AdvaMed
Advanced Medical Technology Association

Response To "Preparing For The Next Pandemic"

June 26, 2020

Tests, Treatments, Vaccines – Accelerate Research and Development

In Vitro Diagnostic Tests

The ongoing experience of manufacturers of *in vitro* diagnostic (IVD) tests during the COVID-19 pandemic provides critical insight into the capability of industry, when faced with a new pathogen, to rapidly develop and manufacture at scale quality COVID-19 tests that are essential front-line tools in the fight against the virus. Normally, a manufacturer's efforts to bring a test to market requires 3-5 years. During this pandemic, however, the diagnostics industry has been able to demonstrate a dramatically increased pace of research, development and manufacturing to bring quality products to market in just months. Nearly 90 commercial IVD tests for COVID-19 so far have received FDA Emergency Use Authorizations (EUAs), permitting these tests to be deployed to laboratories, hospitals, and other testing sites across the country. Manufacturers of these commercial tests have increased coronavirus testing capacity, speed, and throughput since the early days of public sector testing, to guide patient care and protect public health. In June alone, the industry will manufacturer and ship to hospitals, laboratories, and other testing sites across the country a projected 39 million molecular tests, 94 million serology tests and over 7 million antigen tests, which, along with Next Generation Sequencing tests, are just coming online. The industry continues to innovate throughout this emergency and we appreciate the guidance and leadership of the FDA in this process.

We strongly encourage broad recognition and action to ensure all types of diagnostic testing – including molecular diagnostics, antigen detection, serology/antibody and next generation sequencing testing – are available to clinicians across laboratory and point-of-care settings as patients present for care at various points during a potential infection, or thereafter, seek guidance on their health and clarity on their COVID-19 status. Tests such as molecular diagnostics and antigen detection are used to confirm active infections in patients enabling clinicians to quickly diagnose and triage patients. Serology (antibody) tests can help resolve uncertain diagnosis and facilitate the critical work of assessing individual and population-based immune response while also supporting voluntary employer workforce testing programs and guiding social

distancing/quarantine decisions. These tests also support the screening of potential patients for clinical testing of vaccines, drug therapies in development, convalescent plasma therapy, and will prove essential to measuring the success of vaccination trials and campaigns.

Our recommendations throughout this document aim to:

- Accelerate innovation
- Bolster the Emergency Use Authorization (EUA) process,
- Improve future preparedness through strengthening of the Strategic National Stockpile
- Broaden access to testing to support patient care and protect public health
- Establish a National Coordinator for Diagnostic Testing and a public-private Diagnostic
  Testing Advisory Board

Further, during the ongoing emergency, as the industry continues to strive to meet the needs of patients and public health, lessons are being learned about the speed of innovation, the importance of quality testing, and transparency into test performance, among other issues. AdvaMed looks forward to bringing those lessons to bear on ongoing discussion of comprehensive diagnostics regulatory reform. Sponsors of the Verifying Accurate, Leading-Edge In Vitro Clinical Test Development (VALID) Act, Senators Richard Burr and Michael Bennet, and Representatives Diana DeGette and Larry Bucshon, M.D., have taken a critical leadership role towards modernization of regulation of all diagnostic tests. Under VALID, a modernized, diagnostic-specific, regulatory framework overseen by the FDA, would aim to embrace innovation, bringing quality tests more rapidly to patients under a transparent, risk-based approach. AdvaMed looks forward to working with the VALID sponsors to achieve a modernized regulatory framework for all diagnostics.

Sustain Federal Investment for Diagnostic Innovation

AdvaMed is encouraged that federal stimulus funding has launched the National Institute of Health's (NIH) new Rapid Acceleration of Diagnostics (RADx) initiative aimed at speeding innovation, development and commercialization of COVID-19 testing technologies. The RADx program is investing in early innovative technologies to speed development of rapid and point-of-care COVID-19 testing. The investment in diagnostics required to address pandemics exceeds that which the private sector can bear entirely on its own. Establishing and sustaining important programs such as RADx to complement the Biomedical Advanced Research and Development Authority's (BARDA) work will

require ongoing and robust funding to ensure the country and diagnostics manufacturers are ready for future outbreaks of novel pathogens.

Increase Flexibility of BARDA R&D Funding

The Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response, through BARDA, can provide significant support to IVD manufacturers to advance and accelerate the development of emergency diagnostic tests. Innovation should be fully embraced to ensure a broad range of testing, from those that enable advanced surveillance, facilitate triaging of patients based on their potential risk to deterioration, and beyond. AdvaMed encourages the bolstering of this funding and new flexibility to maximize innovation, including allowing funding provided by BARDA to be used to recoup costs already incurred for emergency test development prior to receipt of the funds.

Furthermore, federal contracting procedures and timelines can delay the transfer of R&D funding to manufacturers during an outbreak. This delays the pace of IVD development and provides a significant disincentive to many manufacturers to develop tests at the risk of not being able to recoup initial development costs.

Additionally, more flexibility in how BARDA funds can be applied to reimburse development costs incurred during the earliest states of test development would be a significant incentive to manufacturers to accelerate the development of emergency diagnostic tests.

De-Risk Market for Emergency Test Development

De-risking the market can provide a meaningful incentive to industry to develop and manufacture products for which a viable market may not exist. The government can de-risk the market for IVD manufacturers by negotiating minimum purchase agreements with IVD manufactures in advance of development. Diagnostic tests procured by the government can be immediately deployed or stockpiled centrally within the Strategic National Stockpile (SNS) for nationwide distribution as needed. Guaranteed procurement would provide assurances to IVD manufacturers and help offset opportunity costs as other commercially-viable research and development projects are put on hold and key human and manufacturing resources are redirected to emergency test development activities.

