

Department of Legislative Services  
2011 Session

FISCAL AND POLICY NOTE

Senate Bill 889 (Senator Gladden)  
Education, Health, and Environmental Affairs

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

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This bill requires a dentist to obtain a patient's written informed consent before performing any dental procedure or treatment that includes the *removal* 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. The State Board of Dental Examiners must adopt regulations to implement the bill.

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**Fiscal Summary**

**State Effect:** The State Board of Dental Examiners can adopt and enforce the regulations required under the bill with existing budgeted resources.

**Local Effect:** None.

**Small Business Effect:** None.

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**Analysis**

**Current Law:** Dental amalgams are regulated by the U.S. Food and Drug Administration (FDA)'s Center for Devices and Radiological Health, which 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 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.

**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 are more expensive.

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.” In July 2009, FDA issued a final regulation classifying dental amalgam and its component parts (elemental mercury and a powder alloy) used in dental fillings. The regulation reclassifies the mercury component of dental amalgam from Class I (low risk) to Class II (moderate risk). By classifying a device into Class II, FDA can impose special controls to provide reasonable assurance of the safety and effectiveness of the device. Specifically, FDA recommends that dental amalgam product labeling include:

- a warning against the use of dental amalgam in patients with mercury allergy;
- a warning that dental professionals use adequate ventilation when handling dental amalgam; and
- a statement discussing the scientific evidence on the benefits and risk of dental amalgam, including the risks of inhaled mercury vapor, that will help dentists and patients make informed decisions about the use of dental amalgam.

If a patient’s dental fillings are in good condition and there is no decay beneath the fillings, FDA does not recommend that amalgam fillings be removed or replaced as removal results in unnecessary loss of healthy tooth structure and exposes patients to additional mercury vapor released during the removal process. However, if a patient has an allergy or sensitivity to mercury or any of the other metals in dental amalgam (such as silver, tin, or copper), the patient should discuss treatment options with their dentist.

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### **Additional Information**

**Prior Introductions:** SB 928 of 2009 would have required a dentist to obtain consent prior to conducting *any* dental procedure or treatment that contained mercury. The bill received an unfavorable report from the Senate Education, Health, and Environmental Affairs Committee.

**Cross File:** None.

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

**Fiscal Note History:** First Reader - March 10, 2011  
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