2022 AdvaMedDx Priorities

Approved by the AdvaMedDx Board of Directors on September 21st, 2021

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AdvaMedDx's Agenda Supplements AdvaMed's Agenda

- AdvaMedDx's 2022 agenda, developed with AdvaMedDx member working groups, was approved by the AdvaMedDx Board of Directors, September 2021.
- Provides details on the highest priorities for the IVD industry.
- Is comprehensive when viewed with the AdvaMed agenda that includes priority issues across all association divisions from legal to global.
- **AdvaMedDx's 2022 Priorities are focused in the areas of:**
  - **COVID-19 Response and Pandemic Preparedness**
  - **Payment & Coverage**
  - **Regulatory (FDA-related matters)**
  - **External Relations (Government & Public Affairs)**

Global priorities are developing in collaboration with the International Board Committee of the AdvaMed Board of Directors each spring.

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Prioritization in Agenda Setting

Tiering Framework

- **Tier I Priority:** Success would equate to a significant, positive impact for most AdvaMedDx members.
  - Actionable; requires high level of active engagement and significant resource allocation.
  - High level of board direction and engagement.

- **Tier II Priority:** Success would translate to a moderately positive impact for some or most AdvaMedDx members.
  - Actionable; requires regular engagement and moderate resource allocation.
  - Regular board engagement.

- **Tier III Priority:** Success may benefit some AdvaMedDx members.
  - Not deemed to be reasonably actionable; requires periodic engagement/monitoring
  - Updates to Board as necessary.

COVID-19 Response & Pandemic Preparedness

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AdvaMedDx 2022 COVID-19 and Pandemic Preparedness Priorities

AdvaMedDx aims to encourage the Administration and Congress to establish short and long-term policy to meet the changing testing needs of the current pandemic and to ensure informed preparedness for future public health emergencies.

Tier I Proposals include:

- Development and implementation of policy to ensure maintenance/bolstering of manufacturing capacity via warm base, flexible manufacturing, stockpiling, including vendor-managed inventory, industrial base expansion and other mechanisms to support ongoing national response.
- Establishment of a permanent Public-Private board/forum on testing to ensure regular and meaningful public-private coordination and collaboration.
- Improving the Food & Drug Administration Emergency Use Authorization (EUA) Pathway.
- Alleviating Pending Medicare Cuts to Laboratories under PAMA.
- Modernizing Regulation of *In Vitro* Clinical Diagnostic Tests.
- Longer term: Leveraging expanded IVD manufacturing capacity and instrument augmentation to extend the reach of testing beyond COVID-19, to all diseases and conditions.
    - Diagnostics are foundational to informed clinical care, ensuring equitable access to testing is essential to eliminating overall health care access, treatment and outcome disparities.

Strategy:

- **Administrative** (short and long-term): Continue regular meetings with the White House, HHS (Office of the Secretary; Testing and Diagnostic Work Group), CDC to press for improved pandemic response and preparedness. Engagement under the FEMA Voluntary Agreement continues. Collaborate with the American Clinical Laboratory Association and other stakeholders for joint advocacy as appropriate.
- **Legislative** (short and long-term):
    - Encourage health committees and leadership to press the administration for improved response and preparedness.
    - Pursue Senate Health, Education, Labor, and Pensions Committee support for AdvaMed / AdvaMedDx proposal in the pending bi-partisan preparedness legislation under development.

Proposals and strategy to be continually updated as appropriate.

Payment & Coverage Priorities

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AdvaMedDx 2022 Payment & Coverage Priorities

Tier I

- **PAMA (Medicare Cuts to Most Laboratory Tests) Implementation Improvements**
  - Pursue legislation, in collaboration with labs, to improve the PAMA rate-setting formula
  - Promote PAMA payment reform proposals, developed by AdvaMedDx in 2021, including improving rate-setting methodologies for new tests (Crosswalk/Gapfill improvements)
- **COVID-19 and Future Public Health Emergencies**
  - Secure rapid coverage/coding payment for new tests associated with future public health emergencies

Tier II

- **PAMA – Address coding issues that impact payment** (e.g., PLA coding issues, private payer/Medicaid recognition/coverage, panel test coding, NCCI edits)
- **Coverage –**
  - **Support regulatory and legislative efforts to modernize Medicare coverage for preventive services** (e.g., screening tests)
  - **Improve coverage and payment for breakthrough and other innovative diagnostic products** (post-MCIT repeal / AdvaMed Priority)
- **Mitigate dramatic payment reductions to providers** (Physician Fee Schedule/Outpatient Prospective Payment System, Sequestration cuts to providers)
- **Promote the advancement of diagnostics stewardship** policies with the CDC, Congress, and others to strengthen antimicrobial stewardship programs across healthcare settings

Tier III

- **Expand AdvaMedDx engagement with private payers**
- **Support Value Based Payment (VBP) efforts through education and other efforts; explore use of diagnostic tests in Alternative Payment Models (APMs)**
- **Explore artificial or augmented intelligence (AI) integration into laboratory testing**
- **Support health equity/access to testing (part of AdvaMed-wide initiative)**

2022 Tier I: PAMA – Implementation Improvements

1. Support legislative efforts to improve the payment system established under PAMA.
2. Promote PAMA payment reform proposals, including improving rate-setting methodologies for new tests (Crosswalk/Gapfill improvements).

