AdvaMedDx Priorities ▶ 2021

AdvaMedDx, a division of the Advanced Medical Technology Association (AdvaMed), represents manufacturers of innovative *in vitro* diagnostic (IVD) tests in the U.S. and abroad that are leveraged each day by clinicians across health care settings – including those that are front-line tools in the fight against COVID-19. Diagnostic tests influence seventy percent of all health care decisions[1], including by enabling early detection of disease, determination of the most appropriate clinical pathway for patient care, monitoring treatment and as fundamental support for the cutting-edge practice of precision or personalized medicine.

COVID-19 Response

In 2020, the IVD industry rapidly mobilized to develop and radically scale-up manufacturing to meet the unprecedented demand for quality COVID-19 diagnostics and other critical tests. AdvaMed and AdvaMedDx have prioritized supporting MedTech's mobilization to the pandemic to protect patients and public health through the development of and advocacy on a wide range of policy matters both administrative and legislative to foster innovation, expand access to testing and to bolster testing infrastructure and capability for future pandemic preparedness.

Further, AdvaMed and AdvaMedDx have also proactively established key initiatives including:

- The MedDeviceNetwork platform: Designed to connect medical device and diagnostics companies with component suppliers to help quickly boost production and distribution of vital technologies and to reinforce complex supply chain needs; and
- The AdvaMed COVID-19 Testing Supply Registry: The Registry provides real-time, actionable data on COVID-19 testing supplies shipped to laboratories nationwide – delivered via weekly reports to federal and state policy makers in their pandemic responses. The Registry includes participation from fourteen leading diagnostics manufacturers whose tests together comprise ~90% of the COVID-19 tests on the market in the U.S.

AdvaMedDx's broad agenda for 2021, that include several critical COVID-19 testing priorities, spans Payment and Coverage, Regulatory Affairs (FDA matters), and Global matters. The agenda will be updated to reflect industry priorities in a changing environment.

Regulation: Promoting Modernized Regulatory Oversight of Diagnostics

AdvaMedDx supports policies to advance predictable and risk-based regulatory pathways and policies that recognize advancing science and innovation are essential to ensuring patients and providers have timely access to new, quality clinical diagnostic tests and technologies. In 2021, AdvaMedDx will strive to:

- **Advance Legislation to Establish a Diagnostic-Specific, Risk-Based Approach for All Diagnostic Tests (Tier I):** In early 2020, bi-partisan, diagnostics regulatory reform legislation, the Verifying Accurate Leading-edge IVCT Development (VALID) Act was introduced in the House and Senate. AdvaMedDx seeks the reintroduction of an improved VALID Act early in 2021. Diagnostics regulatory reform would provide clarity to regulatory oversight of all *in vitro* clinical diagnostics tests – both the IVD tests manufactured by AdvaMedDx members for the commercial market that are currently regulated by the Food and Drug Administration (FDA) as medical devices and not specifically as diagnostics, as well as diagnostics tests developed by laboratories, including hospital laboratories, known as Laboratory Developed Tests (LDTs), which, under current HHS interpretation, are not subject to FDA premarket review absent notice-and-comment rule making. Establishment of a single, predictable regulatory framework tailored to all clinical diagnostics tests would include modernized regulatory pathways and policies to foster innovation in diagnostics development to speed patient and clinician access to the latest diagnostics. In partnership with our laboratory and patient organization partners, we will continue our work to improve and expedite the advancement of the VALID Act through the legislative process in 2021.

- **Streamline the Development and Availability of Emergency Diagnostics, Today and for Future Emergencies (Tier I):** Drawing from lessons learned during the COVID-19 response, AdvaMedDx is working to advance proposals to support the development of emergency diagnostics by streamlining access to viral samples for test development, permitting the use of real world data collected during the emergency for product advancement, and clarifying CLIA-waiver status for emergency diagnostics. (CLIA refers to the Clinical Laboratory Improvement Amendments of 1988 that regulates laboratory operations.)

- **Encourage Effective MDUFA IV Implementation (Tier I):** As part of the Medical Device User Fee Amendments (MDUFA) IV agreement, the FDA is required to implement changes to improve total time to decision, enhance agency reporting requirements, and increase the consistency and timeliness of the review and marketing authorization process. The FDA is experiencing tremendous workload due to COVID, placing strain on FDA resources. AdvaMed and AdvaMedDx closely monitor key metrics and regularly engage with the FDA to improve the efficiency and predictability of the agency's review processes.

- **Engage in Negotiations for MDUFA V Reauthorization (Tier I):** AdvaMed and AdvaMedDx, along with member companies, have been preparing for the launch of formal negotiations in early 2021 for MDFUA V, which will be in place fiscal years 2023 through 2027.

- **Reduce Regulatory Hurdles for CLIA-Waived and Point-of-Care Tests (Tier II):** Tests that can be performed near the patient (*i.e.*, at the patient's bedside in the hospital) are often referred to as point-of-care (POC) tests. Some POC tests are also CLIA-waived, meaning they are simple tests with a low risk for an incorrect result and can be performed outside of the central laboratory, including in physician offices, clinic, or even the patient's home.

  Building on progress made in 2020 with the finalization of favorable CLIA-waiver guidances to reduce barriers to the introduction of innovative CLIA-waived /POC tests, AdvaMedDx is working to ensure appropriate implementation of FDA final policy guidances, reflective of AdvaMedDx recommendations to improve CLIA-waiver and dual submission processes. (The dual submission process is a somewhat streamlined process under which FDA reviews both the 510(k) submission and whether the diagnostic is appropriate for CLIA-waiver). Additionally, the association is developing proposals to pursue risk-based review policies for new or modified POC tests.

