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H.P. 1168	House of Representatives, April 23, 2019

An Act To Establish the Vaccine Consumer Protection Program

Reference to the Committee on Health and Human Services suggested and ordered printed.

ROBERT B. HUNT
Clerk

Presented by Representative O'CONNOR of Berwick.
Cosponsored by Senator FOLEY of York and
Representatives: COREY of Windham, GRIFFIN of Levant, JAVNER of Chester, ORDWAY of Standish, SAMPSON of Alfred, WADSWORTH of Hiram, Senator: MIRAMANT of Knox.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 251, sub-c. 2-B is enacted to read:

SUBCHAPTER 2-B

VACCINE CONSUMER PROTECTION

§1071. Vaccine Consumer Protection Program

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Federal Vaccine Adverse Events Reporting System" means a national vaccine safety surveillance program cosponsored by the United States Department of Health and Human Services, Food and Drug Administration and Centers for Disease Control and Prevention.

B. "Health care provider" means a physician, nurse, clinic, hospital or other entity licensed by the State to provide health care services that administers vaccines.

C. "National Vaccine Injury Compensation Program" means the National Vaccine Injury Compensation Program established by 42 United States Code, Section 300aa-10.

D. "Office" means the Vaccine Consumer Protection Office established in subsection 2.

E. "Ombudsman" means the vaccine injury ombudsman appointed pursuant to subsection 2.

F. "Program" means the Vaccine Consumer Protection Program established in subsection 2.

G. "Vaccine" has the same meaning as "immunizing agent" as defined in section 1061, subsection 2.

2. Program established. The Vaccine Consumer Protection Program is established within the department. The program may not be administered as part of the same administrative unit as the Universal Childhood Immunization Program established under section 1066. The Vaccine Consumer Protection Office is established within the department to carry out the purposes of the program. The commissioner shall appoint a vaccine injury ombudsman to assist members of the public who suspect vaccine injury.

3. Vaccine Injury Board. The commissioner shall establish the Vaccine Injury Board to advise the office in providing services under this section. The board must be composed of health care providers and vaccine injury victims or parents or legal guardians of victims who are minors. At least 1/2 of the members of the board must be vaccine injury victims or victims' parents or legal guardians.

4. Services. Under the program, the office shall:

A. Provide information to the public regarding assessment, diagnosis and treatment of potential vaccine injuries by a physician trained and qualified in vaccine injury assessment, diagnosis and treatment, according to an established standard of care, and refer all members of the public reporting suspected vaccine adverse events to such a qualified physician;

B. Take actions necessary to ensure that at least one physician per congressional district, who is trained and qualified in vaccine injury assessment, diagnosis and treatment, agrees to be available, as part of the physician's medical duties, to offer expert witness testimony on behalf of vaccine injury victims in proceedings under the United States Department of Health and Human Services, National Vaccine Injury Compensation Program or civil vaccine injury proceedings;

C. Ensure that health care providers respond to all potential vaccine injury cases brought to the health care providers' attention by reporting the cases to the federal Vaccine Adverse Events Reporting System and referring potential injury victims to the ombudsman for assistance in obtaining evaluations and care;

D. Establish treatment guidelines and ethical standards for health care providers administering vaccines or caring for vaccinated populations based on information provided by the United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Vaccine Injury Compensation Program, vaccine manufacturer package inserts and current research;

E. Every 3 years, provide continuing medical education and vaccine safety and efficacy training for all health care providers based on information provided by the United States Department of Health and Human Services, Centers for Disease Control and Prevention, and National Vaccine Injury Compensation Program, vaccine manufacturer package inserts and current research;

F. At least twice per year, provide a public forum on vaccine adverse events that includes participants who are vaccine injury victims on at least half of the panels at the forum;

G. Establish and maintain a state vaccine information sheet that includes the following disclosures and consent.

(1) Before administering a vaccine to a patient, a health care provider shall provide to the patient or to the patient's parent or legal guardian if the patient is a minor a federal vaccine information sheet developed by the United States Department of Health and Human Services, Centers for Disease Control and Prevention in accordance with 42 United States Code, Section 300aa-26 and the following information via the state vaccine information sheet:

(a) That the patient or the patient's parent or legal guardian if the patient is a minor may decline some or all vaccines;

(b) That the health care provider administering the vaccine is liable for harm to the patient caused by the vaccine or its administration if the provider does not follow manufacturer contraindications listed on the vaccine manufacturer package insert;

(c) That the vaccine manufacturer is not liable for harm to the patient or the death of the patient caused by the vaccine, even if the harm or death was caused by the manufacturer's negligence in the design of the vaccine;

(d) If a health care provider is administering more than one vaccine in a single visit and, if applicable, that no safety studies have been performed, before or after approval of the vaccine, on the combination of vaccines the provider plans to administer;

(e) Information for each vaccine being administered;

(f) If a health care provider plans to administer a vaccine containing mercury, that an alternative vaccine is available that is mercury-free; and

(g) That medical and religious exemptions are available pursuant to sections 1079 and 1080 to individuals who choose not to receive a vaccine that a school or employer requires.

