

Overview of Retail Exemption in Final Device Tax Regulations

AdvaMed Recommendation	Final Rule	IRS Rationale
<p>Facts and circumstances test. Final regulations should make clear to IRS field agents that (1) all facts and circumstances must be viewed <u>in their entirety</u>, (2) the lists in each factor are non-exclusive, (3) manufacturers can provide additional information supporting the position that a product qualifies for the retail exemption, and (4) the fact that a device <u>can</u> be used by a medical professional does not mean that the device necessarily falls outside the retail exemption.</p>	<p>Final rule retains facts and circumstances test but makes clear the factors used to determine whether a device falls within the retail exemption are nonexclusive.</p>	<p>Final Rule: “The facts and circumstances approach requires a balancing of factors enumerated in §48.4191-2(b)(2). No one factor is determinative. Thus, a device may qualify for the retail exemption without meeting all of the positive factors listed under paragraph §48.4191-2(b)(2)(i). Additionally, a device may qualify for the retail exemption even if it meets one or more negative factors under paragraph §48.4191-2(b)(2)(ii).”</p>
<p>“Of a type.” Guidance should explicitly define “of a type” as devices within the same FDA product code.</p>	<p>Does not define a “type” of device to include all devices in the same FDA product code.</p>	<p>Final Rule: “The product code designation is generally too broad to be useful in determining which devices fall within the retail exemption.”</p>
<p>“Regularly available for purchase and use by individual consumers who are not medical professionals”. All of the following should be treated as indicia that a device is primarily intended for use by individuals: (1) routine availability for individuals to purchase over the Internet, by phone, or by mail order; (2) labeling or packaging appropriate for consumers who are not medical professionals; (3) availability for purchase without a prescription.</p>	<p>The Final rule includes internet, phone, and mail order sales as indicia of a retail sale. Labeling and availability without a prescription are not included.</p>	<p>Internet sales: “Under the final regulations, the factor ... provides that consumers who are not medical professionals can purchase the device in person, over the telephone, or over the internet....”</p> <p>Labeling: “Manufacturers may package and label a device in a consumer-friendly manner, even if the device is of a type that is primarily intended for use in a medical institution or office, or by medical professionals.”</p>

<p>Affordability. Treasury should not use a subjective and difficult-to-apply “affordability” factor in the second prong of the retail exemption.</p>	<p>Retains the factor on affordability, but insists each factor is one of several to be considered in determining whether a device falls within the exemption.</p>	<p>Final rule: “Devices used in hospitals, doctors offices and other medical institutions, such as x-ray machines, MRI systems... would likely be prohibitively expensive for an average individual user. Accordingly, the factor that considers cost is meaningful in determining whether a type of device is primarily for use in a medical institution or office or by a medical professional.”</p>
<p>Class III Status. FDA Class III status should not eliminate a product from qualification under the retail exemption.</p>	<p>Retains classification as a Class III device as a factor in determining whether a devices falls within the retail exemption.</p>	<p>Final rule: “The IRS and the Treasury Department, in consultation with FDA, have determined that the vast majority of Class III types of devices are not devices that are of a type generally purchased by the general public at retail for individual use.”</p>
<p>Devices listed in legislative history. All items listed in legislative history should be included in the safe harbor, including: bandages and tipped applicators, pregnancy test kits, denture adhesives, and Class III snake bite kits.</p>	<p>Retains the retail exemption safe harbor included in the Proposed rule without modification, but states all other items will be subject to the facts and circumstances test.</p>	<p>Not directly addressed in the Final rule.</p>
<p>“Capped rentals”. The safe harbor should include “capped rental” devices where title transfers to the user at the end of the rental term.</p>	<p>Does not include capped rentals in the safe harbor, but states they may qualify by an application of the facts and circumstances test.</p>	<p>Final rule: “The IRS and the Treasury Department, in consultation with CMS, have determined that, in most instances, the rental period of a capped rental device terminates before the transfer of title.”</p>