Historically, IVD manufacturers have developed emergency diagnostic tests during public health emergencies with uncertain prospects for selling those tests. These tests often go unsold or are donated as there is often zero, or extremely limited, commercial market for emergency IVDs. While a small market is clearly favorable for

public health, this phenomenon serves as a significant disincentive for IVD manufacturers to invest in the development of emergency diagnostics.

Broaden access to testing to support patient care and protect public health

In the context of the COVID-19 emergency, AdvaMed offers the following legislative and administrative proposals from which policy makers can draw a roadmap to ensure availability of and access to essential testing. A number of the proposals require legislation, while others could be accomplished administratively.

Legislative Proposals: Strengthen Coverage & Reimbursement, Ease Ordering, Authorize National Epidemiological Study

- **Strengthen coverage of testing:** Recently, private health plans have been raising concerns about covering some types or configurations of COVID-19 testing, despite the Families First Act and CARES Act provisions designed to ensure broad coverage of testing. Further, for example, several private sector health plans have issued non-coverage or severely restrictive coverage policies for COVID-19 serological/antibody testing. Congress should clarify that coverage for COVID-19 testing (e.g., molecular, antigen, serology, next generation sequencing and any COVID-19 testing included in respiratory panels or combined COVID-19 – Flu A/B tests, etc.) is available for symptomatic, presymptomatic and asymptomatic individuals to protect both patient and public health, regardless of sites of care/service and regardless of a clinician order. Specifically, for all public and private payers:

    - ***Repeat testing*** should be covered without overly restrictive limitations that impede patient access, regardless of the site of care.

    - ***Parallel testing*** (simultaneous diagnostic (molecular or antigen tests) testing with serological testing) also should be covered without restrictions by all public and private payers.

    - ***Testing prior to medical, surgical or dental procedures, or prior to admission to a healthcare facility*** (e.g., hospital, surgical center, cancer hospital, skilled nursing facility, dialysis center, etc.) should be covered. This could include COVID-19 tests as part of multi-analyte panels that differentiate co-circulating respiratory viral targets (e.g., flu, RSV, CoV-2).

- **Bolster reimbursement for COVID-19 testing; ensure appropriate federal funds for testing:** Laboratories, striving to meet the nation's COVID-19 testing

needs, have experienced significant downturns as elective procedures and services declined dramatically since the pandemic began. To ensure laboratories can provide COVID-19 and other testing, Congress should:

- ***Require reimbursement for all COVID-19 testing at rates not less than Medicare*:** All authorized screening and diagnostic testing for symptomatic, presymptomatic and asymptomatic individuals should be reimbursed at rates not less than Medicare, for all public and private health plans, including plans on the federal exchange, regardless of sites of care/service, regardless of an order from a treating physician or non-physician practitioner. Over the Counter FDA authorized COVID-19 tests also should be reimbursable through an individual's public or private health insurer. Congress should appropriate federal funding to help cover the cost for COVID-19 testing used for surveillance.

- ***Provide full federal support for Medicaid plans for all COVID-19 testing for Medicaid, SCHIP and Uninsured:*** Plans should be reimbursed 100 percent by the federal government. State Medicaid plans, for example, should receive 100 percent Federal Medical Assistance Percentage (FMAP) for all Medicaid and State Children's Health Insurance Program (SCHIP) covered lives and for the cost of testing provided to uninsured individuals.

- ***Freeze future Medicare cuts to the Clinical Laboratory Fee Schedule (CLFS):*** Building upon the CARES Act and in recognition of the flawed implementation of PAMA, Congress should further delay any Medicare cuts to the CLFS cuts until such time as a new framework for establishing payment rates for diagnostic tests can developed.

- **Establish a nation-wide COVID-19 epidemiological survey:** The CDC, NIH, and FDA are collaborating with other public and private sector stakeholders on metropolitan, community and special population seroprevalence studies. The largest of these studies seeks to analyze 300,000 patient samples over the next year nationwide. In order to understand the true prevalence of COVID-19 in the U.S., a bolder, truly comprehensive seroprevalence survey assessing the exposure to COVID-19 in all communities – urban, suburban and rural across the country – is needed. The implications of exposure are being discovered in real time as clinicians and scientists leverage these finding to improve patient care and protect public health. Congress should authorize and fund a large scale, scientifically rigorous, coordinated, local-level serology (antibody) testing survey to ensure clinicians, public health officials, and policymakers have the most robust, real-time information about the virus and its transmission.

- Federal funds should be provided to CDC, NIH and FDA to oversee the program federally, with funds allocated to state, local and tribal governments to support rigorously designed, scientifically valid study regarding disease prevalence at the local level. In addition to the general population, testing also should be targeted at high-risk individuals (i.e., nursing home residents, first responders, and health care workers).

- Continue enforcing measures to ensure that only high-quality serology tests authorized by FDA with EUA that meet performance thresholds determined by the Secretary should be used.

- Congress should further ensure that ongoing seroprevalence studies supported by CDC, NIH and FDA provide full study details including information about which specific serology tests being used, with real-time results reporting.

- **Simplify ordering of all COVID-19 tests for individuals and groups:**

  - Following Medicare's lead, Medicaid and private health plans should remove as a condition of coverage and reimbursement any requirements for an order from a treating physician or non-physician practitioner for COVID-19 molecular, serology, antigen, next generation sequencing or other diagnostic tests for an individual.

  - Congress should clarify that a physician or non-physician practitioner should be permitted to provide blanket testing authorization for non-clinical settings (i.e. workplaces, schools, houses of worship and other locations where groups of individuals gather). These changes should apply to all public and private payers for all COVID-19 testing (i.e., molecular, antigen, serology testing, next generation sequencing, etc.).

