



ANALYSIS

Telephone: (517) 373-5383 Fax: (517) 373-1986

House Bill 4352 (as reported without amendment)

House Bill 4353 (Substitute H-2 as reported without amendment)

Sponsor: Representative Lisa Posthumus Lyons

House Committee: Education Senate Committee: Education

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RATIONALE

Food allergies and the potential for serious reactions have become a major concern at schools. It is estimated that one out of every 13 children suffers from food allergies, or roughly two children per classroom. Within minutes after a person eats a food he or she has an allergy to, a severe allergic reaction called anaphylaxis can occur, and can cause death in as little as 15 minutes. Common food allergens include peanuts and other nuts, milk, eggs, soy, wheat, fish, and shellfish. Other causes of anaphylaxis include bee stings, medications, latex, and exercise.

Epinephrine is a medication that can be used to treat symptoms of anaphylaxis. It is typically administered via injection, and must be administered promptly during anaphylaxis to be most effective. Auto-injectable epinephrine (AIE) devices, commonly referred to as "epi-pens", deliver premeasured doses of epinephrine, and require a medical prescription. Epinephrine can slow an allergic reaction, and provide time for the affected person to reach a hospital or doctor's office for further treatment, or for emergency responders to reach the person.

According to multiple sources, however, 25% of children who experience anaphylaxis while in school are not aware of having a food allergy. If a student is unaware of his or her food allergy, or forgets to bring an epi-pen to school, and has an anaphylactic reaction at school, he or she could die.

Therefore, it has been suggested that schools should be required to have AIE devices stocked and available on site, and staff who are trained to administer the medication, to treat children who have anaphylactic reactions while at school.

CONTENT

House Bill 4352 would amend the Public Health Code to do the following:

- -- Allow a prescriber to prescribe AIE to a school board.
- -- Allow a dispensing prescriber or a pharmacist to dispense AIE to a school board.
- -- Provide civil immunity to a person who prescribed or dispensed AIE to a school in certain circumstances.
- -- Allow a school employee who was a licensed registered professional nurse or was trained in administering AIE to possess and administer it.

House Bill 4353 (H-2) would amend the Revised School Code to do the following:

-- Require a school board to develop and implement policies that provided for each school to possess two AIE devices, and authorized school nurses and trained school

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- employees to administer AIE to an individual on school grounds who was believed to be having an anaphylactic reaction.
- -- Require a school board to have a certain number of employees who were trained in administering AIE.
- -- Provide civil immunity to a school district and certain school officials with regard to an authorized person's provision of medicine or AIE to a pupil under certain circumstances.
- -- Provide civil and criminal immunity to a school employee who in good faith administered AIE and complied with the provisions of the bill and school board policies regarding AIE, except in cases of grossly negligent or willful or wonton misconduct.
- -- Require the Department of Education to identify, develop, and adopt revisions to medication administration guidelines, including training needs and requirements for administering, maintaining, and storing AIE devices.
- -- Require a school district to report all instances of AIE administration to the Department at least annually.
- -- Require a school district to attempt to obtain funding or resources from a source other than the State to meet the bill's requirements.
- -- Allow a school board to apply to the Department for unfunded costs of complying with the bill.
- -- Require the Legislature to appropriate funds for the reimbursement.
- -- Require the Department to submit an annual report to the Legislature.

House Bill 4352 is tie-barred to House Bill 4353.

House Bill 4352

The bill would allow a prescriber to issue a prescription for, and allow a dispensing prescriber or pharmacist to dispense, AIE to a school board for the purpose of meeting the requirements of Section 1179a of the Revised School Code (proposed by House Bill 4353 (H-2), as described below). The prescriber, dispensing prescriber, or pharmacist, as appropriate, would have to insert the name of the school board as the name of the patient when issuing a prescription for or dispensing AIE to a school board.

Under the Public Health Code, a pharmacist may dispense a prescription only if he or she determines, in addition to other criteria, that the prescription was issued pursuant to an existing physician-patient or dentist-patient relationship. A dispensing prescriber must dispense a drug in a container that bears a label that includes the patient's name and record number. An electronically transmitted prescription must include the full name of the patient. Under the bill, these provisions would not apply to an AIE prescription to a school district.

A dispensing prescriber must maintain a complete record, including prescription drug information, in a patient's chart or clinical record. The prescriber must distinguish between prescription drugs dispensed to the patient, and prescription drugs prescribed for the patient. The bill would require that the prescriber also distinguish between these drugs and prescription drugs dispensed or prescribed to school boards according to the requirements in the bill.