- Background:
- 2019-2021: In collaboration with ACLA and other lab, patient, provider stakeholders) AdvaMedDx has secured passage of legislation in multiple years, delaying Medicare payment reductions to tests paid on the CLFS and delaying the data reporting period for the next round of PAMA.
  - First, The LAB Act in 2019 delayed the PAMA data reporting period for one year. In 2020, the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act (CARES) further delayed the data reporting period, froze CLFS rates for 2021 at 2020 rates, and pushed additional cuts to 2022-24 (capped at 15%). Finally, at the end of 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) successfully delayed cuts again until 2023.
- AdvaMedDx leveraged these periods of delay to focus on development of payment reform proposals under PAMA, including improving rate-setting methodologies for new tests (cross-walk and Gapfill). Because PAMA is designed to reduce test payments over time, it is critical to ensure appropriate initial pricing for new tests.

Strategies:

- **Legislative:** Collaborate with ACLA and other stakeholders to develop and pursue legislation to improve the payment system established by PAMA, mitigate future payment reductions and seek modifications to the rate-setting formula (cross-walk and Gapfill).
- **Administrative (short term):** In collaboration with labs, bring forward to CMS AdvaMedDx's proposals developed in 2021 to improve rate-setting for new tests via reformed crosswalk and Gapfill methodologies. This would improve transparency, replicability and results that reflect consideration of important factors.

2022 Tier I: COVID-19 and Future Public Health Emergency-related Coverage & Payment Issues

1. While advances in coverage and payment were made in 2021, AdvaMedDx will continue to pursue COVID-19-related public and private coverage and payment improvements and access to free testing for the full range of COVID-19 tests (molecular, serology/antibody, antigen, T-cell, etc.) including for screening programs.

2. Pandemic Preparedness: Pursue policy using lessons learned from COVID-19 Public Health Emergency (PHEs) to improve rapidity of coverage/coding/payment rate-setting for new tests associated with future PHEs.

Strategies:

- **Administrative and Legislative (short term):** Via continued engagement with the Administration and Congress, encourage public and private coverage and reimbursement improvements to extend the reach of COVID testing, including through screening programs.
- Government procurement of testing to make available tests free of charge, such as under the ICATT program and via early 2022 OTC procurements, will continue to be pursued.
- **Administrative and Legislative (long term):** As pandemic preparedness policy is considered, encourage the Administration and Congress to set long-term policy to transparently and efficiently cover/code/reimburse for all diagnostic and serology/antibody and T-cell tests for all appropriate use cases in future PHEs.

2022 Tier II: PAMA – Coding Issues Impacting Payment

Focus on Coding Issues with Potential Payment Impact

- Background: Coding issues can result in negative or unintended consequences on payment for diagnostic laboratory testing. AdvaMedDx regularly engages when issues arise to ensure coding is not used as a way to address pricing or payment issues.
  - Several examples where coding has significant payment implications include coding and payment for test panels, CMS billing instructions (e.g., National Correct Coding Initiative, or NCCI, manual), and denial of payment for tests with Proprietary Laboratory Analysis (PLA) codes by commercial payers or Medicaid agencies.
- In January 2022, AdvaMedDx met with Center for Medicaid and CHIP Services (CMCS) within CMS and obtained commitment to pursue recognition of PLA codes by State Medicaid Agencies.

Strategies:

- AdvaMedDx will continue to work proactively with laboratory stakeholders regarding coding issues (e.g., private payer recognition of PLA codes).
- **Administrative (short term):** In collaboration with laboratory stakeholders (ACLA, Point of Care Testing Association (POCTA)), ensure clear communications with CMS regarding coding implications on payment.
  - Continue discussions with CMS/CMCS (Center for Medicaid and CHIP Services) regarding payment denials for tests with PLA codes by state agencies.
- Assess and take action, when necessary, as upcoming proposed rulemaking (e.g., CY2023 Physician Fee Schedule rule) or subregulatory vehicles (e.g., CLFS Annual Public Meeting documents, NCCI manual updates, etc.) are released for coding issues.

2022 Tier II: Medicare Coverage & Payment Reforms for Preventative Services and Breakthrough Technologies

Support opportunities to demonstrate value of modernizing Medicare coverage for preventive services (e.g., screening tests) and improvements in coverage and payment for emerging technologies and other innovative diagnostic products.

1. Support development of rulemaking and other CMS activities (e.g., public stakeholder meetings, sub-regulatory policy development) to allow for swift coverage of emerging technologies including diagnostic tests.
2. Encourage Medicare modernization of Medicare preventive services, including coverage of certain screening tests as was done in 2021 for liquid biopsy colorectal cancer screening via an NCD. Seek advancement of Medicare Multi-Cancer Early Detection Screening Coverage Act.

