

**NEW NAMES, SAME PROBLEMS: THE VA MEDICAL
SURGICAL PRIME VENDOR PROGRAM**

HEARING

BEFORE THE

**COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES**

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NEW NAMES, SAME PROBLEMS: THE VA MEDICAL SURGICAL PRIME VENDOR PROGRAM

Thursday, December 7, 2017

COMMITTEE ON VETERANS' AFFAIRS,
U. S. HOUSE OF REPRESENTATIVES,
Washington, D.C.

The Committee met, pursuant to notice, at 10:00 a.m., in Room 334, Cannon House Office Building, Hon. David P. Roe [Chairman of the Committee] presiding.

Present: Representatives Roe, Bilirakis, Coffman, Wenstrup, Bost, Poliquin, Dunn, Arrington, Higgins, Bergman, Banks, Walz, Takano, Kuster, Correa, Sablan, Peters.

OPENING STATEMENT OF DAVID P. ROE, CHAIRMAN

The CHAIRMAN. Good morning. This hearing will come to order. I want to welcome everyone today to the hearing examining VA's Medical Surgical Prime Vendor, or MSPV Program.

And before we get started, I want to just take a moment and remember what happened 76 years ago today at Pearl Harbor in Hawaii, where 2,403 Americans were killed, 1,178 were wounded during the surprise attack on Pearl Harbor. And I had family that—in my family that served there and Hawaii immediately after that. So it is what brought America into World War II. So I just wanted to take a moment and remember that, those lost Americans. And I am sure many of you visited the memorial there and it is really a very moving experience to do that.

I will continue now. Our MSPV is a system of contracts consisting of suppliers and what are called prime vendors that VA has used for over a decade to purchase and distribute medical and surgical supplies in a just-in-time inventory system. The prime vendors handle all logistics in their assigned regions to get supplies to the medical center door. The suppliers provide the items selected by VA to the prime vendors.

Many of you may remember our earlier hearing on the issue in September of 2016. At that time, VA was about to launch the MSPV Next Generation or NG Program. Whereas the older version of MSPV had never sought to limit the medical and surgical supplies that could be purchased, it never saved very much money either. NG is an aggressive attempt to simplify the supply chain and establish a medical surgical formulary containing a vastly reduced universe of products, initially 600,000, now roughly 10,000.

The goal was to leverage VA's buying power with fewer suppliers and items to achieve maximize savings. It was and remains a wor-

thy goal, but the medical surgical formulary represents a huge clinical cultural and operational shift.

Last September, we expressed our reservations that the formulary and its underlying supplier contracts were far from ready. The timeline seemed like a stretch, clinical involvement seemed tentative and belated at best, and only a handful of competitive contracts were in place. Nonetheless, VA launched MSPV NG last December and that launch was rocky. The formulary omitted many necessary products and at the same time included more than a few erroneous items. VA recognized this and decided to keep the old MSPV program in place alongside NG through April.

Since then, physicians, surgeons, and nurses have been put on teams and tasked to review the formulary, which was created with little clinical input. At one point, a group of clinicians was essentially put in a room for a week to concentrate on the task, but the formulary remains troubled. It seems the early decision to concentrate on every group of medical and surgical supply at one time continues to poison the effort.

Meanwhile, a large number of sole-source supplier contracts were put in place to launch the formulary. They were intended to be short-term and replaced with competitive contracts. The competitive contracts remained elusive and VA finds itself continuously awarding new sole-source contracts to replace the old ones as they expire. The prices remain high and the contracting officer's time is consumed by nonproductive activities.

In the midst of these problems with NG, VA recently unveiled a new concept called MSPV 2.0. It entails outsourcing everything, including developing a formulary for every VHA veterans facility to one all-powerful prime vendor. While I absolutely believe there are many functions the private sector is best suited to perform, the 2.0 model as it has been described does not seem to exist in the commercial market. Some things like deciding which medical surgical products it will buy are inherently the responsibility of a health care organization. I am also skeptical that given VA's difficulty in coordinating formulary decisions among all its practitioners an external company would have a better experience.

MSPV has created nervousness and frustration among VA employees, and many of the prime vendors and suppliers for years now, but the volume of complaints has lately become overwhelming.

