of Health, et al.,* No. 25-133 (U.S. docketed Aug. 4, 2025) (linked with application No. 24A987; petition granted, judgment vacated and remanded Dec. 8, 2025), available at https://www.supremecourt.gov/docket/docketfiles/html/public/25-133.html (last visited Apr. 20, 2026).

Arkansas: Addition of a Philosophical Exemption

A 2007 study examined Arkansas school immunization exemption data before and after the state introduced a philosophical exemption in 2003, in addition to its preexisting religious exemption and medical exemptions.[100] The authors reported that total exemptions increased significantly over time after the philosophical exemption became available. They also found that nonmedical exemptions were geographically clustered, which could concentrate outbreaks and risk within communities smaller than an entire county.



The chart above shows the number of Arkansas students requesting immunization exemptions by type, 2001-2005. Exemptions include all students reported to Arkansas Division of Health who attended day care, pre-K programs, K-12, and colleges/universities.[101]

Among Florida's counties and nationwide, higher percentages of students with nonmedical exemptions are associated with lower vaccination rates.[102]

Federal Oversight of Vaccinations

While states generally establish and enforce vaccination requirements for school attendance, the federal government plays a central role in regulating vaccine products, issuing recommendations on vaccine use and supporting vaccine access through coverage and purchase programs. The U.S. Department of Health and Human Services (HHS) is the federal department principally responsible for public health policy and administration. Federal vaccine activity is coordinated through HHS and its operating divisions, including the CDC and the Food and Drug Administration (FDA). In addition, federal law directs the HHS Secretary to establish a National

[100] Joseph W. Thompson et al., *Impact of Addition of Philosophical Exemptions on Childhood Immunization Rates*, 32(3) Am. J. Prev. Med. 194–201, Mar. 2007, available at https://www.ajpmonline.org/article/S0749-3797(06)00497-1/fulltext (last visited Apr. 20, 2026).
[101] *Id*.
[102] Fla. Dept. of Health, *supra* note 34.

Vaccine Program to lead national planning efforts aimed at preventing infectious disease through immunization and preventing adverse reactions.[103]

CDC, ACIP, and the Recommended Childhood Immunization Schedule

The CDC's vaccine-use guidance is traditionally developed through the Advisory Committee on Immunization Practices (ACIP). [104] The CDC publishes consolidated recommendations for clinicians and public health professionals as the Recommended Child and Adolescent Immunization Schedule.[105] The CDC publishes the schedule as an annual, consolidated summary of current ACIP recommendations and organizes the schedule in standard components used in pediatric practice, including an age-based schedule, a catch-up schedule, and notes that describe routine, catch-up, and special-situation guidance.[106] Because school-age vaccination compliance frequently depends on vaccinations received in infancy and early childhood (as well as adolescent boosters and series), the schedule serves as a central federal reference point for routine pediatric vaccination and catch-up vaccination for children who are behind schedule.

The reduced recommended schedule, which was issued via memorandum on January 5, 2026, is stayed in court and is not in effect at this time.[107] That schedule was not established, reviewed, or revised by ACIP.[108] Interest groups and associations such as the American Academy of Pediatrics are challenging in federal court the procedure by which the guidance was adopted, citing conflict with federal laws and regulations.[109] The American Academy of Pediatrics maintains its own recommended schedule.[110]

National Childhood Vaccine Injury Act: Disclosure, Reporting, and Compensation

The National Childhood Vaccine Injury Act of 1986 (Act) established an interconnected set of federal requirements and programs intended to strengthen the childhood immunization system by standardizing pre-vaccination information, requiring the recording and reporting of certain

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[103] 42 U.S.C. § 300aa–1 (2022). See also U.S. Department of Health and Human Services, *Vaccines National Strategic Plan 2021–2025,* Jan. 19, 2021, available at https://www.hhs.gov/sites/default/files/HHS-Vaccines-Report.pdf.
[104] U.S. Centers for Disease Control & Prevention, *ACIP Vaccine Recommendations and Guidelines*, available at https://www.cdc.gov/acip/vaccine-recommendations/index.html (last visited Apr. 20, 2026).
[105] U.S. Centers for Disease Control & Prevention, *Child and Adolescent Immunization Schedule by Age* (Content is being revised to reflect updated CDC recommendations), available at https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (last visited Apr. 20, 2026).
[106] U.S. Centers for Disease Control & Prevention, *Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger — United States, 2025*, 74(2) Morbidity & Mortality Wkly. Rep. 26–29, Jan. 16, 2025, available at https://www.cdc.gov/mmwr/volumes/74/wr/mm7402a2.htm (last visited Apr. 20, 2026).
[107] *American Academy of Pediatrics, et al. v. Robert F. Kennedy, Jr., et al.*, *supra* note 18.
[108] Georgetown Univ. Health Policy Inst., Ctr. for Children & Families, *HHS Announces Changes to Recommended Vaccine Schedule for Children,* Jan. 15, 2026, available at https://ccf.georgetown.edu/2026/01/15/hhs-announces-changes-to-recommended-vaccine-schedule-for-children/ (last visited Apr. 20, 2026).
[109] *See* Fourth Amended Complaint for Declaratory and Injunctive Relief, *Am. Acad. of Pediatrics, et al. v. Kennedy, et al.,* Case No. 1:25-cv-11916 (BEM) (D. Mass. filed Jan. 19, 2026) (ECF No. 180-1), available at https://www.washingtonpost.com/documents/9e2848fb-6b04-49b5-94c5-05906811e882.pdf (last visited Apr. 20, 2026).
[110] Am. Acad. of Pediatrics, *Immunization Schedule*, in Red Book Online, available at https://publications.aap.org/redbook/resources/15585 (last visited Apr. 20, 2026).

adverse events, and creating a no-fault compensation program for certain vaccine-related injuries.[111]