A prescriber who issued a prescription for or a dispensing prescriber or pharmacist who dispensed AIE to a school board as authorized under the bill would not be liable in a civil action for a properly stored and dispensed AIE device that was a proximate cause of injury or death to an individual due to the administration of or failure to administer AIE.

The bill also would allow a school employee who was a licensed registered professional nurse or was trained in administering AIE to possess and administer the AIE under proposed Section 1179a of the Revised School Code.

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House Bill 4353 (H-2)

Department Guidelines

The bill would require the Michigan Department of Education (MDE) to identify, develop, and adopt appropriate revisions to its medication administration guidelines. This would include specification of training needs and requirements for the administration and maintenance of stock AIE devices, including stocking of both junior and regular dose AIE devices, as necessary, and storage requirements. The MDE would have to work in conjunction with the Department of Community Health, and with input from the Michigan Association of School Nurses, the Michigan Nurses Association, the Michigan Parent Teacher Association, the American College of Allergy, Asthma, and Immunology, the Michigan Chapter of the American Academy of Pediatrics, the School-Community Health Alliance of Michigan, and other school health organizations and entities.

School Employees & Board Policies

The bill would allow a licensed registered professional nurse who was employed or contracted by a school district, or a school employee who was trained in the administration of AIE, to possess and administer an AIE device.

Beginning in the 2014-2015 school year, a school board would have to ensure that each school within the school district had a certain number of employees who were trained in the appropriate use and administration of AIE. In a school with an instructional and administrative staff of at least 10, there would have to be at least two trained employees. In a school with a staff of less than 10, there would have to be at least one trained employee. Employee training would have to be conducted under the supervision of, and include evaluation by, a licensed registered professional nurse.

By the beginning of the 2014-2015 school year, a school board would have to develop and implement policies that were consistent with the MDE's revised medication administration guidelines. The policies also would have to provide for the possession of at least two AIE devices, to be used for administration by a licensed registered professional nurse who was employed or contracted by the school district, or by a properly trained school employee, in each school that the board operated. The policies would have to authorize a licensed professional registered nurse who was properly trained in administering AIE to administer AIE to a pupil who had a prescription on file at the school, and any other individual on school grounds who was believed to be having an anaphylactic reaction.

The policies would have to require notification to the parent or legal guardian of a pupil to whom AIE was administered.

Civil & Criminal Immunity

Currently, a school administrator, teacher, or other school employee designated by the school administrator, who in good faith administers medication to a pupil in the presence of another adult or in an emergency that threatens the life or health of the pupil, with written permission of the pupil's parent or guardian, and in compliance with the instructions of a physician, physician's assistant, or certified nurse practitioner, is not liable in a criminal action or for civil damages as a result of an act or omission in the administration of the medication, except for an act or omission amounting to gross negligence or willful and wanton misconduct.

The bill would include within this provision a school employee who in good faith administered AIE to an individual consistent with the requirements in the bill.

The bill also provides that a school district, nonpublic school, member of a school board, or director or officer of a nonpublic school would not be liable for damages in a civil action for injury, death, or loss to person or property that allegedly arose from a person who acted under these provisions.

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Funding

In fulfilling the bill's requirements, a school board would have to attempt to obtain funding or resources from private sources, or another source other than the State. If a school board were unable to get alternative funding, the board could apply to the MDE for reimbursement for the unfunded costs of compliance, in the form and manner prescribed by the Department. The Legislature would have to appropriate funds for making the reimbursement. The MDE would have to make the reimbursement according to the appropriation.

Department & School District Reports

At least annually, a school district would have to report to the MDE all instances of AIE administration to a pupil at school. The reporting would have to be in a manner and form prescribed by the Department and include at least all of the following:

- -- The number of instances of administration of AIE to a pupil at school in a school year.
- -- The number of pupils who were administered AIE at school who were not previously known to be severely allergic.
- -- The number of pupils who were administered AIE at school using the school's stock of AIE.

The Department would have to submit to the Legislature an annual report that detailed the number of school boards that applied for reimbursement and the number that were able to secure alternative funding.

MCL 333.17745 et al. (H.B. 4352) 380.1178 et al. (H.B. 4353)

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Reportedly, one in every 13 children suffers from a food allergy, food allergies among children increased approximately 50% between 1997 and 2011, the number of children with peanut allergies tripled between 1997 and 2008, and children are taking longer to outgrow some food allergies. The bills are needed to make sure that schools have the ability to save students' lives when severe allergic reactions hit. Since an estimated 25% of anaphylactic reactions occur in students who do not know they have an allergy, and some students with knowledge of an allergy might forget to bring an epi-pen to school, schools should have AIE devices stocked and available. Under the current law, a school cannot administer AIE to a student who does not have a prescription, and schools cannot obtain AIE devices. Students who do not have an AIE device must wait for emergency medical attention. Every second counts in the case of an anaphylactic reaction, so any delay could result in a child's death.