At the Committee's request, GAO completed a wide-ranging report after reviewing the program for roughly a year, finding continual missteps and difficulties. The Coalition for Government Procurement has also submitted a white paper to VA with recommendations.

I hope through our discussion today we can identify a viable path forward and make MSPV work and stop repeating the same mistakes. Whether we call it MSPV Next Generation, 2.0 or whatever, it has to make operational sense, work for clinicians, and be timely and safe for veterans.

I now yield to Ranking Member Walz for his opening comments.

OPENING STATEMENT OF TIM WALZ, RANKING MEMBER

Mr. WALZ. Thank you, Mr. Chairman, and I concur with much of the Chairman's statement. I would also like to thank him for pointing out today Pearl Harbor. My favorite great uncle, Morris Ryeman [ph], was a fireman in the Navy in Pearl Harbor and it was a source of pride and family oral history about what he did there. So, thank you for that.

Some of you have heard me, those who have been here for a long time, for the last 11 years I had a saying that I am the VA's great advocate, but when need be, I will be their harshest critic. I will be in the harshest critic mode today.

This program was set up for failure from the very beginning due to a lack of commitment and prioritization by senior VA leadership. It appears to be nearly incompetent in how it was done. If I were a conspiracy theorist, I would believe this is an intentional way to undermine the VA to force outsourcing and privatization. It looks that bad, especially when other hospital systems have been able to do it. VA knew about the best practices and chose to ignore them. And I want to be very clear about that: it appears that the choices were made to ignore what needed to be done.

VA's Medical Surgical Prime Vendor Program is clearly worse than it was 2 years ago. I don't know how VA leadership at its highest levels thought an approach to managing this program would be successful.

As the Chairman said, the previous formulary allowed forwarding hundreds of thousands of items by Federal supply, now the formulary contains 10,000 items. That in itself might not be a note of concern, but what the Chairman also said was they don't meet the needs of the providers at the medical centers. They weren't asked. This has forced medical centers to buy supplies with purchase cards through emergency contracts at added cost to taxpayers.

And this afternoon we will talk to the Secretary about needing more money for the VA; that conversation cannot happen in a vacuum. Clinicians and medical centers know their supply needs. Large hospital systems have done this for decades. When you think about the program this way, it is simple in comparison to requiring something more complex like an electronic medical record.

Think about that. We are going to be asked to spend \$16 billion over nearly a decade on the Electronic Health Record Modernization Program. A project of this size with a requirement like that to be interoperable with other health care systems like DoD and community providers has never been done. I certainly support that decision, I have advocated for it for years, but VA's failure to successfully implement the medical supply acquisition programs is simple in comparison to what we are going to be up against. It does not give me a whole lot of confidence that the VA is capable of successfully undertaking that complex acquisition of size and scope.

This all points to a leadership failure. VA's contracting and logistics organizations do not have permanent leadership. The MSPV Program Office lacks a leader, it is only half-staffed. President Trump's hiring freeze prevented an acting director from filling in.

I want to be clear, there were years here that every single VA person who sat there was responsible and was grilled on everything

that the President of the United States did. We have not taken that mode. We have taken a collaborative mode to getting things done, but I will have to tell you, that honeymoon is nearly over. The logistics contract program officers do not communicate and coordinate their efforts or work with stakeholders. The program has never had a strategic plan.

This program was set up to fail and I want to hear today why that is not the case. VA has the potential to save at least \$150 million, if it is done right. VA has enormous buying power it can leverage to negotiate lower prices by buying in bulk. Instead, it has caused more of a burden for providers. Contracting and logistics staff made it difficult for suppliers to do business with VA.

VA could have done this properly by getting buy-in from its doctors, nurses, and clinical staff, the employees who provide care to veterans. Instead, VA cut corners and incorrectly assumed that orders of previous supply purchases met the needs. Medical centers were left in the dark about the formulary rollout and suppliers chose not to participate because doing business with VA was vastly different from how the medical supply industry does under industry standards. VA had to cancel the rest of the contract solicitations because of low supplier participation.