Federal law imposes informed-consent-adjacent requirements specific to vaccines. The Act requires development of Vaccine Information Statements (VIS) for covered vaccines and imposes duties on vaccine providers to furnish those materials prior to administration of each dose of a covered vaccine. Specifically, each health care provider who administers a vaccine set forth in the Vaccine Injury Table must provide the Vaccine Information Statement to the child's parent or guardian prior to administration of the vaccine.[112] The HHS requires providers to document in the patient's permanent medical record the VIS edition date and the date the VIS was provided at the time the VIS is given.[113]

In addition, federal law requires providers administering covered vaccines to record specified information in the patient's permanent medical record (or in a permanent office log/file):

- The date of administration,
- The manufacturer and lot number, and
- The name/address (and, if appropriate, title) of the provider administering the vaccine.[114]

The Act requires each health care provider and vaccine manufacturer to report specified events to the HHS Secretary, including events set forth in the Vaccine Injury Table within the applicable time period.[115] The national reporting mechanism used for this purpose is the Vaccine Adverse Event Reporting System (VAERS), a passive reporting system co-managed by CDC and FDA. Anyone (health care providers, manufacturers, and the public) may submit a report.[116] VAERS is primarily an early warning signal-detection system; it is not designed to determine whether a vaccine caused a reported event.[117]

The Act sought to incentivize manufacturers to develop vaccinations for market by offering some protection from litigation. The Act established the National Vaccine Injury Compensation Program (VICP), administered by the HHS, under which compensation may be paid for a vaccine-related injury or death. HRSA describes VICP's objectives: to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to have been injured by certain vaccines.[118]

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[111] National Childhood Vaccine Injury Act of 1986, H.R. 5546, 99th Cong. (1986), available at https://www.congress.gov/bill/99th-congress/house-bill/5546 (last visited Apr. 20, 2026).
[112] U.S. Centers for Disease Control & Prevention, *Instructions for Using VISs,* May 29, 2025, available at https://www.cdc.gov/vaccines/hcp/about-vis/instructions.html (last visited Apr. 20, 2026).
[113] *Id*.
[114] *Id*.
[115] Health Res. & Servs. Admin., *Covered Vaccines*, Nat'l Vaccine Injury Comp. Program, available at https://www.hrsa.gov/vaccine-compensation/covered-vaccines (last visited Apr. 20, 2026).
[116] U.S. Food and Drug Administration, VAERS Overview, available at https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview (last visited Apr. 20, 2026).
[117] *Id*.
[118] Health Res. & Servs. Admin., *About the National Vaccine Injury Compensation Program* (last reviewed Jan. 2026), available at https://www.hrsa.gov/vaccine-compensation/about (last visited Apr. 20, 2026).

VICP claims are adjudicated in the U.S. Court of Federal Claims by special masters in the Court's Office of Special Masters (sometimes referred to as "vaccine court"). The Court describes the program as a no-fault compensation system in which petitions for compensation may be brought by or on behalf of persons alleging injury or death from covered vaccines.[119] The vast majority of VICP claims filed are related to influenza vaccinations (flu shots).[120]

According to the CDC, from 2006 to 2023, over 5 billion doses of covered vaccines were distributed in the U.S.[121] For petitions filed in this period, 13,948 petitions were adjudicated by the Court, and of those, 10,193 were compensated.[122] This means for every 1 million doses of vaccine that were distributed, approximately one individual was compensated.[123]

The VICP covers most vaccines routinely administered in the U.S., but it does not cover claims associated with COVID-19 vaccines, which have never been added to the table. Instead, HRSA directs that claims related to COVID-19 vaccines be filed under the Countermeasures Injury Compensation Program.[124]

Vaccines for Children Program and No-Cost Vaccines for Eligible Children

Separate from the Act's reporting and compensation framework, federal law supports access to pediatric vaccines through the Vaccines for Children program, a pediatric vaccine distribution program established in the Social Security Act.[125] The CDC states that there is no cost for vaccines themselves provided by program providers to eligible children.[126]

FDA Regulation of Vaccines

Vaccines are regulated as biological products. The FDA licenses (approves) vaccines for introduction into interstate commerce.[127] In general terms, the FDA evaluates evidence of safety, effectiveness, and manufacturing quality to determine whether a vaccine may be marketed in the U.S.[128]

Before a vaccine may be evaluated by the FDA for licensure, it typically proceeds through preclinical testing and clinical development:[129]

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[119] United States Court of Federal Claims, *Vaccine Claims: Office of Special Masters*, available at https://www.uscfc.uscourts.gov/vaccine-claims-office-special-masters (last visited Apr. 20, 2026).
[120] Health Res. & Servs. Admin., *National Vaccine Injury Compensation Program Data Report,* Jan. 1, 2026, available at https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-01-01-26.pdf (last visited Apr. 20, 2026).
[121] *Id*.
[122] *Id*.
[123] *Id*.
[124] Health Res. & Servs. Admin., *Covered Vaccines, Nat'l Vaccine Injury Comp. Program,* available at https://www.hrsa.gov/vaccine-compensation/covered-vaccines (last visited Apr. 20, 2026).
[125] U.S. Centers for Disease Control and Prevention, *About the Vaccines for Children (VFC) Program,* Sept. 30, 2025, available at https://www.cdc.gov/vaccines-for-children/about/index.html (last visited Apr. 20, 2026).
[126] *Id*.
[127] 42 U.S.C. § 262; 21 C.F.R. § 601.2. See also U.S. Food and Drug Administration, *Biologics License Applications (BLA) Process (CBER)*, available at https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last visited Apr. 20, 2026).
[128] U.S. Food and Drug Administration, *Vaccine Development 101*, available at https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited Apr. 20, 2026).
[129] *Id*.

