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AdvaMed
Advanced Medical Technology Association

Statement for the Record
House Committee on Veterans' Affairs Hearing
"New Names, Same Problems: The VA Medical Surgical Prime Vendor Program"
December 4, 2017

AdvaMed is the leading trade association representing medical technology manufacturers and suppliers that operate in the United States. Our members range from the largest to the smallest medical technology innovators and companies. Collectively, we are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

The sacrifice our nation's veterans and their families make on our behalf cannot be understated. We all have an obligation to ensure they receive the highest quality care and have access to the best medical technology available. In particular, AdvaMed and its member companies believe strongly in our collective relationship with the U.S. Department of Veterans' Affairs (VA) and share the Department's goal of providing our veterans with the highest quality health care possible.

There are approximately 8 million U.S. veterans of the armed services accessing the VA health care system, with another nearly 2.3 million currently serving in the military on active duty that may do so in the future. These Americans can experience unique health care challenges, both in terms of battlefield injuries and the after-effects of their time spent in service. Through earlier diagnosis and intervention, less invasive procedures and more effective treatments, medical technology is revolutionizing health care across the continuum of service and enhancing the lives of America's troops in the field and beyond. Technologies include: spinal cord stimulation; joint/limb replacements; wound care products; neurological devices; cardiac technologies; and many others. Through these technologies, our companies can help provide the standard of care reflective of the respect and commitment we owe to our nation's veterans.

However, recent changes in the VA's procurement of these critical medical technologies have created new barriers within the veteran health care system. The transition from the VA's National Acquisition Center (NAC) procurement process to a new national procurement system for medical devices through the Strategic Acquisition Center (SAC), along with the pre-authorization for certain surgical implants, has resulted in significant inefficiencies in veterans

obtaining access to care, a reduction in the quality of health care accessible to veterans, and risks pushing high caliber providers and suppliers of innovative products out of the VA system.

We believe that the VA's effort to reduce catalog items from 475,000 items is appropriate. However, the lack of clinicians in all aspects of this reform and the award process is problematic because it threatens the quality of patients care and also restricts the VA's ability to retain and recruit high quality healthcare providers. The benefit of providing choice with complex medical-surgical products will improve outcomes. Many VA physicians and providers also practice at the 107 affiliated academic health systems and/or the private sector. Clinicians should have access to a responsible number of highly technical tools available to them at a teaching hospital/private facility in the morning as well as at the VA facility down the street in the afternoon. More broadly, the product catalog should be determined according to a thoughtful and detailed process and not simply reduced to meet a "savings" goal independent of any patient outcome consideration.

While the VA has engaged with industry to break down these barriers as they arise, the approaches taken do not consistently result in positive outcomes or solutions. Concerns remain, including:

- The absence of a dedicated, clinically-led and -managed program office for device procurement at the VA has resulted in a significant void in clinical understanding in the contracting process. This gap in expertise means decisions are made without a basic understanding of the medical supply chain and often on a bottom-dollar basis without thoughtful consideration of provider and patient need.
- The Next Generation – Medical Surgery Prime Vendor (NG-MSPV) distribution program has reduced access to the vast majority of medical products currently available while also adding additional costs to the system.
- The overall experience with the migration to this new system is confusing, burdensome and inconsistent with historical contract management practices and efficient medical care.
- The VA is assigning contracts and making procurement decisions based solely on price rather than measuring value as defined by patient outcomes. There is also little to no clinician input.
- The pre-authorization process for certain technologies (such as surgical implants like stents, total joints, spine implants, pacemakers, and others) is increasing the backlog and amount of unpaid purchase orders, creating challenges for vendors who are trying to support VA health care. More critically, these payment delays have impacted veteran access to care, with delayed procedures and inadequate supplies.
- The NG-MSPV program lacks a mechanism for the timely consideration and addition of new technologies to the program.

The overarching concern is that, collectively, these problems have restricted veterans' timely access to critical technologies and quality care, as well as impacted the ability of the VA to attract and retain medical professionals. The Commission on Care, established under the Veterans Access, Choice, and Accountability Act of 2014, raised many of these same concerns in its July 2016 report. In particular, the Commission noted that the Veterans Health Administration's (VHA's) supply chain for clinical supplies, medical devices, and related services is:

> "inadequate compared to…best practices in leading hospital systems. Its contracting processes are bureaucratic and slow, which can delay veterans' access to care. Purchasing processes are cumbersome, which has driven VHA staff to work arounds…"

The recently released Statement of Objectives (SOO) for MSPV version 2.0 appears to outsource the management of the program to a single commercial contractor and shifts significant responsibility from the VA to this contractor. While we applaud the VA for seeking to increase commercial practices, we question whether there is a commercial entity that has the extensive medical background to perform the expansive responsibilities, including: determining what items would be on the formulary; administering the contracts between it and the manufacturers; managing the procurement process; and distributing the actual medical supplies. It is unclear if such a model exists or who can provide such a service.

Our companies strongly encourage the VHA to follow best practice commercial models and make enterprise level decisions through a program office for medical devices, which will improve efficiencies for both the VA and industry. The overwhelming concern of the medical device industry as well as the VA medical centers is that the VHA Program Office is neither clinically led nor staffed with experienced medical supply professionals. It is roughly the equivalent of trying to fly an airplane with individuals who are not pilots.

An effective VHA Program Office would be staffed in similar fashion to other federal agencies that manage medical products: have a clinical leader and clinical staff, mixed with experienced medical supply chain professionals, and preferably all these individuals would have experience working within the VA system and have knowledge of the unique processes. Models to replicate would be the Defense Health Agency (DHA)'s Medical Logistics (MedLog) division, which is the equivalent operation for the Defense Department. DHA MedLog is led by a critical care nurse, and staffed with seasoned medical logisticians and nurses who have actually worked in military treatment facilities. Within the VA, the VA pharmacy benefit manager (PBM) is a good example of what a program office should look like, led by a pharmacist and staffed with clinicians who have experience working in the VHA system.

Meanwhile, delays in resolving purchase orders and eliminating payment backlogs also continue to impact our industry's ability to serve the VHA and our veterans. For current backlogs, the recent move by the VA to initiate a ratification clean-up process provided some relief, but problems persist and a precise schedule for completing work to resolve these issues is needed. More importantly, the VA has yet to issue any guidance to address future concerns or otherwise demonstrate how the Department will prevent these problems from developing again. Without a real prompt pay requirement, such as 30 days from date of procedure, purchase order issues will continue to persist.

We welcome today's hearing as another opportunity to understand on how the VA, Congress, and industry can take a solutions-oriented approach to these issues and work together on the most effective resolution. We support efforts to ensure the VA, Congress, and industry to work together to review and seek ways to better implement processes and to ensure that all procurement policies evaluate technologies based on the value to patients. Ultimately, the most important measure of the success of the VA's new procurement policies is whether the veterans that they serve are getting access to the best medical care in a cost-effective manner.

Again, we are grateful for the Committee's leadership on this issue and appreciate the work of Reps. Banks and Peters in particular. Thank you for holding this hearing and we look forward to continuing to work with Congress and the VA to provide access to high-quality, cost effective medical technology that meets the needs of our nation's veterans.