VA knows what practices and best practices of their hospital systems follow. Instead, it overestimated its ability to successfully implement the program, and did not provide the leadership, staffing, and resources needed to make the formulary a success. Without Government's leadership and buy-in from the stakeholders, VA's programs will continue to fail.

I want a commitment today from VA that it will take immediate action to turn this program around. This program needs bold leadership. A lot of work will need to be done to get provider buy-in. The same old way of managing won't work.

I would suggest this: how about start small? Find one category of supplies and use it as a beta test through your process to developing the formulary. Involve the providers and medical centers, solicit feedback from suppliers, include other stakeholders, apply lessons learned to the next category of supplies, and work to build the formulary right. This is Project Management 101 and it is also what DoD told you to do.

This Committee is committed to ensuring VA is capable of providing world-class care to veterans and we are committing to helping VA get this effort right. And I want to thank the Chairman for once again being dogged on this issue, continuing to follow up, and making it clear that anything less than world-class won't be accepted.

I yield back.

The CHAIRMAN. I thank the gentleman for yielding.

I would now like to welcome our panel who are seated at the witness table. On our panel we have Mr. Ricky Lemmon, the Acting Chief Procurement and Logistics Officer for the Veterans Health Administration. Welcome. He is accompanied by Mr. Phillip Christy, Acting Executive Director of the Office of Acquisition Operations. Welcome.

Finally, we have Mr. Roger Waldron, President of the Coalition for Government Procurement. And we also have Ms. Shelby Oakley, Director of Acquisition and Sourcing Management at GAO.

If you would, I will ask the witnesses to stand and raise your right hand.

[Witnesses sworn.]

The CHAIRMAN. Let the record reflect that the witnesses have answered in the affirmative.

Mr. Lemmon, you are recognized for 5 minutes.

STATEMENT OF RICKY LEMMON

Mr. LEMMON. Good morning, Chairman Roe, Ranking Member Walz, and Members of the Committee. Thank you for the opportunity to discuss VA's Medical Surgical Prime Vendor Program and the related Government Accountability Office report.

I am accompanied by Mr. Phillip Christy, Associate Executive Director of the Strategic Acquisition Center.

VA is committed to providing our veterans the best care available, while being good stewards of taxpayers' dollars. Part of meeting these commitments is making sure that our medical centers have the right supplies and equipment to deliver the care our veterans need.

In the mid-1990s, VA eliminated its in-house depot system and converted to a commercially-sourced med-surge prime vendor program to provide medical and surgical supplies.

The primary source of supplies for previous generations of MSPV contracts were the Federal Supply Schedules. This approach resulted in our hospitals having access to a clinically viable selection of supplies, but this operational model did not facilitate clinical product decisions on a national level that would allow VHA to leverage its purchasing power. Adoption of clinically-driven strategic sourcing is VA's objective under the existing med-surge prime vendor contract and any future med-surge prime vendor contracts.

The current MSPV contract was conceived in part to leverage VA enterprise-wide purchase volume in order to drive lower prices and improve product quality through the development and use of a national catalog of products. While VA is committed to providing our veterans the best care available, we must do so while also being good stewards of taxpayers' dollars. To achieve this, we must ensure that our medical centers have the right supplies and equipment to deliver the care our veterans need.

In 2016, VA announced the award of four MSPV contracts. Product prices were primarily established by negotiated blanket purchase agreements against FSS contracts, VA national indefinite delivery contracts, and local contracts to support veterans integrated service networks. VA has decided to move forward with either modifying the current contracts or development of replacement contracts to rectify many of the issues identified by the GAO report.

An acquisition plan has not yet been finalized for replacement of MSPV. VA is exploring a different approach to MSPV where potential prime vendors can propose a full catalog of medical and surgical products. This would depart from the current approach where individual contracts are negotiated with each supplier.

The potential benefits of MSPV replacement, known as 2.0, would be a more robust catalog of items than we have today and lower prices. Additionally, the administrative resources and time required to negotiate hundreds of individual contracts would be reduced if VA only negotiated with the prime vendors.

There have been multiple meetings with industry leaders to obtain feedback regarding this approach to MSPV 2.0 and that feedback is currently being considered. Feedback will also be obtained from VA clinicians before any final decisions are made.

