Insight

Immensely Damaging Medical Device Excise Tax Gets Proposed Rule

FEBRUARY 6, 2012

The IRS released the proposed rule for medical device excise tax last Friday. This tax was included as part of the ACA and imposes a 2.3% excise tax on the sale of medical devices to begin in 2013. The language in the rule did not give many specifics as to which devices would be subject to the tax, however, it did list some exemptions: hearing aids, eyeglasses, contact lenses and devices determined by the Secretary of HHS "to be of a type which is generally purchased by the general public at retail for individual use (the retail exemption)." At best, this line in the ACA was ambiguous.

The proposed rule clarifies this by defining "general public" as "non-medical professionals." Rules for defining the retail exemption are murkier. A "non-exclusive list of factors" is used to determine exempt devices, and includes such factors as price, FDA classification and whether a medical professional administers the device.

Does the thought of Secretary Sebelius attempting to determine the taxability of devices, surrounded by piles of papers detailing the intricacies of thousands of medical devices make anyone else chuckle? The tax will simply be a regulatory nightmare for the IRS and HHS.

This tax will apply to medical devices sold in the US, including those that are imported, but does not apply to devices that are manufactured and sold abroad. There is no doubt that the excise tax will place a heavy burden on device companies, costing jobs and slowing innovation. And because the tax does not apply to exported devices, manufacturers have an incentive to focus on EU approval in advance of FDA approval since the European market will be more appealing sans taxation. American patients, therefore, will have to wait longer for treatment options that other countries are already benefitting from.

The US has long been considered the world's leader in providing cutting-edge medical technology, but allowing this tax to exist will bring that era to an end. The medical device excise tax must be repealed immediately.