

Department of Legislative Services
Maryland General Assembly
2010 Session

FISCAL AND POLICY NOTE

Revised

Senate Bill 631

(Senator Conway)

Education, Health, and Environmental Affairs

Health and Government Operations

**State Board of Dental Examiners - Dentists - Use of Dental Amalgam, Mercury,
and Amalgam Alloy**

This bill requires a dentist to comply with the U.S. Food and Drug Administration's (FDA) final rule related to the use of dental amalgam, mercury, and amalgam alloy as it relates to a dentist's treatment of the dentist's patients, including a determination of a patient's allergy status.

Fiscal Summary

State Effect: None. The bill does not materially affect State operations or finances.

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law: Dental amalgams are 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.

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, 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.” On July 28, 2009, FDA issued a final rule that reclassified mercury from a class I (least risk) device to 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.

An individual who has an allergy or sensitivity to mercury, or other components of dental amalgam such as silver, copper, or tin, may be adversely affected by dental amalgam, as oral lesions or other contact reactions may also occur.

Additional Comments: Individuals or consumers groups may petition FDA to issue, change, or cancel a regulation, or to take other action. Currently, FDA is reviewing

two petitions regarding the agency's rule on dental amalgam. Both petitions were filed in September 2009 and call for stricter regulations regarding the use of the product. Once FDA reviews both petitions, it will determine whether or not to grant a petition. This evaluation process may take up to one year depending on the rule's complexity. If FDA were to amend or change its rule on dental amalgam, it is possible the rule will be issued a new citation number under the Federal Code of Regulations. If so, the provisions of this bill would no longer have effect due to the specific reference to the current rule.

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): Department of Health and Mental Hygiene, Department of Legislative Services

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