- **Expand sites where sample collection and sample analysis can occur to non-traditional settings such as workplaces, schools, houses of worship, and other locations where groups gather.** These locations should be permitted to serve as locations for sample collection for laboratory testing, or rapid point-of-care testing. The Administration recently made a change to allow a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility. Presently, the temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate and must be under the direction of the existing lab

director.[1] State policy varies across the country, in many cases precluding this flexibility necessary for public health.

- *Congress should clarify that during the public health emergency, sample collection and sample analysis is permitted at non-traditional testing sites including at schools, places of employment and houses of worship, etc., under the direction of a CLIA-laboratory.* Federal policy should supersede state policy during the emergency period. Note that FDA authorized self-collection kits could be effectively leveraged in such circumstances.

- Further, in cases where molecular, antigen or serology testing (sample collection for laboratory tests, or point-of-care testing) is not intended for any medical decision making, no obligation to meet any CLIA-waiver criteria should be required. As with tests employers might utilize for actuarial medical exams, testing for purposes of informing workforce and workplace measures is not intended for medical decision making.[2]

Administrative Proposals: Testing Guidelines, EUA Policy

- **CDC should broaden guidance on who should be tested; states should align their policies with CDC**: CDC guidance on prioritization for testing of first responders, health care workers and the most vulnerable patients who were symptomatic had been an important guidepost as testing capacity ramped up early this year. Testing is now more widely available and is needed more broadly as communities reopen. CDC should revise testing guidelines to facilitate repeat and parallel diagnostic testing (i.e. molecular, antigen, serology, next generation sequencing testing, etc.) of symptomatic, presymptomatic and asymptomatic individuals with reporting of the total number of tests run and positive results to a national data repository. We also recommend that state health departments follow these recommendations.

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[1] CMS. Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency. Retrieved from: https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf

[2] CMS regulation suggests sites that perform sample collection or testing not intended for medical decision making, are not laboratories and therefore not subject to CLIA, as per 42 CFR § 493.2 Definitions

"Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories."

- **FDA should facilitate rapid updates to tests authorized under EUAs**: Testing needs may change over time as our economy moves towards broader re-opening and we confront possible case increases and new hotspots. Moreover, limitations in testing supplies have led to the need to use alternate forms of swabs, transport media, and other necessary aspects of a test system. FDA should facilitate rapid updates to tests, as necessary, based on appropriate validation of changes of tests that have received EUA authorization.

- **FDA should issue an EUA template for over the counter (OTC) testing*:*** FDA should develop and disseminate, via an EUA template, controls to facilitate over the counter (OTC) testing for COVID-19, subject to testing being performed in appropriate laboratories, or at home with FDA authorized self-collection and self-testing in the home setting options we anticipate will be coming onto the market. Currently, all authorized tests are prescription-only. Providing OTC testing options will broaden availability of and expand access to tests.

- **FDA and States should simplify ordering of all COVID-19 tests:** Medicare changed its policy during the Public Health Emergency so that an order from a treating physician or non-physician practitioner is not required as a condition of Medicare coverage of COVID-19 diagnostic laboratory testing during the Public Health Emergency. CMS similarly removed these requirements for an influenza virus and respiratory syncytial virus (RSV) diagnostic laboratory test that is necessary to establish or rule out a COVID-19 diagnosis. Current FDA requirements for an order for COVID-19 molecular, antigen, serological and next generation sequencing tests should be lifted, and states should be encouraged by HHS to follow suit, reducing barriers to accessing testing.

- **CMS should ensure coverage and payment for new diagnostics tests authorized under EUAs:** A new FDA-CMS parallel review process should be established so that CMS and its contractors can launch coverage, coding, and payment for tests at the same time the EUA is granted.

Establish a National Coordinator for Diagnostic Testing and a public-private Diagnostic Testing Advisory Board

To ensure preparedness and coordination of all stakeholders in the diagnostic testing ecosystem, AdvaMed suggests looking to previous healthcare emergencies that required an intensive level of coordination among government and private sector stakeholders. Two such models to consider are the 2004 establishment of the Office of the National Coordinator for Health Information Technology, led by the National Coordinator for

HIT, and the 2003 launch of the President's Emergency Plan for AIDS Relief (PEPFAR), led by U.S. Global AIDS Coordinator. These two positions have been charged respectively with developing a plan for every American to have access to an electronic health record, and to strengthen and lead global HIV/AIDS treatment, prevention, and research. These efforts have been remarkably successful and can serve as models for other such daunting challenges requiring bold action across a wide set of stakeholders. In the spirit of these models, AdvaMed recommends the establishment of a:

National Coordinator for Diagnostics Testing: The Office of the National Coordinator could be successfully housed within the Office of the Secretary and staffed by individuals who are diagnostic subject matter experts, data analysts and epidemiologists, policy advisors, and grants managers. The National Coordinator should be empowered to coordinate with the agencies of HHS – the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA) and Department of Homeland Security (DHS), Federal Emergency Management Agency (FEMA).

National, Public-Private Diagnostic Advisory Board: Chaired by the National Coordinator for Diagnostic Testing, the Advisory Board could be:

- Comprised of leaders from the private sectors (diagnostic manufacturers, hospitals and health systems, public health laboratories, healthcare distributers, clinical laboratories, and retail pharmacies), and leaders from HHS agencies, CDC, CMS, FDA, NIH, and FEMA.

- Charged with overseeing the implementation of a strategic testing plan and hold limited emergency powers, during Public Health Emergencies that are declared National Emergencies, to facilitate private-public coordination to carry out Strategic Plan.