This is why our efforts to make the current MSPV contracts more robust are important. We want to make sure the needs of our medical centers are met while we develop a better approach to MSPV. In GAO's recently released report, they made ten recommendations concerning our current MSPV management processes and VA has already begun to institute each of them.

VA seeks to continue to provide our veterans with the timely care they have earned and deserved, at the same time we are seeking new and innovative ways to be more responsible stewards of the taxpayers' dollars. We are grateful to GAO for their report and to the Committee for their commitment to helping the Department improve.

I look forward to responding to any questions you may have.

Thank you.

[THE PREPARED STATEMENT OF MR. LEMMON APPEARS IN THE APPENDIX]

The CHAIRMAN. Thank you.

Ms. Oakley, you are recognized for 5 minutes.

STATEMENT OF SHELBY OAKLEY

Ms. OAKLEY. Good morning, Mr. Chairman, Ranking Member Walz, and Members of the Committee. Thank you for having me here today to discuss VA's implementation of its Medical Surgical Prime Vendor Next Generation Program, which I will call NG.

NG is VA's primary means for purchasing the supplies to meet the needs of its 170 medical centers that serve almost 7 million veterans. Some of the goals of NG are to standardize requirements for greater clinical consistency, leverage VA's substantial buying power to achieve cost avoidance, and provide greater efficiency in supply chain management.

Effective supply chain management is an essential element of delivering quality care to veterans. Recently, the VA IG found supply management issues at the D.C. VA Medical Center that posed risks to patient care. Our past work suggests that VA's confusing and outdated procurement framework compounds issues like these and leaves the department without a sound basis for effective and efficient procurement activities to support patient care.

As the Chairman mentioned, we released a report a few days ago on NG. We found that VA underestimated the significance of the change and lacked an overarching strategy, stable leadership and the workforce capacity that, if in place, could have facilitated buy-in for the change. These shortcomings, among others, have kept VA from achieving the goals of the program to date.

Today, I will discuss three topics from that report: first, the challenges that VA faced in setting up NG; second, the effect these challenges had on the medical centers' use of the program; and, third, VA's efforts to address shortcomings in its future plans.

First, I would like to point to a graphic that you might have seen in our report. It identifies practices that leading hospital networks follow in managing their supply chains which have resulted in significant cost savings and improved patient care. These practices include prioritizing categories of supplies based upon the likelihood of cost savings, working closely with medical staff to identify the right supplies to buy, and awarding competitive contracts to achieve the best prices.

VA did not follow these same practices when implementing NG. It did not prioritize which categories of supplies to focus on first or work closely enough with medical staff. For example, VA developed its formulary based almost exclusively on flawed data on prior purchases and not on input from medical staff. This flawed approach for determining what items to buy led VA to take actions directly in conflict with the goals of the program and the practices of leading hospitals. For example, VA resorted to noncompetitive agreements for 79 percent of the items on the formulary to meet its December 2016 date to get NG up and running.

Given how far VA strayed from leading practices in setting up the formulary, it should come as no surprise that the items on the formulary did not meet the needs of the medical centers or enable the Department to leverage its significant buying power.

VA has taken some steps to address the shortcomings with the rollout of NG, but continues to struggle with implementation. Specifically, VA included medical staff in its second round of requirements development. However, it relied on just a small group of medical staff to review more than 4,000 products in 1 weeks' time representing almost half of the formulary. This approach limited their ability to standardize requirements for the formulary.

VA is likely changing its approach to MSPV yet again. It is considering hiring a prime contractor not only to provide distribution services, as they do now, but also to develop and manage the formulary. Many details remain unclear with VA's new approach, but it wouldn't be safe for VA to assume that simply changing its approach will solve the challenges it encountered thus far.

We recommended several steps that VA could take to overcome some of these challenges such as developing and communicating a consistent strategy for NG, prioritizing efforts by supply category, involving medical staff every step along the way, and ensuring stable leadership at all levels of the effort. NG could save both money and enhance services to veterans, but only if VA can get the execution right. Until VA takes steps to address some of the challenges we identified in our report, it will continue to struggle with implementation.

Mr. Chairman, Ranking Member Walz, this concludes my remarks. I am happy to answer any questions you have.