- Preclinical phase. A company or researcher conducts laboratory research and animal testing. If the sponsor is ready to begin studies in humans, it submits an Investigational New Drug application to the FDA. If the application meets the FDA's criteria and is authorized to proceed, clinical development begins and the vaccine enters phased human trials.
- Phase 1 (safety). Generally involves 20-100 healthy volunteers and focuses on initial safety and dosing. If no significant safety concerns arise, the product may proceed to Phase 2.
- Phase 2 (initial efficacy). Generally involves hundreds of participants and evaluates dosing, immune response, and additional safety data across broader demographic groups.
- Phase 3 (confirmatory efficacy and safety). Generally involves thousands of participants and is designed to generate the principal evidence of effectiveness and additional safety data. Participants are randomized into a treatment group and a control group to generate critical information on effectiveness and additional important safety data. The treatment group gets the vaccine and the control group gets the placebo. For a new vaccine, the placebo is saline or similar. In the case of childhood vaccinations, the currently given vaccinations are updated versions of older vaccines. When updated versions of older vaccines are tested in trials, the treatment group gets the new vaccine and the control group gets the old vaccine as the placebo.[130]

After Phase 3, the sponsor generally submits a biologics license application for FDA review of data, proposed labeling, and manufacturing.[131] If the FDA approves the application and licenses the vaccine, the product may be marketed and distributed in interstate commerce.[132] Once distribution begins, the FDA and the CDC continue post-licensure safety monitoring through systems such as VAERS.

Compensation for Clinical Trial Participation

Clinical investigation sponsors may pay human subjects to participate in a vaccine trial and may reimburse subjects for expenses associated with participation, such as travel and lodging. FDA guidance states that payment to research subjects is a common and generally acceptable practice for any pharmaceutical clinical trial.[133]

Federal human-subject protections require informed consent to be sought under circumstances that minimize coercion or undue influence. If research subjects are to be paid, the FDA guidance provides that the Institutional Review Board (the ethics-review committee that oversees research involving human subjects) should review the amount, method, and timing of payment to ensure that payment is not coercive and does not create undue influence.[134] The FDA guidance directs that payment should accrue as the study progresses rather than depend on completion of the

[130] It is considered unethical to deny individuals in a trial access to a proven treatment. U.S. Food & Drug Admin., *Non-Inferiority Clinical Trials to Establish Effectiveness* (explaining that active-controlled/noninferiority designs are used when placebo/no-treatment would be unethical because effective therapy exists), available at https://www.fda.gov/media/78504/download (last visited Apr. 20, 2026).
[131] U.S. Food and Drug Administration, *supra* note 128.
[132] *Id.*
[133] U.S. Food and Drug Administration, *Information Sheet: Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects (last visited Apr. 20, 2026). The FDA guidance also indicates compensation should be treated as a recruitment incentive rather than a study benefit in the risk-benefit analysis.
[134] *Id*. See *also* 21 C.F.R. part 50.

entire study, and that payment terms should be set in the informed consent document.[135] The HHS Office for Human Research Protections has issued recommendations that similarly distinguish reimbursement, compensation, appreciation payments, and incentive payments and recommend that reimbursement and compensation ordinarily be prorated.[136]

Ivermectin

As of September 30, 2025, the DOH had received 59 total complaints involving licensed health care practitioners related to the prescribing or dispensing of ivermectin. The DOH reports that none of these complaints were deemed legally sufficient for probable cause to be found.

FDA Approval of Ivermectin for Treatment of Parasitic Conditions

The FDA website details how the ivermectin drug is used: "Ivermectin tablets are approved by the FDA to treat people with intestinal strongyloidiasis and onchocerciasis, two conditions caused by parasitic worms. In addition, some topical forms of ivermectin are approved to treat external parasites like head lice and for skin conditions such as rosacea. Some forms of animal ivermectin[137] are approved to prevent heartworm disease and treat certain internal and external parasites in animals. It's important to note that these products are different from the ones for people, and safe only when used in animals as labeled or as prescribed. The FDA has not authorized or approved ivermectin for the treatment or prevention of COVID-19 in people or animals. The FDA has not determined that ivermectin is safe or effective for these indications (uses)."[138]

Similar to how the FDA licenses vaccines and other ("large-molecule") biologics, the FDA also authorizes most conventional ("small-molecule") drugs for marketing by approving a New Drug Application.[139] After pre-clinical testing and with approval to proceed, the drug sponsor runs a series of clinical trials in people (typically Phase 1-3) to evaluate safety and efficacy, and then submits those data to the FDA for review.[140] The FDA's review teams then evaluate the submitted evidence (along with manufacturing and labeling information) and decide whether the benefits outweigh the risks for the intended use.[141]

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[135] *Id*.
[136] U.S. Department of Health and Human Services, *Attachment A - Addressing Ethical Concerns Offers of Payment to Research Participants,* available at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html (last visited Apr. 20, 2026).
[137] Heartgard, Heartgard Plus, Tri-Heart Plus, Iverhart Plus, Iverhart Max, PetTrust Plus, Acarexx, Ivomec, Zimecterin, Eqvalan, Noromectin, Bimectin, etc.
[138] U.S. Food and Drug Administration, *Ivermectin and COVID-19,* Apr. 5, 2024, available at https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19 (last visited Apr. 20, 2026).
[139] 21 U.S.C. § 355.; U.S. Food and Drug Administration, 21 C.F.R. pt. 314; Food and Drug Administration, *New Drug Application (NDA)*, available at https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last visited Apr. 20, 2026).
[140] U.S. Food and Drug Administration, Step 3: Clinical Research, available at https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited Apr. 20, 2026).
[141] U.S. Food and Drug Administration, *Step 4: FDA Drug Review*, https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review (last visited Apr. 20, 2026).