Following the conclusion of an emergency, the Advisory Board would agree on a process to create a pandemic preparedness plan, continuing to meet to review readiness and revise the plan, as necessary.

Formal Private-Public Dashboard of Registries Across the Testing Ecosystem: Beginning with a Diagnostic Supply Registry, a private-public registries dashboard should be established to enable the National Coordinator to identify ongoing testing supply and capacity in order to make data-driven policy decisions. Such a dashboard should be modeled on the AdvaMed COVID-19 Diagnostic Supply Registry that includes COVID-19 testing supply data from thirteen leading manufacturers of COVID-19 tests. The AdvaMed Testing Registry will provide to federal and state

governments real-time, actionable data on testing supplies being shipped across the country to support patient care and public health.

Over time, additional Registries from other diagnostic stakeholders would be established, such as a laboratory capacity and test sample Registry. This laboratory capacity Registry would, for example, provide real-time data on timing from patient sample collections to when a result is delivered to the patient and her clinician. Each Registry would provide real-time weekly updates during crises and continued less frequent updates in the future. Taken together, these Registries would provide to the Administration a dashboard view of all key components of the diagnostic testing ecosystem to facilitate efficient and coordinated efforts to address any public health national emergencies, putting patients first.

Food & Drug Administration Emergency Use Authorization (EUA) Improvements

The Emergency Use Authorization pathway has been a critical component of America's robust response to the COVID-19 pandemic. This pathway enabled new and novel diagnostic tests and devices, developed in record time, to be safely utilized by physicians for patients in need. However, this public health emergency is different than any previous situation in which the EUA pathway has been invoked and has led to an unprecedented number of products receiving EUA. Reflecting on collective experience with the EUA pathway, we have four legislative recommendations to streamline and improve the EUA pathway for manufacturers, and two administrative recommendations regarding in vitro diagnostic tests.

Access to Samples

The current pandemic has amply demonstrated that delays in access to viral samples can impede rapid development of testing capabilities. It has also shown the dangers of relying on one sole source for the development of tests. As FDA recently explained, "Typically, with an emerging health threat, the Centers for Disease Control and Prevention (CDC) is the first developer of a diagnostic test in the U.S.… CDC has first access to viral samples that other test developers do not."[3] For COVID-19, viral samples became commercially available to private sector test developers in late February. FDA has recommended that, "In the future, making viral samples available earlier to commercial developers will be crucial to deploying tests quickly."[4]

[3] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expedites-review-diagnostic-tests-combat-covid-19.

[4] *Id.*

AdvaMed's proposed legislation would direct the Secretary 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 (see **Appendix A** for legislative text).

Utilizing EUA Data and Real World Evidence

During this public health emergency, sponsors of a wide array of devices and diagnostics have rapidly deployed resources to test and validate new methods and products for diagnosis, treatment, and prevention purposes, in support of emergency use authorizations (EUAs) and other expanded uses. Moreover, a vast amount of clinically valuable data are being generated for products that are EUA authorized and are currently being used to help patients. These real world data should be leveraged to generate real world evidence to ensure that product advancements made during this public health emergency can be utilized to support full marketing status, via subsequent premarket submissions for devices. In addition, in the case of a test for which as part of the EUA process FDA already determined the test qualifies for waived status, FDA should not have to repeat that assessment if the same test is submitted for a subsequent premarket submission after the emergency is over (see Appendix A for legislative text).

Ongoing Availability of EUA-Approved Tests and Other Devices for Post-Emergency Surveillance and Shortages

Even after the acute phase of the COVID-19 emergency ends, there will be increased need for certain products that received EUAs during this emergency. For example, ongoing COVID-19 testing capacity is likely to be critical to re-starting the economy and monitoring for new outbreaks. More broadly, our country's supplies of PPE, ventilators, and other medical devices will have dwindled, and there may be significant shortages in these products as needed for a variety of conditions—not just COVID-19. In anticipation of these needs, the Secretary should have sufficient authority and discretion to ensure that the official termination of the emergency declaration does not inadvertently undermine our efforts to maintain public health and monitor new outbreaks of the virus. AdvaMed proposed language would ensure that the Secretary can: (1) consider the continued need for products under EUAs in determining whether to declare the end of an emergency; (2) consider such continuing needs in determining the disposition of products after EUAs are terminated; and (3) extend EUAs after termination of an emergency, as appropriate to meet such needs. Moreover, just as providers can determine that it is in the best interests of a patient to continue using an EUA-approved product after the emergency declaration has terminated, providers should have the discretion to continue using EUA-approved products obtained during the emergency declaration, to ensure continuity of care and avoid supply chain disruptions (see Appendix A for legislative text).

Clarification of CLIA Waivers for Tests Receiving Emergency Use Authorization

During the current COVID-19 emergency there has been significant confusion regarding the effect that FDA's grant of an EUA for a test for point of care use has on the CLIA categorization, and potential waiver, of such tests. Typically, a test for use other than by a moderate or high complexity laboratory must receive FDA clearance or approval for that intended use, and must also be determined, by FDA, to be a "waived" test under CLIA. Current law provides FDA the authority to make that waiver determination within the context of an EUA. However, in the current emergency, FDA only belatedly clarified that an EUA approved for a point of care use may indeed be used in those point of care settings under CLIA—i.e., that the EUA also served as a determination of waived status. In the interim, there was significant confusion among the laboratory, provider, and manufacturer communities, resulting in delays in deploying these EUA-approved tests in the manner that was intended. Current law can be further simplified by deeming a test approved by FDA under an EUA for use in one of these waived settings is indeed authorized for use under CLIA as well—without requiring FDA to clarify or separately announce this outcome (see Appendix A for legislative language).

