

Department of Legislative Services
 Maryland General Assembly
 2014 Session

FISCAL AND POLICY NOTE

House Bill 1254 (Delegates Carr and Hucker)
 Environmental Matters

Environment - Dental Amalgam - Reduction in Use

This bill requires a wholesaler or manufacturer of dental amalgam, by September 30, 2014, to submit a plan to the Maryland Department of the Environment (MDE) to reduce the use of dental amalgam in the State and to publish the plan on its website. Beginning October 1, 2014, the bill prohibits the sale of dental amalgam unless the manufacturer or wholesaler has submitted and published such a plan. Beginning March 30, 2015, the bill requires a wholesaler or manufacturer of dental amalgam to submit a specified annual report to MDE.

The bill takes effect June 1, 2014.

Fiscal Summary

State Effect: General fund expenditures for MDE increase by \$9,300 in FY 2014 to hire an environmental compliance specialist to review plans and enforce the bill. Future years reflect annualization and inflation. Revenues are not affected.

(in dollars)	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	9,300	63,000	65,900	69,000	72,200
Net Effect	(\$9,300)	(\$63,000)	(\$65,900)	(\$69,000)	(\$72,200)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: The bill establishes that it is the policy of the State to reduce the use of dental amalgam. A wholesaler or manufacturer of dental amalgam may not sell or offer dental amalgam for sale beginning on October 1, 2014, unless he/she submits a plan to MDE to reduce the use of dental amalgam in the State and publishes the plan on his/her website. Beginning March 30, 2015, and annually thereafter until dental amalgam is no longer sold in the State, a manufacturer or wholesaler must submit a report to MDE that identifies the amount of mercury in dental amalgam that was sold in the State during the previous year.

Current Law: Dental amalgam is regulated by FDA's Center for Devices and Radiological Health (CDRH). CDRH is responsible for ensuring that medical devices are reasonably safe and effective and that the labeling has adequate directions for use and any appropriate warnings. The Health-General Article limits the manufacture or sale of specified items to protect the public's health. For example, a person may not manufacture or sell any food, drug, device, or cosmetic that is adulterated or misbranded.

MDE's mercury program relates primarily to mercury-added products (dyes or pigments, electric switches, fluorescent lamps), thermostats, mercury fever thermometers, mercuric-oxide batteries, the use of mercury in schools, and public outreach and education. Chapter 494 of 2004 established prohibitions and requirements relating to the sale and reclamation or destination of mercury-added products. In general, unless a mercury-added product is labeled, a manufacturer or wholesaler may not sell the product at retail in the State or to a retailer in the State. Unless properly labeled, a retailer may not knowingly sell a new mercury-added product in the State. Beginning October 1, 2007, Chapter 56 of 2006 prohibits a marketer from selling or providing a thermostat containing mercury to a consumer.

Background: Dental amalgam fillings are made of elemental mercury, silver, tin, copper, and possibly other metallic elements. According to the American Dental Association (ADA), dentists use them because they are durable, easy to use, resistant to wear, and relatively inexpensive compared to other materials. ADA reports that, despite safety concerns that have been raised because of its mercury content, the mercury in amalgam combines with other metals to render it stable and safe for filling teeth. Other fillings, such as composite fillings, are available, but more expensive.

However, in June 2008, FDA posted a consumer notice on its website stating that "dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses." On July 28, 2009, FDA issued a final rule that reclassified mercury from a class I (least risk) device to a class II (more risk) device, because during a dental procedure that uses dental amalgam, low levels of mercury vapor are released and inhaled by the patient. High levels of mercury vapor exposure cause adverse effects in the brain and the kidneys. Mercury levels measured in the bodies of

people with dental amalgam fillings were well below levels associated with adverse health effects, even in individuals with 15 or more dental amalgam fillings. Based on scientific evidence, FDA considers dental amalgam filling safe for adults and children older than age six. Therefore, FDA concluded that it is not necessary to require that dentists provide information on the health risks associated with mercury to all patients in order to provide reasonable assurance of the safety and effectiveness of dental amalgam.

FDA recommends that the product label for dental amalgam include a warning against the use of dental amalgam in patients with a mercury allergy, a warning that dental professionals use adequate ventilation when handling dental amalgam, and a statement discussing the scientific evidence on mercury vapor and the benefits and risks of dental amalgam to help dentists and patients make informed decisions about the use of dental amalgam.

According to the Department of Health and Mental Hygiene (DHMH), the use of dental amalgam for restoration procedures in the State has declined by approximately 23% each year in recent years, despite an increase in the total number of restoration procedures performed. In fiscal 2010, dental amalgam was used in 5.3% of all restoration procedures. By fiscal 2013, dental amalgam was only used in 2.3% of all restoration procedures. DHMH advises that the bill likely accelerates this trend.

State Expenditures: General fund expenditures increase by \$9,258 in fiscal 2014, which accounts for the bill's June 1, 2014 effective date. This estimate reflects the cost of hiring one environmental compliance specialist to review reduction plans and annual reports submitted by dental amalgam manufacturers and wholesalers and to enforce the bill's prohibition. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses. The assumptions used in calculating the estimates are stated below:

- Although the number of dental amalgam wholesalers and manufacturers in the State is unknown, this estimate assumes there are a sufficient number of regulated entities to justify a new position within MDE.
- MDE needs to hire the environmental compliance specialist on the bill's effective date (June 1, 2014), to be able to receive and review plans submitted by manufacturers and wholesalers by September 30, 2014, and to enforce the bill's prohibition as if October 1, 2014.

Position	1
Salary and Fringe Benefits	\$4,767
Operating Expenses	<u>4,491</u>
Total FY 2015 MDE Expenditures	\$9,258

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses. Once dental amalgam is no longer used in the State, the position could be eliminated. However, it is unclear when that may happen.

Medicaid expenditures may increase at a faster rate under the bill because composite dental filling materials for use in restoration procedures are more expensive than dental amalgam, and the bill may accelerate the transition from dental amalgam to composite materials. However, any increase in Medicaid expenditures is not anticipated to be significant.

Small Business Effect: It is unknown how many dental amalgam manufacturers and wholesalers there are in the State and if any of them are considered small businesses. To the extent the bill accelerates the decrease in the sale and use of dental amalgam in the State, wholesalers and manufacturers are negatively affected and businesses that sell alternative materials are positively affected. In addition, these entities may incur costs to submit the required plans and reports to MDE. Dentists may also be affected to the extent the bill requires changes in their procedures or results in an increase in costs to purchase dental amalgam or its alternatives. However, it is assumed that any increase in costs is passed on to patients in the form of higher prices.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): American Dental Association, U.S. Environmental Protection Agency, U.S. Food and Drug Administration, Maryland Department of the Environment, Department of Health and Mental Hygiene, Department of Legislative Services

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