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Recent Developments to Impact the Medical Device Industry in 2024

Boston MedTech Advisors is keeping abreast of significant developments impacting the life sciences industry. Among the numerous initiatives undertaken by the various agencies and healthcare organizations, we have selected several guidelines and programs, published during 2023 by CMS, AMA, and FDA, that medical device manufacturers should keep in mind in 2024:

[See **Boston Medtech Advisors blog** for more information on specific bullets highlighted below].

Reimbursement

- For the first time enrollment in Medicare Advantage plans surpassed that of traditional Medicare with 51% of the eligible Medicare beneficiaries now enrolled in one of the Medicare Advantage plans offered by commercial payers.
- CMS proposed the Transitional Coverage for Emerging Technologies (TCET) pathway, enabling manufacturers to pursue early coverage for new devices designated by the FDA as a Breakthrough Device. [See BMTA blog].
- AMA is addressing the growing number of new digital technologies. Among the initiatives taken by the AMA: developing resources to accelerate adoption of digital health innovations, identifying issues and solutions for coding, payment and coverage through the Digital Medicine Payment Advisory Group, and providing briefs on pertinent topics.

Regulatory

FDA published draft guidance documents intended to strengthen and modernize the 510(k) program:

- "**Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission**" (September 2023) outlines choosing predicate devices that were cleared using well-established methods, that meet or exceed expected predicate safety and performance, and that do not include use/design related safety issues or recalls [See BMTA blog].
- "**Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions**" (September 2023) clarifies when clinical data may

be necessary to demonstrate substantial equivalence in support of 510(k) submissions [See BMTA blog].

- **"Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices"** (December 2023) expands and clarifies the previous guidance to aid sponsors in determining whether they can use real-world data to provide supportive evidence in pre-market submissions [See BMTA blog].

FDA announced a proposed rule for Laboratory Developed Tests (LDTs):

- **"Medical Devices; Laboratory Developed Tests"** (October 2023) intended to expand the definition of IVDs to include devices manufactured by a laboratory and phase out, over a period of four years, the general enforcement discretion approach to these devices, to increase oversight of LDTs [See BMTA blog].

FDA published updated guidance documents:

- **"Breakthrough Devices Program. Guidance for Industry and Food and Drug Administration Staff"** (September 2023), expanding the criteria for Breakthrough Devices to include products aiming to eliminate disparities in healthcare, treat rare diseases, or offer non-addictive treatments for pain or addiction. The guidance also adds a new "totality of information" test in deciding whether a device provides a "more effective" treatment or diagnosis [See BMTA blog].
- "**Content of Premarket Submissions for Device Software Functions"** (June 2023) updates FDA's thinking related to the risk-based approach to the documentation sponsors should include for the review of device software functions in premarket submissions. Among the many changes from the previous guidance is the revision from three software levels of concern (Minor, Moderate and Major) to a more simplified documentation level (Basic and Enhanced).
- **"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"** (September 2023) updates the approach to device cybersecurity considering the rapidly evolving cyberthreats. The guidance highlights the importance of an iterative approach throughout the product lifecycle [See BMTA blog].
- **"Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"** (September 2023) represents FDA's current thoughts on the use of ISO 10993-1 in the evaluation of the biological safety of medical devices. The changes from the previous guidance may reduce the burden of required documentation when submitting a premarket application [See BMTA blog].
- **"Digital Health Technologies for Remote Data Acquisition in Clinical Investigations"** (December 2023) outlines recommendations for use of digital health technologies in clinical investigations evaluating new medical products [See BMTA blog].

Boston MedTech Advisors can assist manufacturers of medical technologies and their investors to address relevant issues associated with the current initiatives of the FDA and CMS, such as:

- Can your product meet the criteria for a Breakthrough device?
- When to start discussions with CMS regarding coverage?
- What is the optimal strategy for developing coverage for a new product following FDA approval?
- How can Breakthrough Designation by the FDA and CMS TCET programs affect the company's go-to-market plans?

- How to develop the appropriate clinical evidence to meet CMS criteria for TCET, CED, and other coverage criteria?

If you know others who may benefit from our Mailing List, they can sign up here.

About Boston MedTech Advisors

Boston MedTech Advisors assists medical technology companies and healthcare providers to achieve their business goals by offering ethical, result-oriented, professional and cost effective advice and services.

- 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
- Startups and entrepreneurs
- Private and institutional investors

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