Disease Surveillance - Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Disease

The use of digital contact tracing technologies, wearables for assessing and communicating key health metrics, and other digital health technologies have the potential to substantially augment and expand upon traditional pandemic response and containment measures. The adoption of digital contact tracing technologies in the U.S., however, appears to be limited thus far by various factors, including implementation challenges, public acceptance, and privacy concerns. Other digital tools and platforms for expanded, faster identification of potential infections, especially outside of traditional health care settings, may need further development and scientific and regulatory validation to ensure their accuracy and effectiveness. We urge a focus on these issues to help ensure wider availability and adoption of effective, trusted digital health tools for addressing pandemics.

We note that digital health technologies already are powering a revolution in health care, enabling new insights, supporting health and wellness, improving patient interventions and outcomes, and enhancing the quality and efficiency of health care delivery. Continued support for digital health on all these fronts will also enhance our capacity to leverage these tools for pandemic response.

With regard to privacy specifically, we applaud the HHS Office of Civil Rights for taking important enforcement discretion measures with regard to sharing of data with

public health authorities by Covered Entities and Business Associates under the Health Insurance Portability and Accountability Act (HIPAA). AdvaMed member companies take seriously their obligation to protect the privacy and security of personal health data, but we also recognize that HIPAA regulations may constrain nimble, effective data sharing activities to respond to public health emergencies, including pandemics. In addition, it is widely recognized that there are expanding types of data and data uses in the context of health care that do not fall with the scope of HIPAA. This is a broad issue that we believe should be addressed through comprehensive, national privacy legislation, but there are significant implications as well for how effectively the public health system and health care providers can leverage a wide range of data for pandemic response, while still assuring privacy and ensuring public confidence in emerging digital health tools and data uses.

Stockpiles, Distribution, and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution

In response to the question on how the Strategic National Stockpile can be better managed and how can Congress increase oversight and accountability, AdvaMed believes that stockpile financing is a key issue that must be addressed. The SNS is currently funded for five-year periods, with the most recent amount of $1.657 billion for 2022. Both the amount and the funding periods should be carefully examined. Given the relatively infrequent nature of a major health care crisis, such as a pandemic, ten-year funding might be more appropriate. Funding levels should ensure the stockpile is maintained at pre-determined levels, and products are rotated in accordance with industry-recommended shelf lives and updated to recognize innovative new technologies.

This objective is likely to require an automatic provision for increased funding levels immediately after the emergency has passed, in order to rebuild supplies. The U.S. government should award contracts to willing manufacturers to sell designated quantities at pre-fixed, negotiated prices as production of a particular medical device begins to exceed demand and their inventories return to more normal levels. This approach will provide manufacturers greater confidence that, as they ramp up to meet the initial demand surge, they will not be stuck with significant quantities of unsold merchandise. This system would also fill the SNS when supplies are at more normal levels. The government's goal for each product and the amount of these contracts should be made public to enable manufacturers to plan accordingly. That is, each manufacturer would know how much it should continue to produce, as well as the government's total SNS goal for each product.

Additional Considerations for SNS

Inventory: As the government reviews medical supplies and technologies for their suitability for the SNS, it should account for advances in science and technology as we learn more about COVID-19. Some technologies may become obsolete while others need to be added for consideration. There should be a mechanism to consult with the private sector on advances in medical technology as they pertain to the SNS. Furthermore, an emergency with a rapid medical supply depletion requires a SNS structure that allows for refurbishing supplies on a timely, ongoing basis during non-emergencies and ongoing communications regarding technologies and needs. Utilizing a vendor managed or "revolving" stockpile system for various types of PPE and medical devices, supplies of specific products could be transitioned for commercial use prior to expiration since an inventory buildup for an unlimited amount of time may not be possible due to the shelf life of the supply. These factors need to be product specific and account for the unique factors including changing technology. A series of town hall meetings would facilitate the development of product-specific channels to more proactively address the needs.

Sterilization, including Ethylene Oxide (EtO or EO): Ethylene Oxide (EO) is a colorless gas used in the sterilization of a vast number of medical devices including drapes, gowns, respirators and catheters. As the government looks at regulatory policies to support domestic supply of these kinds of technologies for the SNS, regulatory clarity around the use of EO and reasonable standards for usage will be essential.

Shelf Life: Building on The Shelf Life Extension Program, managed by DOD and FDA, the government should also consider utilizing a vendor managed or "revolving" stockpile system for appropriate PPE and medical supplies in the SNS. Specifically, under such a system (as is currently utilized by the DLA for various forms of PPE), vendors would be responsible for ensuring a specified amount of a particular item are on hand and available for use in the event of a public health emergency. To ensure the revolving stockpile does not contain expired items, the vendors would also rotate the stock by removing items prior to the expiration and replacing them with new products. As a result, the government would not only be assured of a consistent level of items in the revolving stockpile, but also "fresh" stock.

In vitro Diagnostics (IVD): The SNS should have adequate supply of diagnostic testing equipment, materials, and supplies – as it is critical to have the ability to rapidly test and diagnose patients who are sick or have been exposed to a pathogen. While it is not possible to stockpile diagnostic tests for an unknown pathogen, certain tests can be stockpiled that can help rule out other infections. For example, annually, the stockpile could ensure it has flu tests available to rule out flu if a new pathogen causes similar respiratory symptoms. We recommend stockpiling the equipment necessary to process IVD tests – such as test instruments, analyzers and other capital equipment – to rapidly scale up diagnostic testing infrastructure and help to ensure prompt testing of samples in

communities that may not have an existing lab or testing infrastructure. In addition, medical supplies used in the collection, transport and processing of IVD tests should be considered for the SNS. These include swabs, collection tubes, lancets, transport medium/tubes, and reagents such as DNA/RNA extraction kits, which are generally not specific to a particular test or pathogen.

