AdvaMed
Advanced Medical Technology Association

Ensuring Patient Access to Critical Medical Technologies

AdvaMed companies are singularly focused on doing everything possible to meet the needs of patients, providers, and the workforce to manage the crisis today. Our member companies engaged in the manufacture of ventilators, diagnostic tests, personal protective equipment, and other critical medical technologies, have gone to extraordinary lengths to rapidly increase production capacity.

As you continue to work on the next economic stimulus package, we ask that you consider including a number of important recommendations that will strengthen our nation's ability to fight the current pandemic, build the health care infrastructure for an improved health care system, and ensure that patients can receive the care they need. We recommend the following:

Provider Loans for Capital Medical Equipment: Given the impact on hospitals and providers, those treating COVID patients and those that were impacted by the deferral of elective surgeries, plans for capital equipment purchases have been delayed or eliminated. **Congress should provide $2 billion annually for three years for the purposes of providing *loans* for hospitals and other providers to make capital equipment purchases. This would help providers upgrade medical equipment and help rebuild the medtech infrastructure.**

Limit Beneficiary Copayments for Surgical Procedures Furnished in Ambulatory Surgical Centers (ASCs): Medicare statute caps beneficiary cost-sharing for outpatient hospital care procedures at Medicare's inpatient hospital deductible, currently $1,408. The cost sharing liability for beneficiaries using ASCs for procedures is 20 percent of Medicare's recognized payment for that procedure in the ASC setting. This means that the cost sharing charges for many procedures that are done in the ASC setting can be significantly higher—often multiple times greater—than the capped cost sharing liability for the same procedure in the outpatient hospital setting. ASCs can fill a critical need in providing urgent and emergent care at a time when hospitals are overwhelmed by caring for COVID patients. The higher cost-sharing liability patients face in ASCs should not be a deterrent to receiving care in those settings. **Beneficiary cost sharing during the COVID-19 emergency should be capped at the inpatient hospital deductible, the same level that exists for outpatient hospital care.**

Ensure Access to Innovative Medical Technologies during the COVID-19 Emergency Period: Medicare's New Technology Add-On Program (NTAP) provides temporary additional payments, for a two- to three-year period, to inpatient hospitals for certain innovative technologies that have been approved as meeting three criteria demonstrating that they: (1) are new and different from other technologies available for treating a given medical condition, (2) provide substantial clinical improvement to patients who would be treated with the technology, and (3) have costs exceeding certain thresholds that would result in Medicare's reimbursement

being insufficient to encourage hospitals to use the new technologies. A similar program, known as the Pass-Through Program, exists of outpatient hospital care. The Secretary considers applications for NTAP once a year and for Pass-Through quarterly. **During the emergency period and through December 31, 2021, the Secretary should be required to accept and review for approval/disapproval NTAP and Pass-Through applications on an expedited basis for new medical services or technologies that may offer protection from COVID-19 infection; that may treat, diagnose or otherwise be used for patients with COVID-19 during the public health emergency; or that may promote public health or provide protection for providers of services, physicians, non-physician practitioners and other health personnel after such emergency period. The Secretary would be required to approve or disapprove applications within 30 days of receipt, and for those the Secretary approves, provide the add-on payments within 60 days of approval.**

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 the Food and Drug Administration (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."[1] 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."[2] **The Secretary should 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.**

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.**

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

[2] *Id.*