The FDA has granted marketing approval for ivermectin tablets for specified parasitic worm conditions.[142] Those FDA-approved indications are the drug's "on-label" uses. However, a licensed prescriber has the authority to prescribe an FDA-approved human drug for an off-label use when, in the prescriber's professional judgment, such use is medically appropriate for an individual patient.[143]

The FDA at one time led a "You are not a horse!" social media campaign attempting to deter people from using both animal ivermectin drugs and FDA-approved prescription ivermectin drugs as an off-label COVID-19 treatment.[144] The campaign gave rise to litigation clarifying the role of the FDA. The U.S. Court of Appeals for the Fifth Circuit opined that the "FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise."[145]

The American Association of Poison Control Centers reported 2,337 ivermectin poison control reports nationally in 2021.[146] One of the clearest datasets tying veterinary ivermectin to severe outcomes comes from Oregon. A poison center study of COVID-19-related ivermectin exposures that led to a health care visit (Aug. 14, 2021–Jan. 31, 2022) reported 37 cases, including 21 hospitalizations, 13 treated in emergency departments, and one death. Seventeen cases involved veterinary formulations, and 15 involved prescription-only tablets.[147]

Clinical Studies: Ivermectin and COVID-19

Early in the COVID-19 pandemic, ivermectin drew attention because a mix of small clinical studies and early meta-analyses appeared to show benefit, but the limited evidence and its underlying data sets were highly disputed. A CDC health alert issued on August 26, 2021, explained: "Clinical trials and observational studies to evaluate the use of ivermectin to prevent and treat COVID-19 in humans have yielded insufficient evidence for the NIH COVID-19 Treatment Guidelines Panel to recommend its use. Data from adequately sized, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19."[148]

As the evidence base matured, larger, better-controlled randomized trials did not confirm those early signals that appeared to show benefits of off-label ivermectin use. In the TOGETHER

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[142] U.S. Food and Drug Administration, *supra* note 138.
[143] U.S. Food and Drug Administration, *Compliance Policy Guide Sec. 300.600: Use of Approved Drugs for Unlabeled Indications*; United States Supreme Court, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001).
[144] *Apter v. Dep't of Health & Hum. Servs.,* 80 F.4th 579, 595 (5th Cir. 2023), available at https://www.ca5.uscourts.gov/opinions/pub/22/22-40802-CV0.pdf.
[145] *Id*.
[146] American Association of Poison Control Centers, *National Poison Data System (NPDS) Bulletin: COVID-19 (Ivermectin)—Ivermectin Case Counts 2019 vs. 2020 vs. 2021, (Jan. 1–Dec. 31),* 2021, available at https://npr.brightspotcdn.com/06/8e/72f45189455ea8d3561012b1608e/poisoncontrolpdf.pdf (last visited Apr. 20, 2026).
[147] Ruby Hoang et al., *Characteristics of Ivermectin Toxicity in Patients Taking Veterinary and Human Formulations for the Prevention and Treatment of COVID-19*, Clinical Toxicology (Phila.) 60(12):1350–1355, Dec. 2022, available at https://pubmed.ncbi.nlm.nih.gov/36374218/ (last visited Apr. 20, 2026).
[148] U.S. Centers for Disease Control and Prevention, Health Alert Network (HAN), *Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19,* Aug. 26, 2021, available at https://archive.cdc.gov/emergency_cdc_gov/han/2021/han00449.asp (last visited Apr. 20, 2026).

outpatient trial, ivermectin did not reduce the need for hospitalization or prolonged emergency observation.[149] In the U.S. ACTIV-6 platform trial, which included a participation site at the University of Florida, ivermectin likewise did not improve time to sustained recovery, even when tested at higher doses and longer courses.[150]

Because the most rigorous trials have failed to demonstrate meaningful clinical benefit, clinical guidelines largely do not recommend ivermectin for COVID-19 outside of research settings.[151]

Ivermectin Classified as Rx-Only Status; Federal Misbranding

When the FDA approves a drug application for marketing, the agency also determines whether the product will be prescription-only or nonprescription (over-the-counter or "OTC"), and it approves the product's conditions of use and labeling consistent with that status. Under the Federal Food, Drug, and Cosmetic Act, a drug is classified as prescription-only if it is not safe for use without a clinician's supervision (e.g., due to toxicity, method of use, or required monitoring), and prescription drugs must bear the "Rx only" legend consistent with this statutory scheme.[152] If a drug sponsor later seeks to move a drug from prescription to nonprescription status, that occurs through a separate Rx-to-OTC switch process that typically relies on consumer-focused evidence (e.g., label comprehension and self-selection studies, and sometimes actual-use studies) to show the product can be used safely and effectively without a prescriber.[153]

Ivermectin remains classified federally as a prescription drug for human use. Federal law requires that, prior to dispensing, the drug's labeling bear the legend "Rx only." A prescription drug that does not bear this legend before dispensing is deemed misbranded under federal law. Ivermectin is generally well tolerated when used at FDA-approved doses for approved indications; however, adverse effects may occur and can be dose-related. The FDA has warned that ivermectin can interact with other medications, including anticoagulants ("blood thinners").[154] These interaction risks are particularly relevant when ivermectin is obtained without individualized prescriber oversight, as patients taking anticoagulants may not recognize the potential for increased bleeding risk.

For purposes of labeling and misbranding law, nonprescription (OTC) drug labeling must "stand on its own" for a lay consumer and must include adequate directions for use so that an ordinary person can use the product safely and for its intended purpose without professional

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[149] Gilmar Reis et al., *Effect of Early Treatment with Ivermectin among Patients with Covid-19,* New England Journal of Medicine, Mar. 30, 2022, available at https://www.nejm.org/doi/full/10.1056/NEJMoa2115869.
[150] Popp M. et al., *Ivermectin for COVID-19: Systematic Review and Meta-Analysis of Randomized Controlled Trials*, Frontiers in Medicine (2023), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC9941969/ (last visited Apr. 20, 2026).
[151] Am. Med. Ass'n, *AMA, APhA, ASHP Statement on Ending Use of Ivermectin to Treat COVID-19,* Sept. 1, 2021, available at https://www.ama-assn.org/press-center/ama-press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19 (last visited Apr. 20, 2026).
[152] 21 U.S.C. § 353(b)(1)(A), (b)(4)(A).
[153] U.S. Food & Drug Admin., *Prescription-to-Nonprescription (Rx-to-OTC) Switches* (content current as of Dec. 9, 2025), available at https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches (last visited Apr. 20, 2026).
[154] U.S. Food and Drug Administration, *supra* note 138.

supervision.[155] By contrast, prescription (Rx-only) drugs are intended to be used under the supervision of a licensed practitioner and therefore generally fall within the FDA's regulatory exemptions from the "adequate directions for use" requirement, because such directions cannot feasibly be written for safe self-use by the general public. As a result, attempts to market a product for self-directed use without consumer-usable directions (or with labeling that implies an OTC use that actually requires practitioner oversight) raise heightened misbranding risk under federal labeling standards.