Strategies:

- **Administrative (short/mid-term):** Urge CMS/HHS to develop and issue coverage rule for emerging technologies (post-repeal of MCIT final rule in 2021). Support legislation expanding coverage and payment for breakthrough technologies including diagnostic tests.
  - Final MCIT regulation was repealed by CMS and the agency has indicated it will pursue multiple activities including development of a new regulation on Transitional Coverage of Emerging Technologies.
- Participate in stakeholder discussions regarding expansion of coverage and payment for screening tests.
- **Legislative (short/mid-term):** Continue to advocate for breakthrough pathway legislation that includes payment incentives for diagnostic tests, such as in CURES 2.0. Support efforts to modernize coverage for preventative services, including coverage for screening tests, including via advancement of the Medicare Multi-Cancer Early Detection Screening Coverage Act.

2022 Tier II: Support Efforts to Mitigate or Block Medicare Payment Cuts to Providers

Support provider organization efforts to block or mitigate regulatory or legislative Medicare cuts to provider, including under the Physician Fee Schedule/Outpatient Prospective Payment System, or Sequestration cuts, etc.

- For example, in 2021, AdvaMedDx worked with provider organizations to stall and reduce Medicare sequestration cuts applicable to virtually all providers.

Strategy:

- In coalition with hospital, physician, long-term care, and other providers, support efforts via regulation and legislation to alleviate Medicare cuts to providers.

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2022 Tier II: Promote Diagnostics Stewardship Requirements for Hospitals and Ambulatory Providers

Antimicrobial Resistance (AMR) and Diagnostic Stewardship

At the direction of the Antimicrobial Resistance (AMR) Work Group, AdvaMedDx will build upon our work in 2021 to advance diagnostic stewardship – the robust and appropriate use of diagnostic tools and tests, including in the inpatient setting by leveraging the expertise of the laboratory – to strengthen antimicrobial stewardship programs (ASPs).

1. Seek CDC and CMS policy changes to more formally include diagnostic stewardship language in antimicrobial stewardship programs.
2. Support advancement of the PASTEUR Act and/or CURES 2.0 AMR language.
    - Background:
        - In 2021, CDC published a key paper, emphasizing the importance of diagnostic stewardship in the inpatient setting, a first step towards more formal policy making. The paper reflects some AdvaMedDx's inpatient diagnostic stewardship recommendations.
        - AdvaMedDx secured diagnostic stewardship related provisions in the Pasteur Act (introduced in 2021 and included in 21st Century Cures 2.0 draft) that aims broadly to address AMR via new antimicrobials and wise use of such tools.

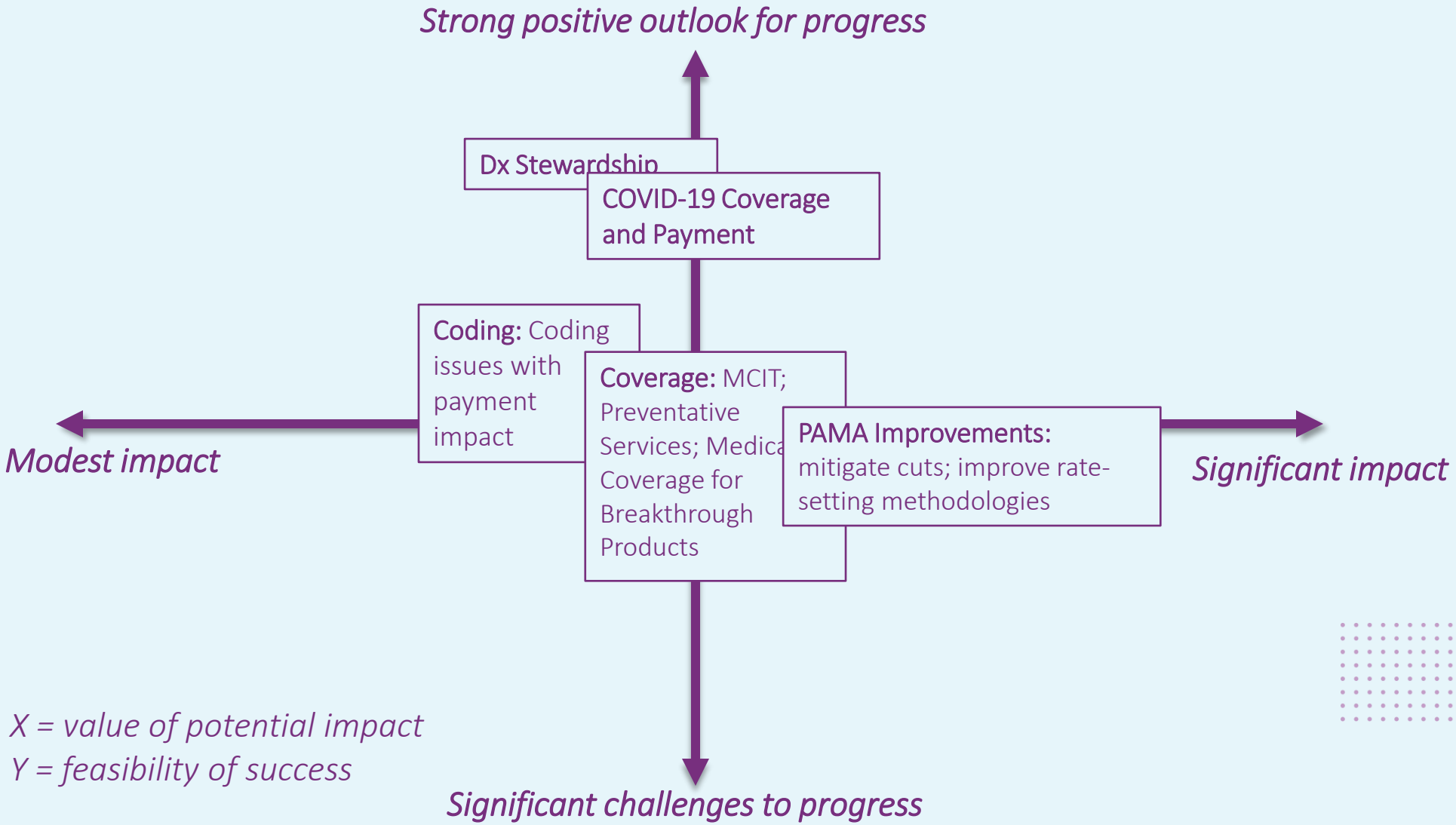
Strategies:

- Leverage and promote AdvaMedDx's inpatient diagnostics stewardship recommendations.
- Finalize AdvaMedDx's outpatient diagnostic stewardship recommendations.
- **Administrative (mid/long-term):** In collaboration with member company experts and stakeholder partners, including professional societies, seek opportunities for direct engagement with CDC to further diagnostics stewardship and incorporate recommendations from the CDC white paper into CDC guidance to clinicians battling AMR and CMS requirements for hospital antimicrobial stewardship programs.
- Seek further engagement with the President's Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB).
- **Legislative (short/mid-term):** Build upon Congressional interest and activity on legislative proposals to address antimicrobial resistance. Seek opportunities to support advancement of the PASTEUR Act, as freestanding legislation and/or as part of CURES 2.0
- **Stakeholders:** Build support for the AdvaMedDx diagnostics stewardship recommendations in the inpatient and ambulatory settings with stakeholder colleagues including the Infectious Disease Society of America (IDSA), American Society for Microbiology (ASM), and others. Strengthen collaboration with these stakeholders, in general.

2022 Tier III: Identifying Opportunities for Progress; Developing Solutions

- Expand Private Payer Engagement Discussions via Diagnostic Payment Work Group.
- Value-Based Payment (VBP)
  - Continue multi-pronged efforts on demonstrating the value of diagnostic and movement toward value-based payment for diagnostic tests and technologies; explore use of diagnostic testing in Alternative Payment Models (APMs), including appropriate quality metrics.
- Explore artificial or augmented intelligence (AI) integration into laboratory testing.
- Support and contribute to discussions of health equity as these relate to access to testing (*Note: part of overarching AdvaMed objective, Slide 26).*

2022 Payment and Coverage Priority Matrix



X = value of potential impact
Y = feasibility of success

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Regulatory Priorities

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AdvaMedDx 2022 Regulatory (FDA-Related) Priorities Overview

Tier I

- **Diagnostics Regulatory Reform.**
  - Secure advancement of AdvaMedDx member-supported VALID Act agreement as rider to MDUFA V.
- **FDA Workload**
  - Encourage resolution of backlog created by increased workload from COVID-19 as part of MDUFA IV implementation.
- **MDUFA V**
  - Secure favorable MDUFA V agreement that must pass into law by September 30, 2022.
- **Secure Legislative Improvements to EUA Process and Access to Samples.**

Tier II

- **Ensure Smooth Transition of EUA IVDs Post-Pandemic through elucidation of streamlined, clear and predictable pathway to obtain clearance (via de novo or 510(k)).**
- **Point-of-Care/CLIA Waiver**
  - Building on momentum gained during COVID-19 with increased FDA recognition of value of POC, reduce barriers to introduction of innovative POC/CLIA-waived tests.
- **Instruments**
  - Secure finalization of favorable draft guidance to modernize instrument policy (replacement reagent and instrument family policy).

Tier III

- **Precision medicine:** Explore development of proposals regarding companion and complementary diagnostics.
- Pursue Administrative and legislative avenues to secure broad-based **change control protocols** (i.e., as part of VALID/MDUFA V rider)

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2022 Tier I: Advance Diagnostics Regulatory Reform

Secure advancement of AdvaMedDx member-supported Verifying Accurate Leading-edge IVCT Development (VALID) Act agreement as rider to Medical Device User Fee Amendments (MDUFA V).

- VALID should ensure a risk-based regulatory framework under the FDA that embraces innovation and applies to all in vitro clinical tests, including LDTs, enhancing patient and public health.
- Key priorities: fully risk-based nature of framework, predictable and efficient Technology Certification pathway for tests and suites of tests that are not high risk, i.e., "moderate", and improved modification policies throughout pathways.