- **Improve Policies to Advance Modern Instrument Technologies and Streamline Modifications to Cleared Diagnostics (Tier II):** AdvaMedDx seeks the finalization of an improved FDA draft policy to help IVD manufacturers modernize instruments by providing a more direct and predictable regulatory pathway. Instruments are the underlying tools laboratories use to run diagnostic tests. Further, AdvaMedDx seeks to secure consistent implementation of broad-based change control protocols – permitting FDA and the manufacturer to agree in advance that certain modifications to an FDA-cleared diagnostic would not require a new FDA submission. Current use by FDA of these "FDA-accepted change control protocols" has been on an ad hoc basis. Standardizing and expanding FDA-accepted change control protocols would support innovation and patient access to new technology.

Coverage & Payment: Improving Access to Innovative Diagnostics

AdvaMedDx strives to improve coding, coverage, and payment policies reflective of the value of diagnostics to improve patient access to innovative IVD tests and technologies, along with renewed investment and innovation in the field of diagnostics.

In both 2019 and 2020, Congress made modifications to ongoing implementation of the Protecting Access to Medicare Act of 2014 (PAMA) that include delays in data reporting periods to provide more time to hospitals to provide payment data to the Centers for Medicare and Medicaid Services, forestalling of previously scheduled reductions in Medicare Clinical Laboratory Fee Schedule rates for 2021, and the pushing back of additional cuts to 2022-2024 (capped at 15%).

In 2021, AdvaMedDx will, in collaboration with our laboratory partners:

- **Seek Improvements to Medicare Reimbursement (Tier I):** AdvaMedDx will leverage the period of delay to explore ways to improve present day payment rate-setting methods under PAMA that reflect consideration of important factors to ensure transparency, replicability, and coherency of resulting payment amounts. AdvaMedDx will also seek to address coding issues can result in negative or unintended consequences on payment for diagnostic laboratory testing. In collaboration with laboratory stakeholders,

AdvaMedDx will work to ensure clear communications with CMS regarding coding, data collection and payment amounts for diagnostics.

- **Urge Policy Makers to Enable Use of All Types of COVID-19 Tests (Tier I)**: AdvaMedDx encourages policy makers to maximize patient access to all types of diagnostic testing – including molecular, antigen, and serology/antibody testing – across laboratory and point-of-care settings to support patient and public health, including through broadening sample collection sites and use of point-of-care testing in non-traditional settings, as well as high-performing at-home testing. The association advocates for Congress to authorize and fund large-scale testing, including serology testing surveys to generate robust, real-time information about COVID-19 and its transmission.

- **Pursue Broad Coverage and Payment for COVID-19 Testing (Tier I):** The association pursues policies to broaden patient access to COVID-19 testing through improvements in coding, coverage, and payment for the full range of COVID-19 tests (molecular, serology/antibody, antigen, etc.), testing when samples are pooled, parallel and serial testing, and increased funding for COVID-19-related testing.

- **Improve Coverage and Payment for "Breakthrough" Diagnostics Tests and Technologies (Tier II):** AdvaMedDx supports opportunities to demonstrate value of modernization of Medicare coverage for preventive services (*e.g.*, screening tests) and improvements in coverage and payment for breakthrough and other innovative diagnostic products. The association urges appropriate coding, coverage and reimbursement for diagnostic tests designated as breakthrough technologies by the FDA, recognizing the value these tests bring to patients.

- **Combat Antimicrobial Resistance Through Diagnostic Stewardship (Tier II):** AdvaMedDx focuses on advancing diagnostic stewardship – the robust and appropriate use of diagnostics tools and tests, including in the inpatient setting by leveraging the expertise of the laboratory – to strengthen antimicrobial stewardship programs (ASPs). Specifically, we aim to leverage and promote our association's diagnostic stewardship recommendations as a key component of our advocacy with the Centers for Disease Control and Prevention (CDC), Congress, and other stakeholders.

Global: Promoting the Value of Medical Technologies Abroad

AdvaMed's global policy priorities are centered around the pursuit of fair market access and the implementation of appropriate regulatory, reimbursement, and trade practices for medical technologies in key markets including China, Japan, Europe, and emerging markets in Asia and Latin America. AdvaMed and AdvaMedDx policy focus includes promotion of free-trade policies, preventing the adoption of cost containment mechanisms that are inconsistent with recognized principles such as transparency, and advocating for improved international regulatory processes, among others.

Together with numerous medical technology and diagnostics associations around the globe, AdvaMed leads the Global MedTech Alliance (GMTA) and the Global Diagnostics Alliance working group (GDA). GMTA is a non-governmental organization (NGO) advancing patient access to safe, quality medical technologies and diagnostics.

In 2021, AdvaMed and AdvaMedDx will continue to serve as part of the Industry Advisory Group of the Access to COVID-19 Tools (ACT) Accelerator – a global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

Additionally, in partnership with GMTA and GDA members, AdvaMed and AdvaMedDx seek to smooth implementation of Europe's *In Vitro* Diagnostics Regulation, advance policies at the World Health Organization (WHO) including through the Essential Diagnostics List (EDL), Prequalification for Diagnostics Program, and the Pandemic Influenza Preparedness (PIP) Framework that support innovation and broaden access to quality diagnostic testing.

ENDNOTES

[1] Rohr U-P, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, et al. (2016) The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. PLoS ONE 11(3): e0149856. https://doi.org/10.1371/journal.pone.0149