

Department of Legislative Services
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FISCAL AND POLICY NOTE
Revised

Senate Bill 365

(Senator Middleton, *et al.*)

Education, Health, and Environmental Affairs

Health and Government Operations

Public Health - Mercury-Free Vaccines - Requirements

This bill requires that, beginning January 1, 2008, an individual must be vaccinated with a vaccine that contains less than 1.25 micrograms of mercury per 0.5 milliliter dose unless a vaccine that meets this requirement is not readily available or appropriate.

Fiscal Summary

State Effect: The bill primarily alters the purposes for which existing funds may be used. Any administrative changes could be handled by the Department of Health and Mental Hygiene (DHMH) within existing resources.

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law: The Secretary of Health and Mental Hygiene must devise and institute the means to prevent and control infant mortality and diseases of pregnancy, childbirth, infancy, and early childhood. The Secretary also must promote the welfare and hygiene of maternity and infancy.

Immunization against certain diseases is required for a student to be admitted and stay in a public or private school. A parent or guardian must provide the school with evidence that a child received the age-appropriate immunizations following the immunization schedule recommended by the Subcommittee on Immunizations and Infectious Diseases of the Medical and Chirurgical Faculty of Maryland and the Secretary of Health and Mental Hygiene.

Background: The Food and Drug Administration (FDA), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Environmental Protection Agency (EPA) have mercury exposure guidelines of what mercury levels are thought to be safe. These standards are based on methylmercury research, rather than ethylmercury, because methylmercury is more easily bound to tissue, remains there a longer time, and is believed to be more toxic, according to the Centers for Disease Control and Prevention (CDC).

Thimerosal, a preservative used in some vaccines and other products, contains approximately 49% ethylmercury. There is no direct causal evidence that thimerosal in vaccines harms individuals, other than causing reactions such as redness and swelling where the injection occurs, CDC states. Vaccines with trace amounts of thimerosal contain one microgram or less of mercury per dose.

The Institute of Medicine's Immunization Safety Review Committee reported October 1, 2001 that scientific data is inadequate to determine whether or not there is a causal relationship between thimerosal in childhood vaccines and neurodevelopmental disorders such as autism, attention deficit hyperactivity disorder, and speech or language delay.

In 1999, FDA reviewed the use of thimerosal in childhood vaccines. FDA found that a child's cumulative mercury exposure from recommended vaccines was within acceptable limits set by FDA, ATSDR, and the World Health Organization. At the same time, FDA learned that, depending on the vaccine formulations and the infant's weight, the cumulative mercury exposure during a child's first six months could exceed the EPA's recommended guidelines for methylmercury. In response, the Public Health Service and the American Academy of Pediatrics urged vaccine manufacturers to reduce or eliminate thimerosal in vaccines.

Thimerosal was removed from or reduced to trace amounts in all vaccines recommended for children six years old and younger, except for the inactivated influenza vaccine, according to the FDA's Center for Biologics Evaluation and Research. A preservative-free inactivated influenza vaccine, which contains a trace amount of thimerosal, is available in limited supply for children and pregnant women.

The U.S. Code of Federal Regulations generally requires multi-dose vials of vaccines to contain a preservative. DHMH advises that removing the preservative often forces manufacturers to distribute vaccines in single-dose vials, which are often more costly to produce, store, and ship. Some manufacturers use thimerosal throughout the manufacturing process and then remove the compound, which also adds to the cost of the vaccine. DHMH reports that most vaccines are produced without mercury.

The proposed Mercury-Free Vaccines Act of 2005 (H.R. 881 and S. 1422), introduced in the 109th Congress, would prohibit vaccines from containing one microgram or more of mercury per dose. It requires the Secretary of Health and Human Services to prohibit the distribution of banned mercury-containing influenza vaccines that are approved as biological products to: (1) any child under age three (beginning July 1, 2006); (2) pregnant women if the vaccine contains thimerosal (beginning July 1, 2006); and any child under age six (beginning July 1, 2007).

