BOSTON MEDTECH ADVISORS

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# July 2024 Newsletter

## Industry News

### CMS Proposes New HCPCS Codes for Behavioral Health Digital Therapeutics

Payments for digital therapeutics have been a challenge for developers of medical technologies that rely primarily on, and which do not fit, traditional reimbursement methodologies. In its proposed rule for the 2025 physician fee schedule, CMS proposes to pay for FDA-approved digital mental health treatments (DMHT) used in conjunction with ongoing behavioral treatment. CMS has proposed three new HCPCS codes, modeled on coding for Remote Therapeutic Monitoring (RTM) services:

- GMBT1 - Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan.
- GMBT2 - First 20 minutes of monthly treatment management services, directly related to the patient's therapeutic use of the DMHT device that augments a behavioral therapy plan; physician or other qualified health care professional time reviewing data generated from the DMHT device, from patient observations, and patient specific inputs in a calendar month, requiring at least one interactive communication with the patient/caregiver during the calendar month.
- GMBT3 – Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the DMHT device.

BMTA supports developers of digital technologies to determine optimal reimbursement strategies for their products and services, including planning for required new codes and favorable coverage policies.

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### FDA is Expanding the Total Product Life Cycle Program

Launched in 2022, the FDA's Total Product Life Cycle Advisory Program (TAP) helps speed the development of innovative medical devices considered critical to public health. TAP fosters communication between device developers, the FDA, and external parties for insights on adoption and reimbursement. TAP is a voluntary program, intended for FDA Breakthrough Designated Devices, and is currently accepting requests for cardiovascular, neurological, and physical medicine devices, with radiological and ophthalmic devices added in October 2024 and orthopedic devices in

January 2025.

The BMTA regulatory team assists developers of medical devices to apply for 'breakthrough' designation and for the TAP, and will be glad to further discuss these programs with manufacturers of innovative technologies.

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### House Committee Requests to Suspend Implementation of the New LDT Rule

The House Appropriations Committee requested the FDA to suspend implementation of its final rule on laboratory-developed tests (LDTs), raising the concerns that the new regulations could reduce patients' access to critical tests. The LDT final rule aims to replace the longstanding enforcement discretion approach with stricter classification of the lab tests as IVDs.

BMTA monitors closely the status of the proposed regulations in order to best advise manufacturers as to the best way to market their tests.

## 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
- Startups and entrepreneurs

### FDA Intensifies Efforts to Address Medical Device Misinformation

The spread of medical misinformation online poses significant health risks, leading the FDA to intensify its efforts to combat this public health challenge. Following the launch in 2022 of the Rumor Control web site, the FDA has recently published a new draft guidance "Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers," helping medical device companies to effectively address misinformation about their products.

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### FDA Assesses AI Generated Data

For companies developing AI-based devices, obtaining real-world data (RWD) about enough patients with specific conditions can be a long and expensive process, coupled with concerns about protecting patients' privacy. The FDA is exploring the use of synthetic data, artificially generated information, mimicking RWD to supplement patients' medical records, leading to more accurate diagnoses, personalized treatments, and improved patient outcomes.

BMTA is well versed on collection of RWD using methods that comply with regulations and preserve privacy, which can assist manufacturers addressing these challenges when designing and

- Private and institutional investors

executing their clinical trials.

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