Ventilators: The SNS should include a range of devices that can provide ventilation support for patients with respiratory syndromes specific to COVID-19. Access to critical care ventilators has been critical to the COVID-19 response and as those resources became stretched, alternative ventilation options such as non-invasive ventilation (NIV) bi-level and CPAP therapy were crucial to stabilize or sustain patients who required respiratory support. Studies have demonstrated that COVID-19 patients with less-severe respiratory distress could benefit from non-invasive ventilation therapy, thus freeing up more invasive ventilation devices for critically ill patients. As governments and health administrations around the world responded to the global demand spike for ventilators, many issued guidance documents on the use of bilevel or BiPAP devices that deliver NIV in patients with confirmed or suspected COVID-19. Moving forward, as the country reopens and braces for a potential second wave or surge in cases, it will be important to support patients in the sub-acute or out-of-hospital care environments on non-invasive ventilation devices that are already used in millions of homes every day. Additionally, the government should ensure it is prepared to support the various maintenance requirements of the ventilators in the SNS.

Data Sharing: Significant data sharing between the public and private sector underpins a number of the objectives detailed in the White Paper, including creating visibility about inventory levels, distribution flows, epidemiological and disease state trends, demand forecasting and distribution. Given that much of this information could include sensitive data such as intellectual property, trade secrets and other competitive information, there should be clear communication and guidance about how this information would be solicited, secured, shared and otherwise utilized.

Transport: AdvaMed's COVID-19 Supply Chain Task Force has identified transport disruptions as a leading barrier to delivering medical supplies to end users. With 3000 passenger airplanes in the United States grounded, and air travel down by 95%, there is a severe shortage in cargo capacity to transport medical supplies that in ordinary times rely heavily on passenger airline belly space. While industry is working with FAA and other relevant authorities to create additional capacity, we expect this issue to persist as it will take several years for passenger travel to resume to normal levels. Constraints on cargo transport – whether by passenger airlines, cargo freight, shipping or trucking –

is a persistent challenge that will drive up costs and continue to create bottlenecks as the pandemic continues in the U.S. and around the globe.

Re-opening and vaccination: Reforms to the SNS should take into consideration the PPE and medical supplies – including diagnostics tests - necessary to prepare for subsequent waves of the virus that may occur as states expand their reopenings and also as we move into colder weather. The government also should begin preparing for and envisioning the investments and infrastructure necessary to provide vaccinations on a mass scale. We are concerned that manufacturing capacity for injection devices (i.e. needles and syringes) is not being addressed alongside vaccine development. COVID-19 vaccines under development will involve at least one skin injection (a second dose may also be required) with specific device requirements for intramuscular injections that current stockpiles are not able to service and adequate quantities of these products may not be readily available. The government needs to invest today to build additional capacity and initiate inventory stockpiling that will be needed to support the anticipated demand as soon as a viable vaccine is available.

Additional Recommendations on Trade

A major source of supply chain disruption has come from governmental interference. Many countries, including the U.S., restricted the export of PPE and/or controlled the allocation of ventilators. Some export restrictions included inputs for production of masks. For example, Taiwan is a major global supplier of meltblown fabric, a key ingredient in face mask production. Beginning in mid-March, the Taiwan government began requisitioning meltblown fabric from the country's factories, resulting in a de-facto export ban and causing global supply chain disruptions. Likewise, India restricted the export of cloth used to manufacture masks. In addition, when governments ordered lockdowns, they initially did not identify "essential" sectors. This lack of planning caused disruptions of medical device manufacturing facilities and in the movement of essential personnel. Such disruptions should be avoided in the future.

The World Trade Organization (WTO) could serve as a forum for a plurilateral agreement among willing governments. Such an agreement would open trade further during a global emergency. There would be no additional burdens or requirements imposed on the private sector.

In brief, governments should collaborate to avoid future disruptions by agreeing in advance that they would take specific steps to improve supply chains and reduce costs. Such measures include: (1) prohibiting export restrictions; (2) designating medical device facilities as "essential" and not threatened with closure; (3) implementing trade facilitation measures to expedite medical supplies through a "fast track" process in

customs; (4) immediately suspending all import tariffs on designated medical technologies among the signatory governments; (5) harmonizing specific regulatory procedures – such as the U.S. Emergency Use Authorizations; and (6) providing designated cargo space for medical supplies. The benefits of this agreement could be limited to signatories in a plurilateral undertaking by using the provisions of Article XX of the WTO, which allows for suspension of certain obligations, such as most favored nation status (MFN), to protect health and safety. The penalty for non-compliance in this agreement could be more contractual in nature than the WTO dispute settlement process, perhaps including financial penalties on the governments for failing to keep predetermined commitments.

In addition, governments should commit to maintaining minimum stockpiles of essential medical technologies to meet immediate demand surges. These stockpiles would provide greater confidence for governments to not impose export or other restrictions. For lower income countries, willing governments and the private sector could join in a coalition to finance stockpiles for them, including with the WHO.

In the meantime, the U.S. government should remove MFN and section 301 tariffs on tests, and testing supplies and platforms. Also, the U.S. tariff systems needs to be reconsidered as it currently favors importation of finished products by charging zero to low MFN on finished goods and imposing, on average, 3.5% (ranging from 2.6 to 6.7%) MFN duties plus section 301 duties on raw materials, if imported from China. As such, the current U.S. tariff systems on medical and diagnostic devices favors offshoring as it is more expensive to import raw materials and manufacture in the U.S. (even, in some cases, after paying section 301 duties) versus importing finished products.