It would authorize the Secretary to declare that an actual or potential bioterrorist incident or other public health emergency makes the administration of vaccines with one microgram or more of mercury advisable for a specified period. It also changes information requirements for vaccines containing mercury. These bills have been referred to committees but no further action has been taken.

Other States Actions

Early childhood immunizations administered in Iowa may not contain more than trace amounts of mercury.

Delaware enacted a law in 2005 that eliminates, over a three-year period, the use of mercury-containing vaccines for pregnant women and children under age eight. No vaccine for children under age eight or for pregnant women that contains more than a trace amount of mercury, except the influenza vaccine, may be made available to medical providers. Beginning January 1, 2007, this prohibition extends to the influenza vaccine. Beginning January 1, 2008, vaccines with more than a trace amount of mercury are prohibited from being made available to *and* administered by medical providers.

Beginning July 1, 2006, California prohibits a person who is knowingly pregnant or who is under age three from being vaccinated or injected with a vaccine or product that contains more than a certain amount of mercury.

In Illinois, a person may not be vaccinated with a vaccine that has more than 1.25 micrograms of mercury per dose. Beginning January 1, 2008, no person may be vaccinated with a vaccine or injected with any product that contains, or prior to dilution, had contained as an additive, any mercury-based product, whether at preservative or trace amount levels.

Beginning July 1, 2008, New York prohibits a person under age three and a woman who knows she is pregnant from being vaccinated with a vaccine that contains more than 0.5 micrograms of mercury per 0.5 milliliter dose, with certain exceptions. Those exceptions are (1) for influenza vaccines, (2) if the vaccines are necessary to prevent or respond to an outbreak of disease and there are not sufficient amounts of vaccine containing the

indicated mercury levels, and (3) when the use of vaccines with greater amounts of mercury than allowed under this bill is authorized because vaccines with lower amounts of mercury are not available and the parent of a person under age three provides informed consent to administer the vaccine to the child.

State Fiscal Effect: Depending on the availability of vaccines without thimerosal and the demand for the vaccinations, DHMH's Community Health Administration (CHA) advises that this bill could result in fewer individuals receiving vaccinations if vaccines without thimerosal are not available. Vaccines distributed by CHA, or by CDC at CHA's request to a specific area of the State, are purchased with federal funds.

CHA advises that implementing the bill would cost \$425,484 in fiscal 2007. This estimate assumes \$375,000 (\$500,000) for a media campaign to educate the general public and vaccine providers on which vaccines are approved for use. It also assumes CHA hiring one epidemiologist to investigate and monitor disease outbreaks it expects to occur once the bill is implemented. CHA further advises that it purchases influenza vaccines for children receiving Medicaid and that it could incur higher costs to purchase single-dose mercury-free products.

CHA expects that federal fund revenues to purchase influenza vaccines for children 17 and younger will be reduced by \$265,804 in fiscal 2007 (\$531,608 annually) because the State will not be in compliance with federal recommendations.

The Department of Legislative Services (DLS) disagrees with this estimate. The bill does not require a media campaign. CHA, in conjunction with the relevant health occupations boards, can alert the health care practitioners that administer vaccines and the vaccine suppliers regarding the bill's requirements using existing budgeted resources. DLS further disagrees that the bill would result in increased costs to purchase vaccines because the bill allows vaccines with more than the specified amount of mercury to be used if the required vaccine is not readily available or appropriate. DLS assumes that if DHMH was faced with losing federal Medicaid funds for influenza vaccines as a result of this bill, and would be required to purchase a more expensive vaccine that does not contain mercury using general funds, this exemption would apply.

Additional Information

Prior Introductions: HB 86 of 2005 would have prohibited an individual under the age of three or a woman known to be pregnant from being vaccinated with a vaccine, or injected with a product, that contains mercury or other heavy metals. The bill received an unfavorable report by the House Health and Government Operations Committee.

Cross File: HB 394 (Delegate Kullen, *et al.*) – Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene; Food and Drug Administration; *Mercury & Thimerosal*, National Immunization Program, Centers for Disease Control and Prevention; *CDC Vaccine Price List*; National Conference of State Legislatures; Department of Legislative Services

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