BOSTON MEDTECH ADVISORS

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March 2024 Newsletter

Industry News

Reduced Medical Device User Fee for Small Businesses. FDA recently updated its guidance for small businesses seeking reduced medical device user fees. The draft guidance update focuses on a new waiver for establishment registration fees, available to qualified small businesses (defined as those with annual gross receipts or sales of $1 million or less) starting in 2025. To qualify, businesses will need to submit a new form to FDA for evaluation, demonstrating financial hardship. By understanding these proposed changes, eligible small businesses can potentially save money on fees starting next year. BMTA can help determine if a business qualifies and assist with submitting the new form.

Fraudulent Laboratory Testing Data in Premarket Submissions. On February 20, 2024, FDA issued a letter to industry urging medical device manufacturers to independently verify performance testing conducted by 'third-party test labs' before submitting data to FDA. Data integrity has been called into question following an increasing number of submissions with fraudulent and unreliable laboratory testing data (e.g., biocompatibility) which deemed these submissions 'not substantially equivalent' (NSE). FDA, through its Bioresearch Monitoring Program, identifies and confronts data integrity violations through on-site inspections, data audits, and remote regulatory assessments. To learn more about maintaining the data integrity of laboratory testing data for premarket submissions contact BMTA.

Remote Monitoring Coding Changes Shelved. During its February 2024 meeting, the American Medical Association's CPT Editorial Panel was set to review proposed changes to CPT codes for remote physiologic monitoring

Recent Presentation

Zvi Ladin, one of our Principals at BMTA, recently presented **"2024 Regulatory Update - CDRH Trends and Key Developments"** to the Life Sciences Collaborative – Boston Chapter.

Click here to view his detailed presentation slides on our website

Zvi Ladin, Principal
Ph.D., Medical Engineering, MIT-Harvard Medical School Division of Health Science and Technology, MA.

Over 35 years of experience in the medical industry, government and academia, focusing on developing and managing clinical, regulatory affairs and reimbursement initiatives. A co-founder of BMTA, focusing on establishing regulatory strategies for therapeutic and diagnostic technologies, submission of regulatory applications, including 510(k) and PMAs for products in Class I-III and drug-device combination products and representing companies in negotiations with the FDA and other regulatory agencies. Zvi taught mechanical and biomedical engineering at MIT and Boston University and served as a scientific advisor to the FDA.

New BMTA Blog

2024 Update to Cybersecurity Guidance

FDA has recently published draft

(RPM) and remote therapeutic monitoring (RTM) services. However, the revisions were once again pulled from the agenda, as had occurred in the AMA's CPT hearings in September 2022. The proposed changes aimed at simplifying the codes for RPM and RTM services, reducing the required period of reviewed data by the physicians, and broadening the covered clinical applications. With the growing number of digital technologies enabling remote monitoring and therapeutic services, BMTA continues to monitor all relevant updates and advise companies as to how such changes could affect their marketing and reimbursement plans. To learn more about BMTA's **reimbursement strategies** or to further discuss the implications of changes to RPM and RTM codes, contact **BMTA**.

updates to its 2023 cybersecurity guidance for medical devices, clarifying the information that device manufacturers should submit to FDA (under the Food and Drug Omnibus Reform Act of 2022 (FDORA). As cybersecurity constitutes an integral component of FDA's determinations of medical devices' safety and effectiveness, understanding these requirements is important for all manufacturers of devices containing cyber components. For more information about the cybersecurity guidance as well as the recent update see **BMTA Blog**.

About Boston MedTech Advisors

Since 2004, BMTA's multidisciplinary team of highly experienced consultants has supported more than 400 medical technologies and life sciences companies around the world to achieve their business goals. BMTA offers valuable, ethical, result-oriented, professional, and cost-effective insights that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.

- Market Analysis and Business Strategy
- Business Development
- Regulatory Affairs and Clinical Trial Management
- Reimbursement and Contracting Strategies
- Financing Support
- Other Services

Boston MedTech Advisors provides practical business services to:

- Established and growing medical technology companies
- Healthcare providers

More Industry News

Massachusetts Life Sciences Initiatives. Governor Healey has unveiled plans to bolster Massachusetts as a **global leader in life sciences and applied AI**. Through reauthorization of the **Life Sciences Initiative,** the Mass Leads Act will add $1 billion, over 10 years, to promote collaborations across the biotechnology and medical technology industries, create new jobs, pursue health equity ventures, and support eligible capital projects . Among other allocations, $100 million will be allocated to the creation of an Applied AI Hub in Massachusetts. **BMTA** can help companies interested in exploring opportunities to participate in any of these initiatives.

New CPT Codes for Sleep Studies. The American Academy of Sleep Medicine (AASM) has proposed a major update of the CPT codes for ambulatory / at-home sleep studies. The new codes are intended to accommodate new technologies introduced in recent years by providing appropriate codes for sleep studies monitoring a greater number of physiological parameters and sleep studies intended to diagnose conditions beyond sleep apnea. Since leading the efforts to establish new codes and coverage for unattended sleep studies, BMTA has supported companies developing and commercializing technologies and services intended to diagnose and treat sleep disorders. Companies providing sleep technologies or planning to introduce new devices in the next few years may contact **BMTA** to explore the implications of the proposed CPT codes on their marketing strategies.

FDA Proposed Ban on Electrical Stimulation Devices. The Food and Drug Omnibus Reform Act of 2022

- Startups and entrepreneurs
- Private and institutional investors

(FDORA) expanded the FDA's authority to ban specific intended uses of medical devices. While this power is seldom used, the FDA recently exercised this broader authority granted by FDORA by **proposing a ban** on electrical stimulation devices intended for self-injurious or aggressive behavior, citing concerns about unreasonable health risks associated with these devices. If finalized, the rule would remove electric shock devices from the market and make their marketing illegal in the United States. The proposal is open for public comments until May 28. For more information on this or future proposed device bans, please contact **BMTA**.

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