[THE PREPARED STATEMENT OF MS. OAKLEY APPEARS IN THE APPENDIX]

The CHAIRMAN. Thank you, Ms. Oakley.

Mr. Waldron, you are recognized for 5 minutes.

STATEMENT OF ROGER WALDRON

Mr. WALDRON. Chairman Roe, Ranking Member Walz, and Committee Members, thank you for the opportunity to appear before you today.

The Coalition is a non-profit association of small, medium and large business concerns representing more than \$145 billion in annual Government sales, including more than \$12 billion in medical surgical products and pharmaceuticals supporting veterans' health care. Today my remarks summarize my written testimony, which I ask be included in the record.

The Prime Vendor Program serves as the brains of the VA's logistic operations because it touches essentially all critical VA health care operations and contractors. It is responsible for developing and communicating the med-surge formulary and thus serves as a bridge connecting requirements holders, the VISNs, hospitals, and health care providers serving veterans, and the VA procurement professionals and contractors.

Given this critical role, it is imperative that the Prime Vendor Office be led and managed by clinicians. A clinical-led program office is a fundamental commercial best practice and it is our understanding that the MSPV Program is the only medical supply chain in the VA and DoD that currently is not led by either clinicians or medical supply chain experts.

This structure has contributed increased inefficiencies and generated medical care concerns. Our members are seeing an incomplete formulary, which causes supply shortages, leaving facilities with no choice but to purchase items on the open market, often at sub-optimal prices.

Clinical leadership will result in well-defined requirements, thereby avoiding these problems and supporting delivery of best-value health care. Without this leadership, many of the challenges of the Prime Vendor Program will continue into the next generation with strategies and decisions that too often are driven primarily by acquisition process needs rather than veterans' health care needs.

Turning to the next iteration, the MSPV 2.0 essentially envisions outsourcing the program to a single super prime vendor that would determine what the agency buys and how the items sought will be sourced. The super prime vendor would develop the formulary, manage and distribute items, administer subcontracts, and ensure quality control. Nationwide electronic ordering and invoicing would be facilitated using the super prime vendor's e-commerce platform. Coalition members report no comparable commercial model that delivers the extensive scope of management services and med-surge items contemplated by 2.0.

Although our members support improving the Prime Vendor Program, the 2.0 initiative has generated significant confusion. With the needs of more than 9 million veterans in the balance, the Coalition believes that prior to any decision to shift to a new commercially untested platform, the VA should undertake a thoroughly vetted and methodical approach with ongoing evaluations over time to ensure success.

We also note that the 2.0 vision would give rise to an inherent business conflict as one company would be responsible for both developing the formulary and delivering the items listed on it. The Coalition is concerned that this structure risks incentivizing contractor formulary decisions based on vendor financial incentives rather than best interest of patients.

Similarly, the current proposal stipulates that cost savings will be a significant objective for the 2.0 program. If this objective translates into low cost technically acceptable veterans' care, however, it would be inconsistent with the VA's mission, the expectation of our veterans, and the interests of the American people. For this reason, Coalition members also believe that the VA must clearly assert that value, not low price, is the objective when acquiring medical equipment and supplies for our Nation's veterans.

Finally, we are concerned that by focusing on a single-vendor approach, the 2.0 proposal fails to adequately leverage competition necessary to bring innovation to our veterans' health care. Further, 2.0 places no discernible checks on the super prime vendor; rather, it cedes inherently governmental discretion and authority to a private entity. From a program perspective, vesting a single contractor with too much authority has negative implications for Government and industry regarding market power, the Government's ability to replace a non-performing prime vendor, and the ability of the private sector, including service-disabled veteran-owned firms, to either contract with the VA directly or be subcontractors to the super prime vendor.

The Coalition believes that there is a path to success here, starting with assuring that the Prime Vendor Program Office is led and managed by clinicians; that inherently governmental decisions are not outsourced to a super prime vendor; that conflicts of interest are avoided; and that market competition is leveraged appropriately to access innovation for veterans.

Chairman Roe and Ranking Member Walz, thank you again for the opportunity to address the Committee, and I look forward to answering questions.