State Trends in Ivermectin Laws

When a state authorizes a pharmacist to furnish a prescription drug without a patient-specific prescription, questions arise as to whether the transaction constitutes "dispensing" under state law and what labeling and documentation requirements apply, particularly in light of the federal "Rx only" classification.

Several states have enacted laws authorizing pharmacists to provide ivermectin without an individual patient-specific prescription, notwithstanding ivermectin's federal prescription-only status. These laws generally fall into two models: an OTC authorization declaring that ivermectin suitable for human use may be sold or purchased without a prescription, or a standing order or collaborative practice model authorizing dispensing pursuant to a non-patient-specific prescriptive order or protocol.

Vaccine and Testing Mandate Prohibitions

In 2023, CS/SB 252 was enacted to prohibit a business entity,[156] governmental entity,[157] or educational institution[158] from requiring any person to provide any documentation certifying vaccination with listed vaccines or postinfection recovery from COVID-19, or requiring a COVID-19 test, in order to gain access, entry upon, or service from entity or institution.

The 2023 bill, now codified in ss. 381.00316 and 381.00319, F.S., applies to the following vaccines:

- "COVID-19 vaccine" means a preparation designed to stimulate the human body's immune response against COVID-19.
- "Emergency use authorization vaccine" means any vaccine that is authorized for emergency use under 21 U.S.C. 360bbb-3(a)(1) and qualifies as an unapproved product under 21 U.S.C. 360bbb-3(a)(2)(A).

[155] U.S. Food & Drug Admin., *Labeling Requirements—Exemptions From Adequate Directions for Use* (content current as of Feb. 21, 2018), available at https://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-exemptions-adequate-directions-use (last visited Apr. 20, 2026).
[156] "Business entity" has the same meaning as in s. 606.03, F.S., and also includes a charitable organization as defined in s. 496.404, a corporation not for profit as defined in s. 617.01401, a private club, or any other business operating in this state.
[157] "Governmental entity" means the state or any political subdivision thereof, including the Executive, Legislative, and Judicial branches of government; the independent establishments of the state, counties, municipalities, districts, authorities, boards, or commissions; or any agencies that are subject to chapter 286, F.S.
[158] "Educational institution" means a public or private school, including a preschool, elementary school, middle school, junior high school, secondary school, career center, or postsecondary school.

- "Messenger ribonucleic acid vaccine" means any vaccine that uses laboratory-produced messenger ribonucleic acid to trigger the human body's immune system to generate an immune response.

Those statutes prohibit:
- Requiring such documentation or testing as a condition of contracting, hiring, promotion, or continued employment;
- Using a knowledge or belief of a person's vaccination with any of the listed vaccines or COVID-19 postinfection status, or a person's failure to take a COVID-19 test, to:
  - Refuse to hire, or discharge, the person;
  - Deprive or attempt to deprive the person of employment opportunities;
  - Adversely affect the person's status as an employee or as an applicant; or
  - Otherwise discriminate against the person.

Current law also provides that if a governmental entity fails to comply with the above provisions, an employee terminated based on such noncompliance is eligible for reemployment assistance under ch. 443, F.S., in addition to any other remedies available for such violation.

Additionally, for matters related to any vaccine other than a defined vaccine, a defined entity or institution must provide for reasonable religious and medical accommodations in compliance with federal law.

The definitions for "messenger ribonucleic acid vaccine" in ss. 381.00316 and 381.00319, F.S., were scheduled to automatically expire on June 1, 2025, but the enactment of a 2025 bill, CS/CS/HB 1299, delayed the automatic expiration until June 1, 2027, effectively eliminating the prohibitions relating to that type of vaccine on that date.[159]

Messenger Ribonucleic Acid (mRNA) Vaccines

Messenger RNA is a molecule that contains the instructions or recipe that directs cells in the human body to make a protein using their natural machinery. To enter cells smoothly, mRNA travels within a protective bubble called a Lipid Nanoparticle. Once inside, mRNA causes cells to read the mRNA as a set of instructions, building proteins that match parts of the pathogen called antigens. The immune system sees these foreign antigens as invaders, dispatching defenders called antibodies and T-cells, and training the immune system for potential future attacks. So, if and when the real virus comes along, the body might recognize it, sounding the alarm to help defend against infection and illness.

Though many people first became aware of mRNA technology because of COVID-19 vaccines, the technology is not new to the scientific community. For decades, scientists have studied mRNA, looking for ways to unlock its potential to prevent and treat disease. While the mechanism of action for mRNA technology is relatively simple, researchers have worked for years to develop technologies to allow mRNA to work in the real world.[160]

[159] Sections 1-3, ch. 2025-114, Laws of Fla.
[160] Johns Hopkins University, *5 things to know about the power of mRNA technology,* Apr. 15, 2025, available at https://washingtondc.jhu.edu/news/5-things-to-know-about-

In 2024, the FDA approved an mRNA vaccine for the prevention of respiratory syncytial virus (RSV). There are mRNA vaccines in Phase 3 of clinical trials, including vaccines for Influenza and Norovirus.[161] Research is ongoing for various infectious diseases, and researchers are also working on mRNA vaccines for cancer and genetic diseases as well as treatments for food and environmental allergies.[162] Most recently, researchers at Memorial Sloan Kettering Cancer Center announced promising results of a Phase 1 clinical trial of an mRNA-based vaccine against pancreatic cancer, which is one of the most difficult cancers to detect and treat effectively.[163] A larger Phase 2 clinical trial is underway.[164]

Anti-Kickback Laws

A kickback is money or something else of value given or received to induce or reward a referral for health care services. Federal and state law both prohibit kickbacks in health care, but they differ in scope and application.