Strategies:

- Collaboration in advocacy with AdvaMedDx member companies is essential.
- **Administrative (short and long-term):**
- Seek action from FDA leadership and other senior Biden Admin leaders to press House and Senate health committees to improve and advance the VALID Act as a rider to the MDUFA V legislative package that must pass into law by September 30, 2022.
- Engage in dialogue with FDA on AdvaMedDx member priorities, building on 2019-21 series of AdvaMedDx/FDA sessions along with member companies' experts.

- **Legislative (short and long-term):**
- Engage and coordinate with committees of jurisdiction, maintaining our priorities as each focus on the bill. In Q1, Senate HELP Committee is most engaged in bipartisan process to improve VALID.
- Q1-Q2 time frames are critical in VALID becoming a viable rider to MDUFA as User Fee hearings and mark-ups will take place during this time frame
- Continue AdvaMedDx, American Clinical Laboratory Association (ACLA), Friends of Cancer Research (FOCR), and American Cancer Society Cancer Action Network (ACS CAN) joint advocacy to the Administration and the Hill. Inform and collaborate with AdvaMedDx and ACLA jointly-led group of wide-ranging stakeholders (Dx companies, Labs, patient groups – including, provider groups) that share high-level goal of risk-based Dx regulatory reform.

2022 Tier I: Resolve FDA Workload Challenges

Encourage resolution of backlog created by increased workload from COVID-19 as part of ongoing implementation of MDUFA IV.

- AdvaMedDx members are encouraged to participate and guide AdvaMed FDA Strategy Group in weekly meetings to maximize efforts to work with FDA to resolve backlog.
- **Strategies:**
  - **Administrative (short and mid-term):** Continue regular AdvaMed and AdvaMedDx member discussions with CDRH leadership, press FDA to achieve performance metrics; encourage FDA hiring of additional reviewers, and FDA leveraging of third-party reviewers;
  - **Legislative (short and mid-term):** Continue regular engagement with key congressional committees with oversight of FDA on agency workload to press the agency to resolve the backlog.

2022 Tier I: Secure Favorable MDUFA V

Secure Favorable MDUFA V

- AdvaMed, other stakeholders and FDA negotiated agreement to be delivered by FDA to Congress, Q1.
- Package finalized Q3 2022.

Strategies:

- AdvaMed is key stakeholder "at the table" with FDA negotiating the agreement in advance of delivery to Congress in Q1.
  - Negotiation strategies and tactics discussed weekly with AdvaMed FDA Strategy Group; determined by AdvaMed Board.
  - AdvaMedDx member participation and guidance in weekly AdvaMed MDUFA V strategy sessions encouraged.
- AdvaMed / AdvaMedDx educating key Congressional health committees on MDUFA processes and association priorities.

2022 Tier I: Secure EUA Process Improvements

Secure Legislative Improvements to EUA Process: Use of Real-World Evidence; CLIA Waiver; Access to Samples for All Tests.

- **AdvaMed-supported legislation has been introduced in the House and Senate; we aim to include on any moving legislative vehicle, such as pandemic preparedness bills.**
  - Real-World Evidence: Data collected during EUA should be leveraged to generate Real-World Evidence to ensure that product advancements made during a public health emergency can be utilized to support full marketing status, via subsequent premarket submissions for devices. AdvaMed supported legislation has been introduced in the House and Senate.
  - CLIA Waiver: Additionally, in cases where FDA already has determined the test qualifies for waived status as part of the EUA process, FDA should not have to repeat that assessment if the same test is submitted for a subsequent premarket submission after the emergency.
  - Access to Samples: Advance legislative proposal directing HHS to establish a streamlined process for manufacturers and other test developers to access viral samples to complement CDC development efforts and ensure diversification of testing development and capacity.

Strategies:

- **Administrative (short and mid-term):**
  - Encourage FDA to use existing authority to leverage Real-world evidence.
  - Press HHS (FDA, CDC) to improve existing policy to facilitate sharing of patient and contrived samples held by the USG to facilitate test development.

- **Legislative (short, long-term):**
  - Advocate for inclusion of proposed legislative language regarding EUAs, CLIA waiver, and access to samples in any moving legislative vehicle, including potential pandemic preparedness legislation expected to be released in the Senate, Q1.
  - AdvaMed-supported legislation has been introduced in the House and Senate.

2022 Tier II: Seamless Transition for EUAs to 510(k), *de novo*

Secure and Ensure Seamless Transition from EUAs to Clearance:

Elucidation of seamless, streamlined, clear, predictable path forward for COVID-19 IVDs to transition from EUA and obtain clearance (via de novo or 510(k).

- Sufficient time to make transition, e.g., appropriate grace period to prepare submissions.
- Pursue opportunities for input into transition policy development.

On December 22, 2021, FDA released two draft guidances on transition.

Strategies:

- **Administrative (short and mid-term)—**Continued discussions with CDRH leadership and using all opportunities for public comment to shape policy.
- AdvaMedDx is developing formal comment on the two draft guidances on transition released at the end of 2021.
  - Draft guidances include positive policies consistent with AdvaMed recommendations.
- Advocate for FDA development and public release of detailed template developed by OHT7 outlining FDA expectations for 510(k) or de novo submissions for IVDs under EUAs; template would be similar in level of detail of templates regarding expectations for EUAs.