[THE PREPARED STATEMENT OF MR. WALDRON APPEARS IN THE APPENDIX]

The CHAIRMAN. Thank you, all of you all, and for remaining within the 5-minute timeframe. I will try to do the same and I will start the questioning.

And just sort of open that large medical centers do this all the time. This is not putting the Voyager III up. This is how we as clinicians are able to practice every day. The vendors and the hospital provides the products and tools necessary for us to provide care and do our jobs.

Just the first question, Mr. Lemmon, has the VA had cases, surgical cases cancel because of a lack of needed equipment?

Mr. LEMMON. I probably have to take that question for the record. I do believe there has been a very small number, but I would want to research that and get back with you.

The CHAIRMAN. That's fair enough. I know we have heard that there have been cases cancelled.

In my 31 years of practice, I was trying to remember as you all were testifying, I don't ever remember a case being cancelled because I didn't have the supplies I needed to do the case. We knew ahead of time, unless it is an emergency, and those cases were scheduled a week, 2 weeks, 3 weeks, a month ahead. The surgical team and the hospital team went right ahead and made sure I had every bit of equipment. I have had the surgical nurses call me and say, Dr. Roe, do you need this, this, and this before this procedure, and we would go over that ahead of time.

And that is why clinicians have to be involved in this, because they are the only ones that know when they are in those situations what tools they need. And I don't expect someone else to know that, but I do expect them to ask me, so that they can—that you in the supply chain can provide it for me.

I think that the other question I have, the second question I have is, who decided—and I am not necessarily saying this is bad, but who decided to go with a program that has never been done with an organization that doesn't exist?

Mr. LEMMON. Well, that decision, it has not been made.

The CHAIRMAN. So, the 2.0 is not—I mean, I am not saying it is bad, I am just asking the question.

Mr. LEMMON. Yeah, it is a concept that is being explored, but there has not been any decision to go forward with 2.0.

The CHAIRMAN. Okay. So during this exploration, what exactly is VA doing to—because this is critical for patient care, there is no question, and I know there is a lot of work that goes on behind the scenes before I show up gowned and gloved in an operating room, getting ready to make an incision.

So is the system that we have gone to, we have gone from 500,000 different items on there to 10,000 or so items on there, are the clinicians, the nurses, the providers being given in a timely fashion the tools they need to do their job?

Mr. LEMMON. Generally, the answer is yes, but because of the limited formulary it is not being done nearly as efficiently as it could be. So, there is an imperative on the part of our office working with clinicians and the strategic acquisition center to make the formulary more robust.

The CHAIRMAN. I know how—and, Ms. Oakley, I want to ask you this question, because my time is running out, can you explain how the formulary was developed and ultimately who makes the decision about who is on there? That is Ms. Oakley.

Ms. OAKLEY. Sure. As I understand it, VA began the formulary development effort by running what is called a spend analysis on purchase data, supply purchase data. And documentation that I have seen indicates that this was deemed sufficient to have clinical input, because the physicians and clinicians voted with their dollars by making prior purchases. Unfortunately, what wasn't recognized was that this data wasn't the best data to use and it didn't reflect all the things that the medical centers needed to use on a daily basis.

And so that provided the basis of the initial formulary and the logistics office began writing requirements based upon that spend analysis with limited input from clinicians. And what resulted was

more manufacturer-specific requirements than general requirements that more than one manufacturer could meet.

The CHAIRMAN. So this was basically built from the top down—
Ms. OAKLEY. From the top down.

The CHAIRMAN [continued]. —not the bottom up?

Ms. OAKLEY. From the very beginning, the faulty process from the very beginning kind of flowed down throughout all of the subsequent actions that impacted how useful the formulary was.

The CHAIRMAN. This would have taken some time, but if I had been building that model, I would have done it just the opposite. I would have gotten that information, but I would have gone down to my clinicians and said, what do you need to do your job? On the nursing floor and whatever. And then I would have built it up this way medical-center-by-medical-center and then seen how that data meshed.

Would that seem reasonable?

Ms. OAKLEY. That is in fact what we found when we talked to leading hospital networks is that the basis of all of their efforts is involving clinicians and including them from the very beginning as a part of the process.

The CHAIRMAN. Thank you. My time has expired.