The federal anti-kickback statute makes it a crime to knowingly and willfully offer, pay, solicit, or receive remuneration, directly or indirectly, in cash or in kind, to induce or reward referrals or the purchasing, leasing, ordering, or recommending of items or services for which payment may be made in whole or in part under a federal health care program.[165] Thus, federal anti-kickback laws apply only when the item or service is reimbursable by a federal health care program, such as Medicare, Medicaid, TRICARE, or another federally funded health care program. The statute contains express statutory exceptions, and the HHS Office of Inspector General has adopted additional regulatory "safe harbors" for certain arrangements.[166]

The Florida anti-kickback statute, s. 456.054, F.S., makes it unlawful for *any* health care provider or provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients, and defines a "kickback" as remuneration or payment made as an incentive or inducement to refer patients when the payment is not tax deductible as an ordinary and necessary expense.

A violation of this Florida statute is considered patient brokering and is punishable as provided in s. 817.505, F.S., which provides graduated criminal penalties. A violation is generally a third-degree felony, punishable as provided in s. 775.082 or s. 775.084, F.S., and the offender must be ordered to pay a $50,000 fine. If the prohibited conduct involves 10 or more patients, but fewer

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mrna/#:~:text=Since%20mRNA%E2%80%99s%20discovery%20in%20the%201960s%2C%20researchers%20have,get%20this%20groundbreaking%20health%20solution%20to%20the%20public. (last visited Apr, 20, 2026).

[161] Moderna, Inc., *mRNA Pipeline* (as of Jan. 12, 2025) available at https://www.modernatx.com/en-US/research/product-pipeline (last visited Apr. 20, 2026).

[162] Penn Medicine, *The Future of mRNA Vaccines,* available at https://www.pennmedicine.org/mrna, (last visited Apr 20, 2026).

[163] Kaitlin Sullivan, et al., "Pancreatic cancer mRNA vaccine shows lasting results in an early trial," *NBC News,* Apr. 18, 2026, available at https://www.nbcnews.com/health/cancer/pancreatic-cancer-mrna-vaccine-shows-lasting-results-early-trial-rcna331969 (last visited Apr. 22, 2026). *See also:* https://www.nature.com/articles/s41586-024-08508-4 (last visited Apr. 22, 2026).

[164] *Id*.

[165] 42 U.S.C. s. 1320a-7b(b).

[166] 42 C.F.R. s. 1001.952; see also U.S. Dept. of Health & Human Servs., Office of Inspector Gen., *Safe Harbor Regulations*, available at https://oig.hhs.gov/compliance/safe-harbor-regulations/ (last visited Apr. 20, 2026).

than 20 patients, the offense is a second-degree felony and the offender must be ordered to pay a $100,000 fine. If the prohibited conduct involves 20 or more patients, the offense is a first-degree felony and the offender must be ordered to pay a $500,000 fine.

In addition, for allopathic and osteopathic physicians, ss. 458.331(1)(i) and 459.015(1)(j), F.S., respectively, make it grounds for disciplinary action to pay or receive any commission, bonus, kickback, or rebate, or to engage in any split-fee arrangement, directly or indirectly, for patients referred to providers of health care goods and services; however, those provisions do not prohibit a physician from receiving a fee for professional consultation services.

III. Effect of Proposed Changes:

Section 1 creates a short title. The act may be cited as the "Medical Freedom Act."

Section 2 repeals section 9 of Chapter 2023-43, L.O.F., as amended by section 1 of Chapter 2025-114, L.O.F. In effect, this repeals the scheduled repeal date of June 1, 2027, for the statutory definition of "messenger ribonucleic acid vaccine," ensuring the continued enforceability of the definition in both s. 381.00316(2)(g) and s. 381.00319(1)(e), F.S."[167] In practice, this maintains existing prohibitions against mandates by governmental entities, business establishments, and educational institutions that a person must be vaccinated with an mRNA-based vaccine.

Section 3 amends s. 381.00315(2)(d)4., F.S. That statute currently provides that the State Surgeon General, upon declaration of a public health emergency, may order an individual to be treated for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. The bill amends this subparagraph to clarify that the State Surgeon General's authority to order an individual to be treated does not include authority to order the individual to be vaccinated.

In 2021, the Legislature amended the statute to remove the State Surgeon General's overt authority to order an individual to be vaccinated for such a disease.[168] Although the State Surgeon General's authority to order an individual to be vaccinated was already removed from this section, this bill goes a step further to state that limitation affirmatively. The bill forecloses negative-implication and prevents arguments that vaccination is simply a form of "treatment" authorized within that section.

Section 4 amends s. 456.054, F.S., the Florida Anti-kickback Law, to establish that it is unlawful and considered patient brokering for a vaccine manufacturer to offer or pay, a commission, bonus, kickback, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, for the administration of a vaccine.

This section also establishes that it is unlawful for a health care practitioner to receive such a commission, bonus, kickback, or rebate from a vaccine manufacturer for the administration of a vaccine.

[167] "Messenger ribonucleic acid vaccine" means any vaccine that uses laboratory-produced messenger ribonucleic acid to trigger the human body's immune system to generate an immune response.
[168] Chapter 2021-7B, Laws of Fla.

A violation of either provision is considered patient brokering and is punishable as provided in s. 817.505, F.S.

Section 5 amends s. 456.0575, F.S., to revise procedures surrounding vaccinations of minor children.

