

May 2023 Newsletter

Recent Webinar by David Barone

A recent webinar "[Introduction to the U.S. Healthcare System, the Largest and Most Complex Market](#)" provided by David Barone, Principal of BMTA, was attended by approximately 50 U.S. and offshore companies.

In addition to providing an overview of the healthcare system, the webinar highlighted the strategic benefits of identifying early the optimal market segment targeted for initial commercialization of new technologies.

Boston MedTech Advisors Welcomes a New Member

[Mythili Tummalapalli, Senior Consultant:](#)

Bachelors and Masters in Polymer Engineering, PhD in Medical Device Design from IIT Delhi, India, and MBA in Health Sector Management from Boston University. Mythili's prior experiences include science communications, consulting, and business development. Her current activities include market research, reimbursement support, commercial strategy, and regulatory strategy development.

[The Massachusetts Next Generation Initiative](#) (MassNextGen) is now supporting women and diverse entrepreneurs within the Commonwealth of Massachusetts. Ten awardees will receive up to \$100,000 in non-dilutive funding along with access to executive coaching.



Join the [New England Israel Business Council \(NEIBC\)](#) for two upcoming webinars offered by the Principals of BMTA:

US Regulatory Affairs, Best Practices

Speaker: Zvi Ladin, Ph.D.

When: Tuesday, May 16, 2023 @ 10:00am ET

[RSVP](#)

Early Reimbursement Strategy, a Driver of Valuation

Speaker: David Barone

When: Tuesday, June 6, 2023 @ 10:00am ET



[RSVP](#)

Industry News

With growing adoption of remote patient monitoring (RPM), manufacturers of electronic health record (EHR) systems, such as Epic, Oracle, Cerner, and Meditech [have begun to incorporate RPM tools](#) into their systems, allowing healthcare providers to track patients' vital signs remotely. Adoption of RPM is accelerated as growing evidence reports improved outcomes in multiple specialties. Most EHR systems do not yet include native remote monitoring capabilities, providing opportunities for other manufacturers to integrate their devices and gain competitive advantages. [BMTA](#) has supported many companies in analyzing opportunities for RPM technologies, including market assessment, regulatory strategy, reimbursement opportunities, and more.

The FDA's [Payor Communication Task Force](#) can help reduce the time between FDA clearance and payors' coverage determinations by obtaining early feedback from payors as to collect clinical evidence to support positive coverage determinations. With this opportunity, medical device sponsors can plan clinical trials, with the help of [BMTA](#), to simultaneously address both FDA and payors' expectations.

Is the LDT (lab developed tests) for IVCT (in vitro clinical tests) regulatory loophole going to be closed? [The VALID \(Verifying Accurate, Leading-edge IVCT Development\) Act](#) has been reintroduced by the Congress. The bill seeks to create a new regulatory framework for in vitro diagnostics, separate from medical devices. Supporters of the bill believe that it will encourage innovation in the development of IVCTs, and ensure their safety and effectiveness, while opponents believe it could limit access to new tests. Evolving regulations within the medical device industry are monitored closely at [BMTA](#) to help its clients strategize proactively.

The Department of Health and Human Services (HHS) is planning for the **COVID-19 public health emergency (PHE)**, to [expire today: May 11, 2023](#). [FDA published a notice](#) addressing the Agency's COVID-19-related guidance documents, including which guidance documents will no longer be in effect after the expiration of the PHE, and which guidance documents FDA is revising to temporarily continue in effect. Examples of devices that might be affected include:

- Remote Digital Pathology Devices.
- Non-Invasive Fetal and Maternal Monitoring Devices.
- Digital Health Devices for Treating Psychiatric Disorders.
- Remote Ophthalmic Assessment and Monitoring Devices.
- Ventilators and Accessories and Other Respiratory Devices.

[FDA developed the Transition Plan for Medical Devices Issued EUAs Related to COVID-19](#) to, among other things, help avoid disruption in device supply and help facilitate compliance with applicable FD&C Act requirements after the termination of the relevant device EUA declaration related to COVID-19. FDA recognizes that it will take time for manufacturers, health care facilities, providers, etc. to transition from

Emergency Use Authorizations (EUA) devices and the policies that support them.

The [Medical Group Management Association \(MGMA\) has shared a timeline](#) to help explain the details of telehealth ending as an accepted benefit with the expiration of the PHE.

Ending on:

May 11, 2023:

- Cross-state licensure.
- Allowance of Non-HIPAA compliant platforms (if they were not public facing).

December 31, 2023:

- Reimbursement of qualifying telehealth visits at the in-person rate.

December 31, 2024:

- Federally Qualified Health Centers and Rural Health Clinics qualifying as distant site providers for nonbehavioral and mental health. FQHCs and RHCs can still serve as distant site providers for behavioral and mental health.
- Audio-only services (mental and behavioral health services will remain permanent).
- Extension of telehealth providers to include physical therapists, occupational therapists, and speech-language pathology therapists.

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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