# Department of Legislative Services

Maryland General Assembly 2009 Session

### FISCAL AND POLICY NOTE

Senate Bill 928 (Senators Conway and Dyson) Education, Health, and Environmental Affairs

## State Board of Dental Examiners - Dentists - Informed Consent - Materials Containing Mercury

This bill requires a dentist to obtain a patient's written informed consent before performing any dental procedure or treatment that includes the use of dental materials containing mercury. The informed consent must contain information regarding mercury vapor and the harmful effects of mercury exposure. The dentist must keep the original written informed consent signed by a patient in the patient's dental chart.

### **Fiscal Summary**

**State Effect:** General and federal fund expenditures increase by \$487,600 (50% general funds, 50% federal funds) in FY 2010 for 90% of the fillings that dentists had been filling with amalgam fillings to become composite fillings. Future years reflect increased enrollment, utilization, and inflation. No effect on revenues.

(in dollars)	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	243,800	341,300	358,400	376,300	395,100
FF Expenditure	243,800	341,300	358,400	376,300	395,100
Net Effect	(\$487,600)	(\$682,600)	(\$716,700)	(\$752,600)	(\$790,200)

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

Local Effect: None.

Small Business Effect: None.

## Analysis

**Current Law:** Dental amalgams are regulated by the U.S. Food and Drug Administration'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.

The Maryland Department of the Environment'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, the U.S. Food and Drug Administration (FDA) posted a consumer notice on its web site stating that "dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses." FDA is in the process of reviewing comments to issue a rule that may classify a dental amalgam as a class II device with special controls. FDA's final rule is expected July 2009.

Only pregnant women and children enrolled in the Medicaid Children's Health Program (MCHP) are eligible for dental services under Medicaid.

**State Effect:** General and federal fund expenditures increase by \$487,580 (50% general funds, 50% federal funds) in fiscal 2010 for 90% of the fillings that dentists had been

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filling with amalgam fillings to become composite fillings, which reflects the October 1, 2009 effective date. This estimate is based on a total of \$14,659,979 spent on fillings in fiscal 2010 increasing to a total of \$15,279,128 under the bill.

DHMH advises that under Medicaid and MCHP, dentists decide what type of restoration is appropriate for a patient's teeth. Given that pregnant women and children are the only populations eligible for Medicaid dental coverage, and that they are groups most at-risk from mercury poisoning from dental amalgam, Legislative Services assumes most patients object to having teeth filled with amalgam fillings once they have been notified of the risk, prompting the dentist to use another, more expensive material to fill teeth. DHMH advises that a composite filling can be as much as \$46 per unit more than an amalgam filling.

Future year expenditures increase by 5% due to increased enrollment, utilization, and inflation.

# **Additional Information**

Prior Introductions: None.

Cross File: None.

**Information Source(s):** Department of Health and Mental Hygiene, American Dental Association, U.S. Food and Drug Administration, Department of Legislative Services

**Fiscal Note History:** First Reader - March 24, 2009 ncs/mcr

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