Public Health Capabilities – Improve State and Local Capacity to Respond

Medicare's Coverage of Telehealth Services

With the numerous expansions of Medicare's coverage of telehealth services authorized by Congress and through waivers provided by HHS during the public health emergency (PHE), we are seeing played out in real time the true potential benefits to patients of greater availability of these services when they are less constrained by Medicare law and regulatory restrictions. During the PHE, Medicare beneficiaries have had access to critically needed health care services provided through telehealth without regard to whether they live in rural or urban areas, are in a facility or in their own homes, or use their smart devices rather than the limiting requirements for technologies specified in Medicare regulations. They are receiving care through many different health care practitioners and can receive specific types services that would not otherwise be covered by Medicare. Additionally, the HHS Office of Civil Rights took important steps to ensure

that the provision of telehealth services during the PHE would not be unduly restricted by Health Insurance Portability and Accountability Act (HIPAA) regulations.

AdvaMed strongly endorses all of these expansions. We also recommend that the Centers for Medicare and Medicaid Services (CMS) extend, beyond the end of the PHE, the telehealth expansions already in effect. We anticipate that the health care system will be struggling to meet the demands of patients who have deferred needed care and/or delayed care because of safety concerns for a significant time following the end of the PHE. Telehealth technologies and services will continue to be effective tools for providing access to care and for monitoring beneficiary well-being during this transition.

AdvaMed has identified several additional ideas for expansion of coverage and payment of telehealth and other technology-based services (see **Appendix B**).

AdvaMed recommends that the Committee ask CMS to evaluate these service expansions beyond simply assessing their impact on utilization and spending. We believe that CMS should be using this opportunity to capture the extent to which these services improve patient care outcomes and quality of care. We recognize that telehealth is not always sufficient for assuring high quality care and that certain face-to-face visits will always be necessary, e.g., for detecting certain cardiovascular conditions or complications following surgery. However, telehealth service expansions are demonstrating how they provide a pathway for beneficiaries to receive timely care that can lead to improvements in patients' well-being and health and to reductions in use of other more expensive care.

The benefits of telehealth should be considered for how and under what circumstances they improve beneficiary outcomes--not just during the emergency period and any transition period, but also should be assessed for their contribution to beneficiary health in the longer term if incorporated on a permanent basis into Medicare's benefit structure. While in certain instances, Medicare statute would have to be amended to accommodate permanent expansions, policymakers should be advised by CMS about both the benefits and costs of expansions regardless of whether the law and/or regulations should be changed.

For instance, the merits of using the subregulatory process to add new services to the Telehealth List throughout the year, rather than only once a year through the finalized update to the Physician Fee Schedule, are obvious. The basic telehealth benefit limitations that prohibit beneficiaries in urban areas to receive telehealth services means that urban hospital emergency departments may not serve as an originating site of service for telehealth or that beneficiaries living in urban areas may not receive mental health services covered in rural areas. The PHE and CMS's flexibility in using waiver authority

to improve patient access to care provides a unique opportunity to approach coverage for telehealth through a very different lens, but also for finding pathways to coverage for the broader array of digital technologies becoming available for health care delivery in the near future.

Appendix A

Emergency Use Authorization Improvements

Access to Samples

Section 564 of the Food, Drug, and Cosmetic Act is amended by adding at the end the following:

"(n)(1) In the case of a declaration by the Secretary pursuant to subsection (b), for which the Secretary determines that biospecimen materials or suitable surrogates or alternatives will support the development, review, and introduction of products for emergency use pursuant to this section, the Secretary shall publish on the internet websites of the Food and Drug Administration and the Centers for Disease Control and Prevention, notification of and a streamlined process for sponsors to access such materials, surrogates, or alternatives.

"(2) The Secretary shall issue guidance regarding the notification and streamlined process described in paragraph (1), including the method for requesting samples, the publication of notifications, criteria for sample availability, use of suitable surrogates or alternatives, and information to be provided by sponsors."

"(3) For purposes of this subsection, a biospecimen is defined as a sample of material, such as urine, blood, tissue, cells, DNA, RNA, or protein, from humans, animals, or plants."

Utilizing EUA Data and Real World Evidence

Section 564 of the Food, Drug, and Cosmetic Act is amended as follows:

(1) In subsection (k), after "RELATION TO OTHER PROVISIONS.—," adding "(1)."

(2) At the end of subsection (k), adding the following:

"(2) Data generated to support an authorization under this section, and real world evidence relating to a device pursuant to such authorization, may constitute valid scientific evidence and shall be considered a least burdensome approach for purposes of submissions pursuant to sections 510(k), 513(f), and 515, and for purposes of meeting other requirements of this Act."

"(3) In the case of a device receiving an authorization under this section for which the Secretary has determined, in accordance with subsection (m), that a laboratory

examination or procedure associated with such device is deemed to be in the category of examinations and procedures described in subsection (d)(3) of section 353 of the Public Health Service Act, such determination shall apply with regard to a subsequent submission pursuant to sections 510(k), 513(f), and 515 of this Act for such device."

Ongoing Availability of EUA-Approved Tests and Other Devices for Post-Emergency Surveillance and Shortages

Section 564 of the Food, Drug, and Cosmetic Act is amended as follows:

(1) In subsection (b), by adding at the end of paragraph (2) the following:

"(C) In considering a determination under subparagraph (i) of paragraph (A), and in considering the appropriate disposition of product under paragraph (B), the Secretary shall take into account the need for, and potential shortages or disruptions in the supply of, products authorized under subsection (a) as a result of the circumstances justifying the declaration under subsection (b), notwithstanding a mitigation of or other change in the circumstances themselves, including the need for ongoing testing to assess the status of or return of circumstances justifying the declaration or otherwise for post-emergency surveillance."

