

# STATEMENTS OF POLICY

## Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF DENTISTRY  
[ 49 PA. CODE CH. 33 ]

### Use and Replacement of Dental Amalgams

The State Board of Dentistry (Board) amends § 33.213 (relating to use and replacement of dental amalgams—statement of policy) to read as set forth in Annex A. This statement of policy is intended to provide guidance to Board-regulated practitioners and the general public regarding the use and replacement of dental amalgams.

#### *Effective Date*

This final-form statement of policy will be effective upon publication in the *Pennsylvania Bulletin*.

#### *Background and Purpose*

The Board originally adopted a statement of policy on dental amalgams on January 18, 1965, and amended § 33.213 at 5 Pa.B. 2397 (September 13, 1975) and 25 Pa.B. 2492 (June 24, 1995). The Board again finds it necessary to make minor amendments to § 33.213 to reflect recent information regarding mercury in dental amalgams.

A dental amalgam is a mixture of metals consisting of liquid mercury and a powdered alloy composed of silver, tin and copper. Approximately 50% of dental amalgams are elemental mercury by weight. Mercury is used to bind the alloy particles together into a strong, durable and solid filling. Mercury's unique properties (the only metal that is a liquid at room temperature and that bonds well with the powdered alloy) make it an important component of a dental amalgam that contributes to its durability. Dental amalgam fillings are also known as "silver fillings" because of their silver-like appearance. The advantages of dental amalgam fillings are that they are strong, long-lasting and less likely to break than some other types of fillings. Also, a dental amalgam is the least expensive type of filling material.

A possible disadvantage of dental amalgams is that they contain elemental mercury. An amalgam releases low levels of mercury vapor that may be inhaled. High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys. The United States Food and Drug Administration (FDA) has reviewed the best available scientific evidence to determine whether the low levels of mercury vapor associated with dental amalgam fillings are a cause for concern. Based on this evidence, the FDA considers dental amalgam fillings safe for adults and children 6 years of age and older. The amount of mercury measured in the bodies of people with dental amalgam fillings is well below levels associated with adverse health effects. Even in adults and children 6 years of age and older who have 15 or more amalgam surfaces, mercury exposure due to dental amalgam fillings has been found to be far below the lowest levels associated with harm. Clinical studies in adults and children 6 years of age and older have not found a link between dental amalgam fillings and health problems.

The FDA has recommended that individuals whose fillings are in good condition without decay beneath the filling should not have their amalgam fillings removed or replaced. According to the FDA, removing sound amalgam fillings results in unnecessary loss of healthy tooth structure and exposes patients to additional mercury vapor released during the removal process. Therefore, the Board retains its position expressed in § 33.213(b) that the unnecessary replacement of amalgams may implicate section 4.1(a)(8) and (9) of The Dental Law (act) (63 P. S. § 123.1(a)(8) and (9)) and lead to disciplinary action by the Board.

Some individuals have an allergy or sensitivity to mercury or the other components of dental amalgams (such as silver, copper or tin). Dental amalgams might cause these individuals to develop oral lesions or other contact reactions. The FDA recommends, therefore, that individuals who are allergic to any of the metals in dental amalgams should not get amalgam fillings. Individuals who believe that they have an allergy or sensitivity to mercury or the other metals in dental amalgam should discuss treatment options with their dentist. For this reason, the Board retains § 33.213(c)(1)(i), which provides that dentists should explain to the patient the current status of research on the safety of dental amalgams.

On July 28, 2009, the FDA issued a press release on dental amalgams in which it stated: "The U.S. Food and Drug Administration issued a final regulation classifying dental amalgam and its component parts—elemental mercury and a powder alloy—used in dental fillings. While elemental mercury has been associated with adverse health effects at high exposures, the levels released by amalgam fillings are not high enough to cause harm in patients."

The Board amends § 33.213 to provide updated guidance on dental amalgams to assist and inform dentists so that they may conform their conduct to the requirements of the act, and are aware of the guidelines that the Board will consider in the event a disciplinary action is brought against a dentist for treatment associated with the use or replacement of dental amalgams.

#### *Description of Final-Form Amendments*

The Board amends § 33.213(a) to restate the FDA's determination that "[w]hile elemental mercury has been associated with adverse health effects at high exposures, the levels released by amalgam fillings are not high enough to cause harm in patients." The Board is also amending this subsection to add language addressing the use of alternative restorative materials, as well as the replacement of dental amalgams. The Board is not aware of conclusive evidence that the use of alternative restorative materials or removal of amalgams will prevent, cure or ameliorate disorders other than those associated with confirmed allergic reactions to mercury.

#### *Additional Information*

Persons who require additional information about this statement of policy should submit inquiries to Board Counsel, State Board of Dentistry, P.O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7200, ST-DENTISTRY@pa.gov.

LISA P. DEEM, DMD, JD,  
*Chairperson*

(*Editor's Note:* Title 49 of the *Pennsylvania Code* is amended by amending the statement of policy in § 33.213 to read as set forth in Annex A.)

**Fiscal Note:** 16A-4623. No fiscal impact; (8) recommends adoption.

**Annex A**

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**

**PART I. DEPARTMENT OF STATE**

**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

**CHAPTER 33. STATE BOARD OF DENTISTRY**

**Subchapter C. MINIMUM STANDARDS OF CONDUCT AND PRACTICE**

**§ 33.213. Use and replacement of dental amalgams—statement of policy.**

(a) *Background.* The safety of dental amalgams, specifically, whether the mercury in amalgams causes or contributes to a variety of health problems, has become a recurring issue in dentistry. The Food and Drug Administration has determined that while elemental mercury has been associated with adverse health effects at high exposures, the levels released by amalgam fillings are not high enough to cause harm in patients. The Board is not aware, however, of conclusive evidence that the use of alternative restorative materials or removal of amalgams will prevent, cure or ameliorate disorders other than those associated with confirmed allergic reactions to mercury. Nonetheless, nonallergic patients may request the use of alternative restorative materials or replacement of amalgam restorations in the belief, or merely the hope, that a medical condition will thereby disappear or improve. Dentists receiving these requests must make ethical and professional decisions compatible with the best interests of their patients.

(b) *Purpose.* Section 4.1(a)(8) and (9) of the act (63 P. S. § 123.1(a)(8) and (9)) authorizes the Board to take disciplinary action against licensees who engage in unprofessional conduct or commit acts of negligence, incompetence or malpractice. The replacement of amalgams may implicate both provisions by, for example, generating complaints of unnecessary or even harmful treatment. The Board therefore provides the following guidelines to assist its licensees in conforming their behavior to the requirements of the act. In a disciplinary action brought against a dentist for treatment associated with replacing amalgams, the Board will consider whether these guidelines were followed.

(c) *Guidelines.*

(1) The Board recommends that, before replacing amalgams in a nonallergic patient, the dentist:

(i) Explain to the patient the current status of research on the safety of dental amalgams.

(ii) Provide the patient with information on contraindications and costs associated with removal/replacement of amalgam restorations.

(iii) Advise a patient relying on third-party payment to ascertain whether the insurer will cover removal/replacement procedures.

(iv) Encourage a patient seeking amelioration of a medical condition to consult with a physician and, as appropriate, secure from the physician documentation of recommendations made to the patient.

(v) Memorialize in writing the disclosures made to the patient and the patient's informed consent.

(2) The Board recognizes the right and duty of dentists to refuse to replace amalgam restorations when, in their professional judgment, this procedure would not be in the best interests of the patient.

[Pa.B. Doc. No. 13-1989. Filed for public inspection October 25, 2013, 9:00 a.m.]