

Internal Revenue Service  
CC: PA: LPD: PR (Notice 21010)  
Room 5203  
Post Office Box 7604  
Ben Franklin Station  
Washington, DC 20044

RE: Internal Revenue Notice 2010-89: Request for Comments Regarding the Excise Tax on Medical Devices

The Academy of General Dentistry, the American Academy of Oral and Maxillofacial Pathology, the American Association of Oral and Maxillofacial Surgeons, the American Association of Orthodontists, the American Dental Association, the Dental Trade Alliance and the National Association of Dental Laboratories submit the following comments regarding the excise tax on medical devices.

We urge the Secretary to exercise the authority in Section 4191(b) (2) of Public law 111-152 to determine that the excise tax does not apply to dental devices manufactured by dental laboratories and orthodontic manufacturers.

Devices from dental laboratories, such as crowns, bridges, dentures and other appliances are made and customized and then are delivered directly to the patient by the dentist as part of an overall treatment service. This is also true of orthodontic appliance systems. These devices are designed, fabricated and delivered only for that individual patient's use. We believe that, for purposes of the excise tax exemption, delivery of a device from a dental laboratory by a dentist to the patient should be categorized as a "retail" transaction. These items are not intended for resale.

- While not expressly addressed in the final legislation, during the legislative debate of the Patient Protection and Affordable Care Act (PPACA) some Members of Congress indicated that Class I devices, which include many products, along with Class II devices sold to consumers at retail for less than \$100, should be excluded from the medical device tax. The rationale for exclusion was that these devices were largely considered supplies rather than devices. Class I devices in particular present minimal potential for harm to the user, are simpler in design than Class II or Class III devices and are often used as routine supplies in a dentist's office. Examples include elastic bandages, examination gloves, and paper items. In addition 95% of Class I devices are exempt from regulatory oversight due to their simplicity and routine use. We would ask that these Class I devices that are used as routine supplies by a dental provider be exempted from the tax.
- The congressional debate for inclusion of a medical device tax was largely based on the assumption that near universal coverage and the individual mandate for citizens to carry health insurance would increase the demand for medical devices, thereby offsetting the impact of the device tax. However, dental benefits, except for an undefined oral health benefit for children, are not specifically required as part of the minimum essential coverage which individuals must maintain. So dental device manufacturers and oral health providers would be impacted with absorbing the cost of the tax but may not realize a very significant increase in the number of consumers or patients to offset those costs. According to the Dental Trade Alliance, which represents over 200 manufacturers, distributors and dental laboratories in the United States, the increase in profits for dental manufacturers will amount to an increase of only \$2 million in net profit across the entire industry. The tax on dental devices is estimated to be \$150 million, which is over seventy times the estimated increase in profits for the industry.
- The PPACA added an additional and disproportionate burden on dental providers when it capped the use of pre-tax health care Flexible Spending Account (FSA) dollars to \$2,500. Consumers often use these FSA dollars for health care needs not covered under typical health insurance plans, such as vision and dental care.

- Finally, PPACA specifically exempted eyeglasses and contacts from the medical device tax, but did not exempt any dental devices or provider supplies. We believe this “double taxation” represents an undue burden on dental providers.

If dental devices are not totally excluded from the tax we urge the Secretary to make provisions for those circumstances in which a manufacturer sells devices that are intended to be included in a distinctive kit or tray. These kits are recognized as devices. The tax should not apply to both the components and the final product.

We believe that the Secretary should recognize distinctive pricing issues in the dental market if the tax is found to apply to dental devices. Many manufacturers offer rebates to distributors after a product has been purchased by a consumer. There is an obvious lag time between the sale to the distributor and the rebate. Some provision for reconciliation of rebates should be made. The same applies to other pricing arrangements such as discounts, rebates and bonuses.

We further urge the Secretary to expressly exclude from the excise tax definition of “manufacturer,” “provider,” and “importer” any dentist who has a direct treatment relationship with the patient. We believe that making this point explicit will avoid any unintended consequences that may arise when these terms are defined.

The dental professional and trade organizations listed below appreciate the opportunity to make these comments for consideration regarding Notice 2010-89. We ask for an opportunity to meet with IRS officials to identify certain dental medical devices, outside of those considered supplies and Class I devices, which we believe should be exempted from the tax. Feel free to contact Dr. Frank Kyle at 202-789-5175 or [kylef@ada.org](mailto:kylef@ada.org) if you have questions or to arrange a meeting with dental organization representatives.

Sincerely,

Academy of General Dentistry  
American Academy of Oral and Maxillofacial Pathology  
American Association of Oral and Maxillofacial Surgeons  
American Association of Orthodontists  
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National Association of Dental Laboratories