(2) In subsection (f), by adding at the end of paragraph (2) the following:
", or otherwise for use by the healthcare entity or practitioner to which it was provided during such period."

(3) POST-EMERGENCY SURVEILLANCE.—Notwithstanding the termination of the declaration under subsection (b), the Secretary may extend an authorization under this section for a product or products based on a determination that it is in the public interest to continue authorization of such products or to support ongoing surveillance testing of patients, health care professionals, employees, or the general public."

Clarification of CLIA Waivers for Tests Receiving Emergency Use Authorization

Section 564 of the Food, Drug, and Cosmetic Act is amended in subsection (m) as follows:

(1) After paragraph (2), adding the following:

"(3) Notwithstanding paragraph (1), an authorization under this section for an intended use in a setting or settings outside a laboratory certified to perform moderate

or high complexity tests shall be deemed to be a laboratory examination and procedure described in subsection (d)(3) of section 353 of the Public Health Service Act with regard to such settings, without further determination by the Secretary."

(2) Changing "(3) EFFECTIVE PERIOD.—" to "(4) EFFECTIVE PERIOD.—".

Appendix B

AdvaMed has requested that CMS consider the following measures to enhance support for telehealth and telecommunication-based services during the Public Health Emergency and any subsequent transition period:

- CMS should continue to waive strict application of RPM coding requirements, such as the minimum time standards, thereby improving providers' ability to use the codes, for any patient who could benefit from remote services during the public health crisis, and reducing documentation burdens.

- CMS should allow hospitals and providers to be compensated for costs associated with RPM (either through direct/earmarked federal funds or waiver of existing billing requirements).

- In recognition of the vital role respiratory therapists and registered nurses are playing in providing critically needed care, including remote patient monitoring, during the COVID-19 crisis, CMS should develop a new reimbursement mechanism for paying for these clinicians' services during the public health emergency (given these services are not now recognized for separate payment under Medicare statute) and allow Medicare providers to contract and bill for such services under arrangement with external vendors.

- CMS should allow a home health agency to provide disposable NPWT to a patient via telehealth and still meet labeling requirements.

- CMS should add to the eligible telehealth list CPT codes for disposable negative pressure wound therapy (e.g. CPT codes 97607 and 97608), so that patients have access to this medical technology and potentially reducing the number of subsequent therapeutic interventions, future hospitalizations, or physicians visits. Allowing patients to access disposable negative pressure wound therapy through telehealth also mitigates exposure risk for patients and for healthcare professionals.

- CMS should allow range of motion testing, CPT 95851, to be done remotely.

- CMS should encourage States to consider temporarily lifting/waiving in-state nurse licensing and scope of practice requirements for the duration of the emergency so that nurses can work in a centralized location and provide services, including remote patient monitoring, across state lines.

- CMS should include neurostimulation device programming visit coding (CPT codes 95970, 95971, 95972, 95983, and 95984) on the covered List of Telehealth Services. These services are currently covered as a physician service when furnished in the physician's office but can also be furnished in the patient's home through telehealth provided regulatory approval is in place to ensure patient safety. We request that CMS provide expedited telehealth designation for these procedures through its new subregulatory process.

- CMS should add interrogation of ventricular assist devices (VAD) to the list of telehealth services. While VAD interrogation CPT code 93750 references "in-person" (no specific VAD remote interrogation code exists), this procedure may be conducted under the telehealth definition of using real time two-way electronic audio-visual communications to deliver health care services. We recommend that CMS provide expedited designation for remote interrogation using products with regulatory approval for this capability through its new subregulatory process.

- CMS should extend its remote physiologic monitoring flexibilities to cardiovascular remote monitoring services, including pulmonary artery pressure monitoring (e.g., CPT codes 93264, 93295, 93296, 93297, and 93298). This would align with the Heart Rhythm Society COVID-19 Task Force recommendations to perform these services remotely when possible during the PHE.

- CMS should establish coverage for FDA-approved or cleared software-based medical devices and Class I Enforcement Discretion devices as well as information technologies certified by the Office of the National Coordinator for Health IT (ONC), including smart devices, apps, and mobile transmitters that will enable cure, mitigation, treatment, or management of medical conditions or diseases in a home setting during the public health crisis. This would include HCPCS codes for (1) new Category III RPM/telehealth-based technologies that will allow patients to be remotely served by their providers, and (2) Class I Enforcement Discretion devices or technology certified by ONC or regulated medical device products according to section 201(h) of the Food, Drug, and Cosmetic Act for which the software, rather than any hardware, drug, or biologic provides the primary mechanism for the product's clinical effectiveness.

- Given the disruptions and closures of addiction and mental health in-person treatment services during the public health emergency, CMS should, in addition to allowing audio/video based counseling and therapy, provide Medicare and Medicaid coverage for FDA-cleared prescription digital therapeutics for substance use and opioid use disorders and mental health conditions.

- CMS should work with the OIG to clarify whether devices with multiple functions (consumer with medical functions) issued by medical professionals to beneficiaries in federal healthcare programs during the PHE trigger Civil Monetary Penalties (CMP) when they are primarily used for healthcare purposes. In addition, OIG should issue safe harbors during the PHE for potential CMP violations by providers who must issue medical devices (and other connectivity platforms) for purposes of remotely monitoring beneficiaries participating in federal healthcare programs. Medical professionals assume there are potential civil and criminal risks for providing patients with digital medical devices, tools, and connectivity, as they may be construed as improper "beneficiary inducements" under CMP.