- **Legislative (short and mid-term)—**Continued advocacy for legislation to require FDA to consider real-world evidence gathered under EUA as part of the de novo or 510(k) submission.

2022 Tier II: Point-of-Care/ CLIA-Waived Tests

Secure Improvements for FDA Consideration of Point-of-Care/ CLIA-Waived Tests

- Building on momentum gained during COVID-19 with FDA's increased recognition of value of POC/CLIA-waived tests, reduce barriers to introduction of innovative tests.

Strategies:

- **Administrative (short and mid-term)—**Advocate for elimination of current policies that require FDA review of a submission for a POC new or modified test even if the new test or modification is low risk, e.g., .9 limitation and exclusion from favorable RRIFP policy.

- **Legislative (short and mid-term)**
  - Seek advances for point-of-care /CLIA-waived tests in diagnostics regulatory reform legislation, The VALID Act.
  - Advocate for inclusion of proposed legislative language regarding EUAs and CLIA waiver in any moving legislative vehicle.

2022 Tier II: Advance Modern Instrument Technologies

Advance Modern Instrument Technologies Policy

Address challenges manufacturers experienced with inappropriate, inconsistent application of key policy that permits instrument updates and addition of reagents without 510(k). Regulatory hurdles creating barriers to timely updates and public health.

- **Strategy:**
  - **Administrative (short and mid-term)—**Ascertain any roadblocks to finalization of improved FDA draft policy guidance that would revise Replacement Reagent and Instrument Family Proposal and implement improved risk-based treatment in policies. Develop and seek member alignment on AdvaMedDx proposal to address any identified roadblocks.

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2022 Tier III: Support Precision Medicine

Support Precision Medicine: Companion and Complementary Diganostics

Under the Dx Task Force, develop policy priorities that would address evolving FDA policies impacting personalized medicine, specifically companion and complementary diagnostics.

Strategy:

- **Administrative (short and mid-term)—**Based on policy development of the Dx Task Force, promote streamlined policies, including better coordination among centers, that support efficient requirements for developers and reduce redundancy.

2022 Tier III: Advance Change Control Protocol Policy

Advance Change Control Protocol Policy

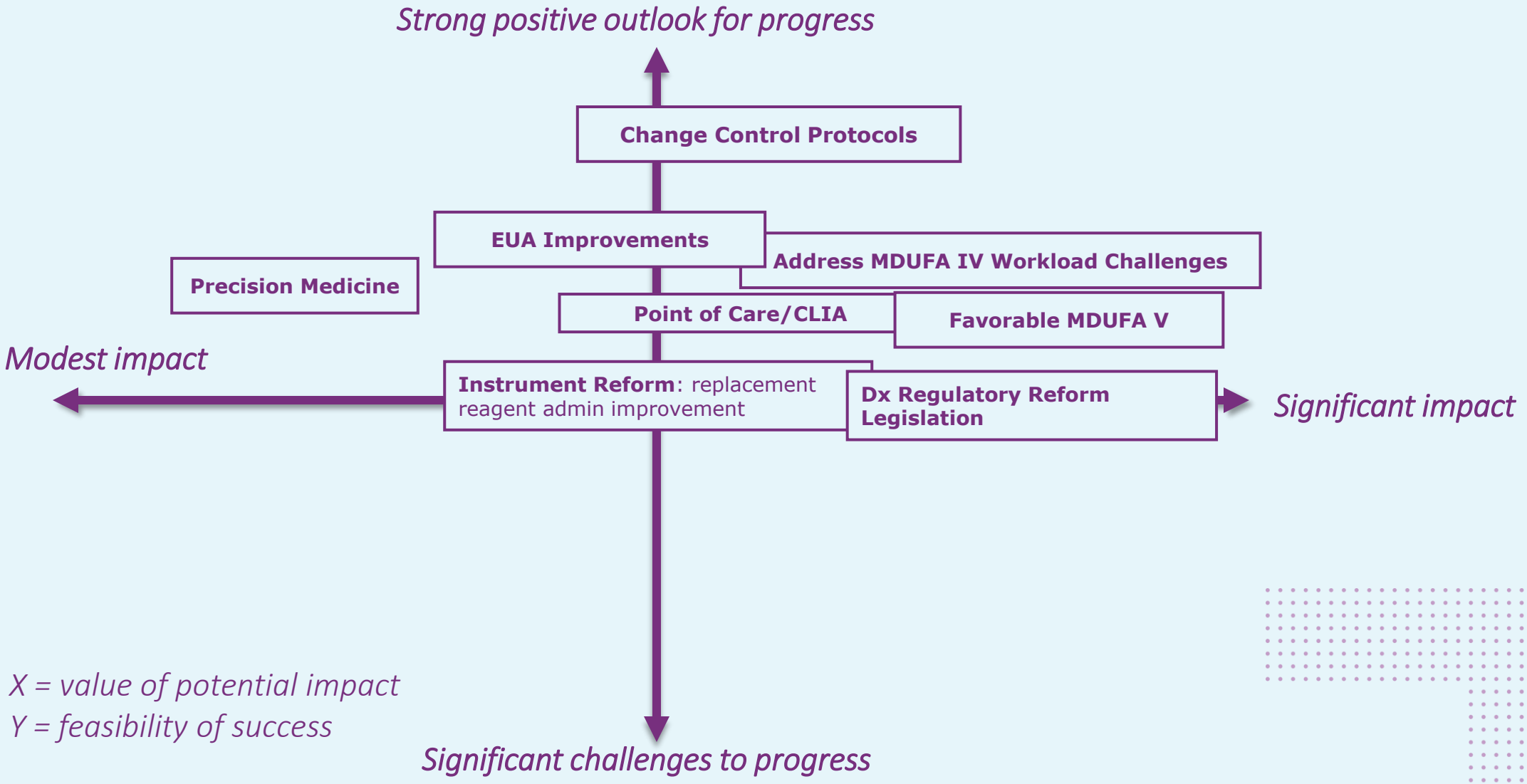
Change control policy should be predictable and broadly applicable.