"Health care practitioner" is defined for ch. 456, F.S., in s. 456.001(4), F.S., [169] but only the following professions are granted authority in their respective practice acts to administer vaccinations to minors: allopathic physicians and physician assistants, osteopathic physicians and physician assistants, registered nurses, advanced practice registered nurses, and licensed practical nurses.

Under s. 401.272(2)(c), F.S., paramedics may administer immunizations in a nonemergency environment, within the scope of their training, and under the medical direction of a physician through two-way communication or pursuant to established standing orders or protocols.

Under the bill, before administering a vaccine to a minor child, such health care practitioner or paramedic must:

- Provide the child's parent or guardian with the most recently issued Vaccine Information Statement (VIS) published by the U.S. Centers for Disease Control and Prevention pertaining to each vaccine being administered and materials approved and adopted by joint rule of the Board of Medicine and the Board of Osteopathic Medicine (collectively, the Boards) relating to the role of immunizations in communicable disease prevention, including risks, benefits, safety, and efficacy.
- Obtain the signature of the parent or guardian acknowledging receipt of that information.

In addition to obtaining the signature of the parent or guardian acknowledging receipt of the information required by the bill, the practitioner or paramedic must document additional information in the minor child's medical record. The National Childhood Vaccine Injury Act establishes a federal requirement for health care providers to provide a VIS to a child's parent or guardian prior to administration of vaccines covered by the Act, a category that includes most routine pediatric immunizations and flu shots.[170] Federal law requires providers to record in the medical record that the VIS was provided; the date the VIS was provided; the edition (publication) date of the VIS; the name, address and title of the individual who administers the vaccine; the date of administration; and the vaccine manufacturer and lot number of the vaccine used.

If more than one vaccine is to be administered, the bill requires a health care practitioner to discuss the timing of multiple vaccinations with the child's parent or guardian and the parent or guardian's options for such timing before administering the initial vaccination. The bill

[169] Section 456.001(4), F.S. "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I, part II, or part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

[170] While COVID-19 vaccines are not NCVIA-covered vaccines, CDC guidance indicates that vaccinators should provide the COVID-19 VIS before each dose. *See:* U.S. Centers for Disease Control & Prevention, *COVID-19 Vaccines by Product*, available at https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html (last visited Apr. 20, 2026).

affirmatively authorizes the health care practitioner to administer vaccines to a child over multiple encounters if the parent or guardian requests it.

The Department of Health (DOH) has indicated that the Board of Medicine, Board of Osteopathic Medicine, Board of Nursing, and Board of Pharmacy may need to amend their disciplinary guideline rules to create a range of penalties for violating the new requirements in s. 456.0575, F.S., as amended by the bill.[171]

Section 6 provides that the amendments to s. 456.0575(2)(a) and (b), F.S., in section 3 of the bill relating to information that must be provided to parents or guardians before vaccinating a minor, become effective 30 days after the Board of Medicine and the Board of Osteopathic Medicine adopt the informational materials by joint rule. The Boards must adopt the joint rule no later than 120 days after the bill becomes a law and must notify the Division of Law Revision immediately upon adoption. The bill, if enacted, would take effect before the informational materials are finalized. This delayed effective date relating to the informational materials ensures that practitioners and paramedics can continue to provide vaccinations to minors with parental consent, as generally required for the provision of all health care services pursuant to s. 1014.06, F.S., while the materials are being developed by the Boards.

The bill provides this section takes effect upon becoming a law, enabling the Boards to begin the rulemaking process as soon as practicable.

Sections 7, 8, and 9 create ss. 458.3351, 459.0156, and 464.0181, F.S., respectively, to grant immunity from civil or criminal liability and disciplinary action under Florida law to a health care practitioner licensed under chs. 458, 459, or 464, F.S., whose license includes prescribing authority, for prescribing or administering ivermectin[172] to an adult, in good faith, in accordance with the applicable standard of care and in accordance with the applicable practice act and pertinent rules.

- Section 7 grants such immunities to allopathic physicians, and physician assistants delegated prescriptive authority by their supervising physician, licensed under ch. 458, F.S.
- Section 8 grants such immunities to osteopathic physicians, and physician assistants delegated prescriptive authority by their supervising physician, licensed under ch. 459, F.S.
- Section 9 grants such immunities to advance practice registered nurses (APRNs) operating within the framework of an established protocol, or autonomous APRNs, licensed under ch. 464, F.S.

Section 10 amends the Florida Pharmacy Act by creating s. 465.1897, F.S., to authorize a licensed pharmacist to provide ivermectin[173] to a person who is 18 years of age or older without a prescription as a behind-the-counter medication until the U.S. Food and Drug Administration (FDA) approves ivermectin for over-the-counter sale. Current prescription-only ivermectin drugs include oral tablets for the treatment of parasitic conditions and topical ivermectin for the treatment of rosacea.

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[171] Fla. Dept. of Health*, Legislative Bill Analysis: SB 1756,* Jan. 22, 2026 (on file with Senate Committee on Health Policy*).*

[172] These sections of the bill address ivermectin broadly and could be interpreted to encompass all formulations for on- and off-label use, including drugs manufactured for human use and animal use.

[173] The bill does not specify whether the ivermectin authorized to be dispensed by pharmacists under this section must be manufactured for human use.

Before providing ivermectin under this provision, the pharmacist must provide written information regarding indications and contraindications, appropriate dosage, and the need to seek follow-up care from the person's primary care physician. Because the FDA has classified all tablet forms and some topical forms of ivermectin as prescription-only drugs, meaning that the drugs may be dispensed to a specific patient pursuant to a practitioner's prescription and used under that practitioner's supervision, they are exempted from federal "adequate directions for use" requirements. This exemption would no longer apply if they were to be dispensed without a prescription.