Massachusetts is one of 27 other states that reportedly have passed similar legislation. According to the *Detroit Free Press*, Massachusetts schools have reported that AIE is administered about 200 times a year, and 25% of the students who received it were not aware of a life-threatening allergy.

In addition to safeguarding students, the bills would protect providers and prescribers of AIE from liability when they dispense to schools, and protect school officials from liability with regard to administering medication or stocking and administering AIE. Since AIE devices are prepackaged, there is little to no risk that a prescriber or pharmacist would prescribe or dispense the wrong dose or medication. Without civil immunity, however, school officials could be hesitant to administer AIE due to liability concerns.

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Opposing Argument

House Bill 4353 (H-2) would result in an unfunded mandate for schools to ensure employee training and the acquisition and storage of AIE devices. The possibility that nonprofit organizations and other groups could provide or pay for AIE devices and training would not negate the absence of funding to comply with mandatory AIE policies.

Response: The bill would allow a school board to apply to the MDE for reimbursement if the board were unable to secure alternative funding. Reportedly, there are already programs that are prepared to provide these resources to schools, and passage of the bills would enable them to do so. Regardless, the cost of AIE devices is minimal, especially when compared to the risk of death in the absence of the devices, so the bill would not pose any unreasonable burdens.

Opposing Argument

House Bill 4352 would unnecessarily lower the standard of care for prescribers and providers of AIE who prescribed or dispensed AIE devices to schools. The proposed immunity would make it difficult, if not impossible, to hold prescribers and providers liable if they supplied tainted AIE devices, or the wrong medicine altogether. Students should have the same recourse against prescribers and providers as other injured parties.

Response: The immunity would apply only if the AID were "properly stored and dispensed".

Opposing Argument

School staff could give AIE to students who did not medically require it, which could have dire consequences. For example, if a child showed symptoms of an allergic reaction but were really having a heart attack, administering AIE could kill the child.

Response: The bills would require staff to be trained in administering AIE, which would include recognizing whether it was necessary. Typically, administering AIE to someone who does not medically require it has little to no side effects. A person without allergies who received an injection could have bruising at the injection site and feel jittery or excitable for about 15 minutes, which is roughly the duration of the medicine's effectiveness. Many believe that the benefits of administering an injection are outweighed by the risk of withholding it, even if it turns out that an injection was not required.

Legislative Analyst: Glenn Steffens

FISCAL IMPACT

House Bill 4352

The bill would have no fiscal impact on State or local government.

House Bill 4353 (H-2)

The bill would increase costs to the Michigan Department of Education by requiring the Department to identify, develop, and adopt appropriate revisions to the medication administration guidelines as specified under the bill. Costs likely would be minimal.

Under proposed Section 1179a, costs for local schools would increase because of the requirements for two epinephrine auto-injectors at each school building, training in the administration of epinephrine auto-injectors, and annual reporting on instances of administration of epinephrine auto-injectors, as specified under the bill. The bill would require school boards to seek funding or resources from private sources or sources other than the State, but if those funds were insufficient to cover the costs identified above, the school boards could apply to the Department for reimbursement. The bill would require the Legislature to appropriate funds for making the reimbursement.

It is unknown the extent to which private or other non-State funds would be available to pay for the requirements of this legislation under Section 1179a. To estimate conservatively (by assuming no private or other non-State resources), the cost to the State for epinephrine auto-injectors could range from \$500,000 to \$600,000 per year (using a cost of \$140 for a two-pack

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of epinephrine auto-injectors multiplied by the number of school buildings in Michigan), on top of the cost for training staff in the administration of the medication, along with the potential cost of paying for a contracted nurse if a school board chose to use a contracted nurse instead of district staff for the administration of the medication, as allowed under Section 1179a(2).

The bill also could result in savings to affected local school districts because of the proposed language added in Section 1178(3) that would remove any liability for damages in a civil action for injury, death, or loss to person or property allegedly arising from a person administering medication under this section. Current law states that personnel of a school are not liable in a criminal action or for civil damages, but does not provide such immunity to the districts themselves. Therefore, the proposed language could provide district savings if there were situations in which a district was sued for damages due to the administration of medication by district personnel, and the district was found guilty and, without this language, would be ordered to pay damages.

Fiscal Analyst: Kathryn Summers

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.