- Background: In certain instances, FDA and the manufacturer have agreed in advance that certain modifications to a 510(k)-cleared diagnostic would not require a new 510(k) so long as agreed upon criteria are met. Current use by FDA of these "FDA-accepted change control protocols" has been on an ad hoc basis.

Strategy

- **Administrative (short and mid-term):** Explore development of AdvaMedDx policy to standardize and expand FDA-accepted change control protocols, building on concepts in redlines, even without legislation.
- **Legislative (short and long-term):** The VALID Act of 2021 includes concept and AdvaMedDx has advanced recommendation to improve the language. In addition, AdvaMed has identified change control protocols as a priority for a rider for MDUFA V, independent from VALID, given the potential benefits to all devices, including IVDs.

2022 Regulatory Priority Matrix



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External Affairs—Government & Public Relations Priorities

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AdvaMedDx 2022 External Affairs Priorities Overview

Tier I

- **AdvaMed to Reorganize and Reorient Public Affairs: Q1-Q2 will be used to build AdvaMed/AdvaMedDx PA Infrastructure to include:**
  - Expanded AdvaMed PA team
- **Communicate the Value of Diagnostics as Part of AdvaMed's Developing Value of MedTech Campaign**
  - Leverage COVID—19 to highlight the value and impact of diagnostic tests through broad public affairs campaign.
- **Revitalize AdvaMed Board Industry Communications Committee – Open to all AdvaMed/AdvaMedDx member CEOs.**
- **Launch AdvaMed Public Affairs Coordinating Council & Dx subcommittee.**

Tier II

- **Congressional Briefings/Education Sessions (may continue to be virtual):** 2—3 sessions per year, including subjects such as Antimicrobial Resistance, Oncology, Precision Medicine, etc.
- **Capitol Hill Fly-In / Virtual Sessions**
- **Dedicated AdvaMedDx Days/ Virtual Engagement with CDC and FDA**
- **Broad Stakeholder Engagement on AdvaMedDx Priorities: Laboratories, Patient Groups, Professional Societies, etc.**
- **Expand diagnostic testing resource library, including new Test to Treatment fact sheets; educational materials**

Global Priorities

Note: Global Priority agenda setting is aligned with AdvaMed International Board Committee (IBC) each spring

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AdvaMed 2022 Global Priorities Overview

Tier I

- **China:** Industrial Policies; Volume-Based Procurement: national and sub-national levels; Buy Local; Phase one purchase commitments; Regulatory Approval Times/Processes ; Standards.
- **Japan:** Reimbursement (including Foreign Average Pricing and market expansion repricing ; Regulatory procedures and approval times.
- **India:** Price policies ; Public Procurement Restrictions; Regulatory/Indigenous standards; Healthcare cess (tax on medical device imports).
- **Brazil:** Price Controls; Regulatory convergence, Standards and Good Regulatory Practices; Trade Facilitation.
- **Trade Policy:** Trade Agreements; Internal Restrictions OUD and US (including Buy American; use of DPA); New Post-COVID International Supply Chain Measures to Ensure Market Access.
- **EU Regulatory Implementation:** Continue Advancing Improvements in IVDR Implementation

Tier II

- **Value-Based Purchasing vs Price Controls.**
- **Western Europe:** Market Access; VOT; Brexit; US-UK FTA; Data Privacy.
- **Korea:** Payment; Regulatory and KORUS Issues.
- **ASEAN:** Regulatory Harmonization and Price Controls.
- **Global Ethical Business Practices/Compliance (GC leads)**
- **Kenya FTA**
- **USAID COVID Medical Device Regulatory Convergence Project**
- **Latin America:** Regulatory Convergence, Standards and Good Regulatory Practices.

