BOSTON MEDTECH ADVISORS

More Experience ▸ Better Results

June 2024 Newsletter

Industry News

Home as a Health Care Hub

FDA recently announced a new program "Home as a Health Care Hub", which supports home care devices that show potential to improve outcomes, enhance patient satisfaction and reduce costs. The program will initially focus on helping people with chronic conditions, especially in rural settings and other underserved populations.

BMTA has gained considerable experience helping companies to obtain regulatory approvals and develop commercialization and reimbursement strategies for medical devices intended to support care of patients in the home setting.

Women's Health Research Roadmap

Women have historically been underrepresented in clinical trials, creating gaps in understanding how women respond to new therapies. A systematic review of trials published from 2016-2022 found that only 33% of study subjects were women. Among the proposed solutions - enrollment of women equivalent to their share in the population with the relevant disease and planning a sample size that could detect gender differences.

The FDA Office of Women's Health published the Women's Health Research Roadmap which outlines areas where

New BMTA Blogs

MEDCAC Clinical Evidence Review: Impact on New Medical Devices.

Discover how the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Clinical Evidence Review impacts coverage of new medical devices by Medicare. The Blog summarizes the MEDCAC review process, which significantly influences device go-to-market and reimbursement plans.

Reimbursement Q&A: Medical Device Coding and Coverage

Understanding coding and coverage options are essential to developing an optimal reimbursement strategy for a new medical technology. How is a medical device assigned a billing code? What are ICD-10 codes, and why are they relevant to medical device coverage? These questions and others reviewed on the medical device reimbursement blog address some the pertinent issues. To further explore optional strategies, contact info@bmtadvisors.com.

additional research is needed to better understand the performance of medical devices in women.

BMTA CRO Group assists developers of medical devices to properly design and manage clinical trials that address FDA requirements, including the understanding of genders' response to novel procedures and technologies.

Medicare continues to lead the transition to value-based alternative payment models (APM):

According to the recent APM Measurement Report, in 2022 only 16% of payments made by Medicare were traditional 'fee-for-service', While 42% of payments were fee-for-service linked to quality and value (including 'pay-for-reporting' and 'pay for performance'), 32% of payments structured as 'bundled' or shared savings, and 10% population-based payments.

BMTA helps companies understand how the shift towards value-based reimbursement may impact their pricing and reimbursement strategy.

Laboratory Developed Tests (LDTs) final rule.

FDA unveiled its final rule aimed at increasing oversight of LDTs. This decision stems from concerns about the potential for inaccurate or misleading test results, potentially harming patients. The new rule clarifies that LDTs fall under the same regulatory framework as other in vitro diagnostic products (IVDs), subjecting them to stricter quality and safety standards. FDA's general enforcement discretion approach for LDTs will phase out over a period of four years and will be fully implemented by May 6, 2028. See BMTA Blog for more detail.

The New England - Israel Business Council (NEIBC) is hosting a live webinar on Tuesday, July 9, 2024 at 11:00am ET:

Unlocking the Future Value and Impact of Neurotechnology in Healthcare

RSVP for this informative webinar

Click here to listen to NEIBC's past webinars, including recordings of BMTA's Principals: David Barone and Zvi Ladin

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

More Industry News

Emergency Use Authorization (EUA):

FDA issued two new draft guidances on enforcement policies for tests during a public health emergency (such as the COVID pandemic) and for in vitro diagnostic devices for immediate public health

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
- Private and institutional investors

response in the absence of a declared public health emergency. FDA describes the considerations for issuing an EUA to allow the use of unapproved tests to increase access to testing during emergencies, including the risks of the disease, the availability of other tests, and the accuracy of the unapproved tests. Specific requirements for these tests are outlined in their draft guidance documents.

Private Equity investment in healthcare impacts purchasing decisions:

According to a recent article in the Wall Street Journal, the number of physician offices sold to hospitals or to corporate entities (most often owned by private equity funds) has exceeded 73%, an increase from 62% only 5 years ago. The primary reasons for physician-owned practices selling to a corporate entity are the ever-increasing regulations burden and the difficulty for small entities to deal with insurers. This consolidation is just one element of the rapidly changing healthcare landscape in the U.S. leading to diminished competition, with hospital systems continuing merging smaller hospitals and health insurance companies integrating vertically. These changes affect patients and physicians and require manufacturers of medical devices to assess their marketing strategies, as decisions about purchasing and utilization are now influenced by other parties, in addition to the users of the technology.

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

To learn more about our organization and services
please visit our website at
www.bmtadvisors.com and www.bmtCROgroup.com.
You can also contact us by phone at 781-407-0900, or email
info@bmtadvisors.com

Boston | Germany | Israel