(2) After providing the disclosures required in subparagraph (1) and before administering a vaccine to a patient, a health care provider shall obtain written, informed consent for each vaccine from the patient or the patient's parent or legal guardian if the patient is a minor; and

H. Notwithstanding any other provision of law to the contrary, establish mandatory guidelines for vaccine administration for health care providers and a complaint and censure process under which a member of the public may bring a complaint against a health care provider when the health care provider:

(1) Vaccinates outside guidelines contained in vaccine manufacturer package inserts or guidelines established by the program or the United States Department of Health and Human Services, Health Resources and Services Administration and Centers for Disease Control and Prevention;

(2) Before vaccine administration, fails to provide a document describing potential contraindications and adverse events to the patient or the patient's parent or legal guardian if the patient is a minor;

(3) Before vaccine administration, fails to provide the state vaccine information sheet and a federal vaccine information sheet to the patient or the patient's parent or legal guardian if the patient is a minor;

(4) Before vaccine administration, fails to acquire written informed consent for vaccination from the patient or the patient's parent or legal guardian if the patient is a minor;

(5) Fails to report a patient-reported vaccine adverse event or suspected vaccine injury to the federal Vaccine Adverse Events Reporting System;

(6) Fails to refer to the office a patient who has reported a vaccine adverse event or the parent or legal guardian of the patient if the patient is a minor;

(7) Engages in coercive practices as defined by program guidelines;

(8) Makes public or private vaccine safety and efficacy claims, outside of personal belief claims, to the public or patients that are unsupported by

information from the United States Department of Health and Human Services, Health Resources and Services Administration and Centers for Disease Control and Prevention, vaccine manufacturer package inserts or published research, such as the claim that vaccines are safe;

(9) Engages in the harassment of patients, parents, legal guardians or members of the public for the vaccine choices of those individuals; or

(10) Vaccinates a child under the age of 18 without the written informed consent for each vaccine being administered from the child's parent or legal guardian, or outside the physical presence and supervision of the child's parent or legal guardian.

§1072. Health care provider's rights

The department may not coerce a health care provider to administer a vaccine or subject a health care provider to punitive action for:

1. Medical exemptions. Providing a medical exemption for a vaccine;

2. Decline to administer. Declining to administer a vaccine;

3. Decline to recommend. Declining to recommend a vaccine be administered;

4. State and federal childhood immunization programs. Choosing not to participate in the Universal Childhood Immunization Program established under section 1066 or a federal childhood immunization program; or

5. Advocate. Advocating for potential vaccine injury cases or acting as an expert witness for vaccine injury victims.

§1073. Patient right of refusal

A patient or the patient's parent or legal guardian if the patient is a minor has the right to refuse a vaccine, and any such refusal may not be taken into consideration in a child protective services complaint. Vaccine administration may not be required for reunification in a child protective services case. The Office of Child and Family Services may not authorize or facilitate the administration of any vaccine to a child in its custody without written parental consent.

§1074. Vaccine death investigations

Upon the request of the next of kin of the deceased person, the office shall investigate a death that is suspected to have been caused by the administration of a vaccine. The office shall provide the next of kin a detailed report regarding the investigation.

§1075. Incentive prohibition

A state agency may not approve a financial or other incentive that encourages the increased use of vaccines, including, but not limited to, higher reimbursement rates to health care providers based on patient vaccination rates, awards to health care providers

for increased vaccination rates of patients, payments or rewards to patients for receiving a vaccine or any other incentive that may encourage the increased use of a vaccine based on a consideration other than the best interests of the individual receiving the vaccine.

§1076. Vaccine prescriptions

Notwithstanding any other provision of law to the contrary, a person who is not a health care provider may not administer a vaccine without a prescription from a health care provider.

§1077. Standing orders

Notwithstanding any other provision of law, a vaccine may not be prescribed by standing order.

§1078. Annual report

The office shall provide an annual report to the United States Department of Health and Human Services, Centers for Disease Control and Prevention, Immunization Safety Office on the number of vaccine adverse event reports, assessments and diagnosed cases of vaccine injury and death in the State.

§1079. Religious exemptions

Notwithstanding any other provision of law to the contrary, a person or the person's parent or legal guardian if the person is a minor has the right to refuse a vaccine based on a sincere religious belief that is contrary to a vaccination requirement without coercion, consequence or retaliation.

§1080. Medical exemptions

Notwithstanding any other provision of law to the contrary, the department or any other state agency may not limit the application of any law that allows a health care provider to provide a medical exemption if the health care provider determines that administration of a vaccine is medically inadvisable for a patient, and a patient has the right to refuse a vaccine without coercion, consequence or retaliation.

§1081. Administration of certain vaccines prohibited

A person may administer a vaccine only if:

1. Vaccine safety. The study relied on by the United States Department of Health and Human Services, Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine:

A. Against a control group that received an inert, saline placebo; and

B. For a sufficient time to identify potential autoimmune, neurological or chronic health conditions that may arise on or after the first anniversary of the date the vaccine is administered;

2. Evaluation. The vaccine has been evaluated for the vaccine's potential to:

A. Cause cancer;

B. Mutate genes;

C. Affect fertility or cause infertility; and

D. Cause autism spectrum disorder;

3. Known injuries and diseases. The department has posted on the department's publicly accessible website a disclosure of any known injuries or diseases caused by the vaccine and the rate at which the injuries or diseases have occurred; and

4. Study of effect of vaccine. The chemical, pharmacological, therapeutic and adverse effects of the vaccine and the rate of injury of the vaccine when administered with other vaccines have been studied and verified.

§1082. Rules

The department shall adopt rules to implement this subchapter. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Reference Manual; publicly accessible website. The Department of Health and Human Services shall add the vaccine injury table of covered vaccines and associated injuries established by 42 Code of Federal Regulations, Section 100.3 (2000) and information related to the National Vaccine Injury Compensation Program to the Provider Reference Manual created by the Department of Health and Human Services, Maine Center for Disease Control and Prevention, division of disease surveillance and to the department's publicly accessible website.

Sec. 3. Health care provider licensing boards; rules. Each board responsible for the licensing of a health care provider as defined in the Maine Revised Statutes, Title 22, section 1071, subsection 1, paragraph B shall amend that board's rules as necessary to conform to the provisions of this Act.

SUMMARY

This bill establishes the Vaccine Consumer Protection Program within the Department of Health and Human Services and describes the activities under the program.