Tier III

- **Taiwan:** Self-Pay Reimbursement; Regulatory.
- **GMTA:** Industry Alignment on Global Issues of Common Interest.
- **WHO:** Essential Diagnostics List; Pandemic Influenza Preparedness; Prequalification.
- **Antimicrobial Resistance.**
- **APEC Forum:** Regulatory Harmonization.
- **Middle East:** Data Privacy; Regulatory Compliance
- **Africa (South Africa, Ghana, Kenya**): Regulatory Convergence, Standards Good Regulatory Practices.
- **Russia:** Regulatory; Localization.
- **Rest of the World.**

= diagnostic-specific priorities

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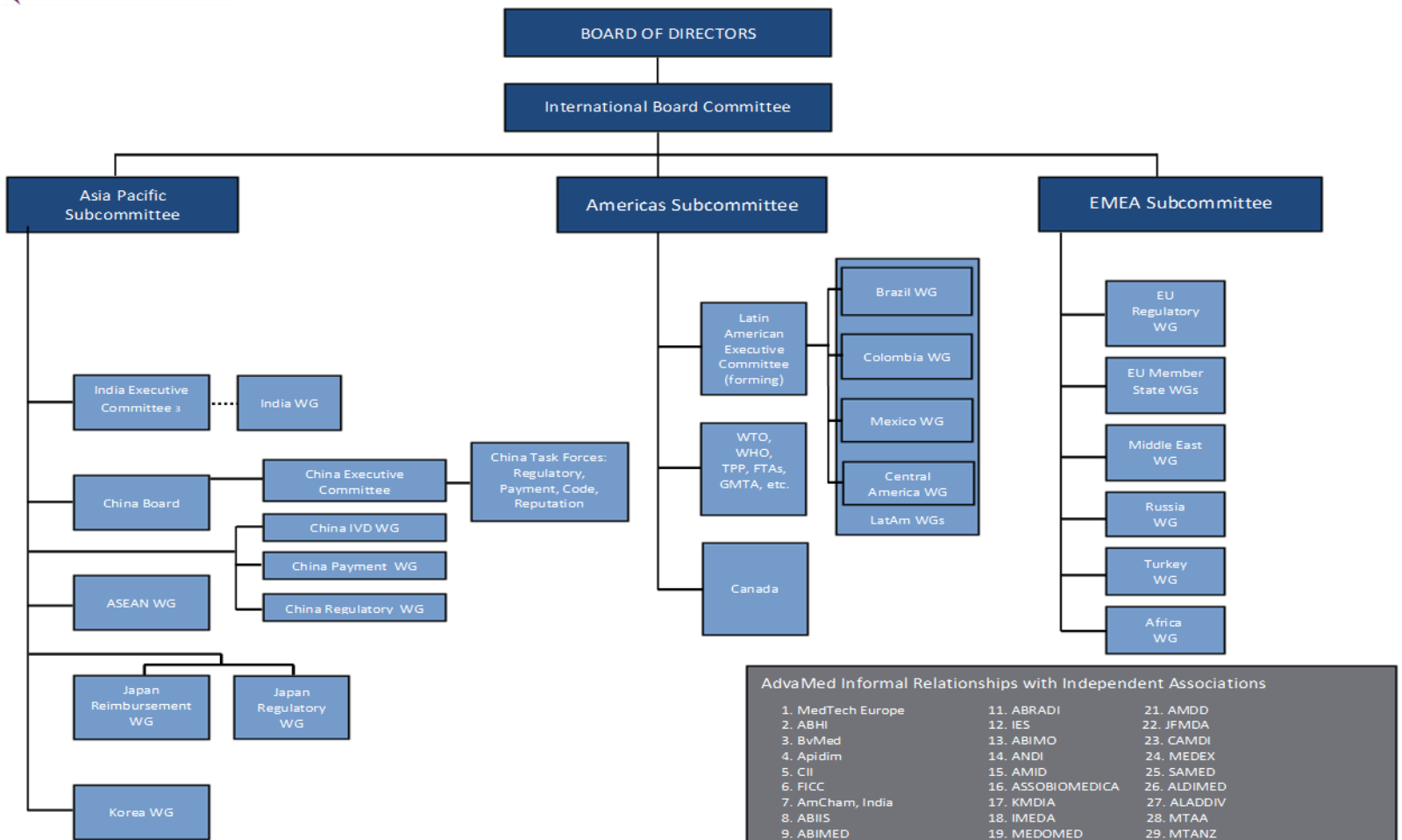
AdvaMed
Advanced Medical Technology Association

ADVAMED INTERNATIONAL ORGANIZATION



AdvaMed Informal Relationships with Independent Associations

1. MedTech Europe
2. ABHI
3. BvMed
4. Apidim
5. CII
6. FICC
7. AmCham, India
8. ABIIS
9. ABIMED
10. CBDL
11. ABRADI
12. IES
13. ABIMO
14. ANDI
15. AMID
16. ASSOBIOMEDICA
17. KMDIA
18. IMEDA
19. MEDOMED
20. ARTED
21. AMDD
22. JFMDA
23. CAMDI
24. MEDEX
25. SAMED
26. ALDIMED
27. ALADDIV
28. MTAA
29. MTANZ

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