E-ALERT

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TAX EXEMPTION ALERT

New Licensing Requirements for Medical Device Manufacturers

The Puerto Rico Department of Health has published a draft regulation that would impose a licensing and registration requirement on entities engaged in the manufacture, sale and distribution of medical devices in Puerto Rico. Although for years the Health Department has required manufacturers of pharmaceutical products to register and obtain licenses for such activities, the requirement has not extended to medical devices.

At the end of 2012, the outgoing Secretary of Health issued Administrative Order number 297 ("Order 297") establishing an electronic system for the registration of medicines and medical products. Order 297 mentioned medical devices in a passing, and seemingly unintended, manner but since there was no statute or regulation clearly requiring the registration of manufacturers and distributors of medical devices, the Health Department never attempted to impose the requirement on manufacturers and distributors of medical devices. In fact, in July of 2013 the new Secretary of Health issued a new administrative order authorizing electronic filing of applications for registration of medicines which also repealed Order 297.

In addition to documentary requirements, such as copies of FDA approvals and compliance with federal good manufacturing practices, draft regulation imposes a $250 filing fee for each manufacturing or distribution site and a $25.00 fee for each device registered. The registration and license will be valid for two years and will have to be renewed thereafter.

For updates on this matter, you may contact any of the attorneys of our Tax Exemption Practice Team:

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