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Healthcare Reform Law Imposes New Tax and Other Requirements for Device Manufacturers

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The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), presents a number of new issues for medical device manufacturers. Device manufacturers will need to be aware of the various requirements and programs established by the new law, and monitor implementation efforts by those federal agencies tasked with enforcement and oversight of these new provisions.

- **New Device Tax:** The law includes new tax provisions intended to help fund healthcare reform, which requires device manufacturers to pay a 2.3% excise tax on medical device sales beginning January 1, 2013. The tax applies to medical devices intended for human use, but exempts eyeglasses, contact lenses, and hearing aids, as well as devices that are "generally purchased by the general public for retail or individual use," as determined by the Secretary of the Treasury. Because the excise tax does not include a blanket exemption for Class I devices, the large category of nonretail Class I products, including low-risk hospital and physician office supplies, will be subject to the new tax. Further, while the text of the new law states that the excise tax is applicable to the "sale" of medical devices, device leases also will be considered taxable events under the Internal Revenue Code.

- **Transparency Requirements:** Device manufacturers will need to establish systems and controls to ensure compliance with new transparency provisions, which require reporting of (1) payments and other transfers of value to physicians and teaching hospitals for values of $10 or more (or $100 aggregate in a calendar year), and (2) physician ownership of or investment in the device manufacturer. The statutory language is limited to applicable manufacturers of devices, drugs, biologics, and medical supplies for which "payment is available" from certain designated federal healthcare programs and does not appear to include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format. Additional information on the new transparency requirements is available in our March 29, 2010 LawFlash, "Healthcare Reform Law Delivers New Transparency Requirements for the Health Industry," available at http://www.morganlewis.com/pubs/WashGRPP_FDA-TransparencyRequirements_LF_29mar10.pdf.

- **Comparative Effectiveness:** Device manufacturers should keep abreast of comparative effectiveness research activities initiated under the Healthcare Reform Law and assess whether their products may be impacted. The law creates a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research

priorities; establishing a research project agenda; and contracting with entities to conduct the research in accordance with the agenda. Research findings published by the Institute will be publicly disseminated. However, the law imposes restrictions on the Center for Medicare and Medicaid Services' (CMS's) ability to use such findings to make decisions related to coverage, reimbursement, or incentive programs. Additional information on the new comparative effectiveness will be available in a forthcoming Morgan Lewis LawFlash.

- **Fraud and Abuse:** Device manufacturers also will be affected by Healthcare Reform Law amendments related to fraud and abuse, including amendments to the Anti-Kickback Statute, False Claims Act, healthcare fraud criminal statute, and program integrity provisions. Additional information on these amendments is available in our March 31, 2010 LawFlash, "Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions," available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf.

- **Coverage of Costs for Certain Clinical Trials:** Device manufacturers may be affected by new provisions in the Healthcare Reform Law aimed at encouraging participation in clinical trials. Specifically, the new law prohibits health plans from denying coverage of certain routine patient costs associated with participation in "approved clinical trials," and from discriminating against individuals for participating in clinical trials. Although the term "approved clinical trials" is directed primarily at trials involving pharmaceuticals, the term also may include medical device trials that are (1) for the prevention, detection, or treatment of cancer or other life-threatening disease or condition; and (2) federally funded *or* conducted pursuant to an investigational new drug application (IND) or exemption (e.g., for drug-device combination products).

- **Women's Health:** Manufacturers of medical devices affecting women's health likely will soon become familiar with the Food and Drug Administration's (FDA's) new Office of Women's Health Issues created by the Healthcare Reform Law and established within the FDA Commissioner's Office. This new office is tasked with reporting to the Commissioner information related to women's participation in clinical trials, establishing FDA goals and objectives for issues concerning women's health, providing information to women and healthcare providers on those areas in which differences between men and women exist, and consulting with stakeholders on women's health policies. Based on its placement within the FDA Commissioner's Office, the creation of this office may result in an increased focus by FDA on therapies targeted to women. In addition to the new FDA office, the Healthcare Reform Law also creates a new women's health office within the Office of the Secretary for the Department of Health and Human Services (HHS) and within several other HHS agencies (including the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the Centers for Disease Control and Prevention).

- **Medicare Payment Issues:** Certain device manufacturers also may be affected by Medicare payment changes. Specifically, changes to the imaging equipment utilization rate assumption will reduce the reimbursement rate for imaging centers with lower utilization rates. Additionally, the new law increases the discount applied for multiple imaging scans on contiguous body parts, which will impact users of X-ray, ultrasound, PET, MRI, CT, and fluoroscopy devices.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **M. Elizabeth Bierman** (202.739.5206;

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