The bill provides that a pharmacist acting in good faith is immune from civil or criminal liability or disciplinary action for providing ivermectin to an adult in accordance with this portion of the bill. However, any prescription drugs so dispensed would be misbranded in violation of federal law.[174] Although the bill provides protection from state actions, a pharmacist or pharmacy acting in accordance with this section would risk federal enforcement.

The Board of Pharmacy is authorized, but not required, to adopt rules to implement this new section of law.

Section 11 amends s. 1003.22, F.S., to create a statutory nonmedical exemption from immunization requirements for a child attending a K-12 school if the administration of immunizing agents conflicts with the parent's conscience.

Like the existing religious exemption, the conscience exemption would also be available to children attending preschool or day care in a child care facility[175] or family day care home facility[176] who are subject to immunization requirements pursuant to rules of the Department of Children and Families.

Under the bill, a single nonmedical exemption form would provide for both conflicts with religious tenets or practices and conflicts with conscience.[177] In accordance with current DOH rule for the religious exemption form, the new form must be adopted by DOH rule.

The bill statutorily requires the nonmedical exemption form to be made available on the DOH website. Nothing in current law prevents the DOH from making the form available on its website today. Under the bill, the DOH would be required to do something it may already do of its own volition but has chosen not to.

Upon making the nonmedical exemption form available on its website and upon the Boards' adoption of a rule, the DOH must ensure that the form and the materials approved and adopted

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[174] *See:* "Constitutional Issues" and "Present Situation: Ivermectin Classified as Rx-Only Status; Federal Misbranding" portions of this analysis.
[175] Fla. Dept. of Children & Families., *Child Care Facility Handbook,* https://flrules.org/Gateway/reference.asp?No=Ref-13928 (last visited Apr. 20, 2026).
[176] Section 402.313, F.S.
[177] Neither the bill nor the Florida Statutes define the term "conscience." Section 381.00321(1)(b), F.S., defines the term "conscience-based objection" for purposes of that section as an objection based on a sincerely held religious, moral, or ethical belief." One Merriam-Webster definition of "conscience" is "conformity to what one considers to be correct, right, or morally good." *See:* Merriam-Webster, *Conscience*, available at https://www.merriam-webster.com/dictionary/conscience (last visited Apr. 20, 2026).

by joint rule of the Boards under s. 456.0575(2)(a), F.S., as amended under Section 5 of the bill relating to the role of immunizations in communicable disease prevention, are downloaded as a single document. This requirement takes effect upon the adoption of the joint rule.

The web page containing the download link must also include and prominently display a link or links to the CDC's current Vaccine Information Statements.

A parent seeking a nonmedical exemption must obtain a signature from the director or administrator of the county health department pursuant to existing DOH rule before presenting the form to the school or facility, as required by the bill and in accordance with rule, effectively exempting their child from immunization requirements.

The bill makes a technical change to paragraph (5)(b) regarding a permanent medical exemption to clarify that a child may be exempt from one or more required immunizations, which is in accordance with Part C of the DOH's current Certificate of Immunization Form.

The bill also makes a technical change to paragraph (5)(c) to correct verbiage providing that a child who has a temporary medical exemption, which may be issued by an allopathic physician, an osteopathic physician, or a chiropractic physician under current law, is in the process of completing the other required immunizations, thereby conforming to Part B of the DOH's current Certificate of Immunization Form.

The bill makes other non-substantive edits to improve clarity within this statutory section and to improve consistency within the statutes. For example, the bill replaces "permit" with "allow" to clarify that no formal permit is issued, and hyphens are added to "follow-up."

Section 10 provides an effective date of July 1, 2026, except for the provisions directing the Boards to adopt informational materials by rule which would go into effect upon becoming law. The bill directs the Boards to adopt the joint rule no later than 120 days after the bill becomes a law. The provisions requiring a parent's signature documenting the receipt of informational materials do not go into effect until 30 days after the Boards adopt the materials by joint rule.

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:

Because the bill authorizes behind-the-counter access to an U.S. Food and Drug Administration (FDA) Rx-only ivermectin product, a court could find conflict preemption under the Supremacy Clause because the state authorization would permit conduct that federal law treats as unlawful misbranding for prescription-only drugs. See *Present Situation: Ivermectin* portion of this analysis.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None identified.

B. Private Sector Impact:

None identified.

C. Government Sector Impact:

SB 6-D requires the Board of Medicine and the Board of Osteopathic Medicine to jointly adopt materials to convey to parents the role of immunizations in communicable disease prevention. The Department of Health (DOH) will be required under the bill to update its Immunization Guidelines and its Exemption from Immunization for Religion form. The Department of Children and Families will need to update its handbooks for childcare facilities and family day care homes. It is expected that these operational impacts may be absorbed within existing resources.[178]

VI. Technical Deficiencies:

None identified.

VII. Related Issues:

The bill amends s. 456.054, F.S., to establish that it is unlawful for a vaccine manufacturer to offer or pay, or for a health care practitioner to receive, any form of compensation for the administration of a vaccine. Any such act is considered patient brokering, punishable as a felony under existing law.

As with any pharmaceutical needing FDA approval, before a vaccine may be approved, the vaccine manufacturer must guide the vaccine through a series of clinical trials on human subjects to confirm safety and efficacy. When vaccine manufacturers are testing a new product before it may be offered on market, they are required to conduct a series of clinical trials.

[178] Fla. Dept. of Health, *supra* note 171.

Participants in clinical trials are often incentivized to participate through compensation and travel reimbursement by pharmaceutical manufacturers. Such compensation for vaccine clinical trials could be interpreted as an indirect financial incentive that is prohibited as patient brokering under this bill, thus outlawing such compensation for participants in clinical trials of vaccines conducted in Florida. Meanwhile, compensation for participants in clinical trials of other types of pharmaceuticals would remain lawful.

If that outcome is not the bill's intent, an amendment should be considered.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.00315, 456.054, 456.0575, and 1003.22.

This bill creates the following sections of the Florida Statutes: 458.3351, 459.0156, 464.0181, and 465.1897.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.