Mr. Walz?

Mr. WALZ. And thank you, Mr. Chairman.

I would like to associate myself with the Chairman's question about have there been delays, affected patient outcomes, cancelled medical procedures, or other issues to patient access. So if you would take questions too, I would like both of us to be addressed by this.

For all the members who are new here, again, this Committee, we have addressed this before. And we said in here and I listened to the testimony a year and a half, 2 years ago, and the abject failure of President Obama and Secretary McDonald to fix this program, we were going to do something about it. Here we sat, it is right here.

Now, keep in mind that the suggestion to be made is to allow the private sector to fix it. There is no one in the private sector to do this.

So, this is our responsibility, these are questions that have been brought up before, this is—as I said in my opening statements, there is an abject failure in leadership to get this right. We are going to get responses back that there were adverse impacts on veterans, so I fully would expect the outrage to be equally strong as it was 2 years ago when we talked about this as it is today. And at this point in time, I think what is different is, we are going to look for some answers on how to fix that.

So, if it is a lack of leadership, how come we don't have anybody in leadership positions in the Procurement and Logistics Office, Medical Surgical Prime Vendor Program office, and, more importantly, the Chief Acquisition Officer; how come that is not filled, Mr. Lemmon?

Mr. LEMMON. Well, the Chief Acquisition Officer, that was filled by Greg Giddens was Acting, he just retired at the end of November. With the Chief Procurement and Logistics Office position, I know that leadership is looking at that.

I think part of the modernization effort in determining how those functions would be aligned within the Department has kept from making a decision to permanently fill that position or recruit it, but it does need to happen. I have been acting for some time.

We also are recruiting the program manager for our health care team that will oversee Prime Vendor, that announcement is on the street. We have had prior attempts that were unsuccessful to hire that position. We have also had some hiring freezes that we have dealt with, but—

Mr. WALZ. So what exactly does that mean? We are not getting supplies to people, we have veterans waiting. Did you just tell me one of the potential reasons is because we have a hiring freeze that does not allow us to fill those positions?

Mr. LEMMON. Within our program executive office structure where those positions that will do this work, we have been impacted by a hiring freeze at the headquarters level with those key positions. We have attempted to recruit the Health Care Commodities Program Manager and that position is now being advertised again.

Mr. WALZ. Well, that is pretty disconcerting and I would hope there would be a concerted effort by this Committee to get to the bottom of that and to address that. It is simply not good enough to say we are going to cut Government freeze positions and get rid of them. When that initially came out, we had to start backing away from it. Oh, yeah, we will get the doctors. And then we said, well, what about the emergency room nurses? Oh, yeah, we will get the emergency room nurses. And then we said, what about the people who wash the sheets? Oh, yeah, we will take them off the freeze. You fall into that chain too. Everybody plays a role in this.

So this lack of leadership position, I would go back, Ms. Oakley, with my remaining time, you said that this new approach won't solve the problems. We are piloting this, you heard that, it is not on the street yet. Is there a retool to this or is this the wrong approach in general of what is being described with the Prime Vendor, the 2.0? Or should we retool and go back again, as I think the Chairman clearly and I think adequately said we are building at the wrong direction?

Ms. OAKLEY. I think fundamentally the concept of MSPV NG as it stands now is solid, it was the execution that fell down. So I am not necessarily convinced that a complete reboot of the approach is necessary, especially given that some of the steps that VA could have taken to better implement the program are, you know, fairly common steps: include the clinician, communicate a strategy, make sure everybody understands their role in implementing this change.

And I think, just to comment on the leadership, this is a huge shift for VA to an NG program and when you are talking about leadership vacancies from the CAO on down to the program office in the height of the transition to this new program, it is no wonder that there wasn't a captain steering the ship at this point—

Mr. WALZ. Yes.

Ms. OAKLEY [continued]. —and it went a little off course.

Mr. WALZ. Yes, very well said.

I yield back.

Mr. BILIRAKIS. [Presiding.] Yes, I recognize Dr. Dunn for 5 minutes. Thank you.

Mr. DUNN. Thank you very much, Mr. Chairman.

Let me start out by saying that I share the outrage that Mr. Walz has expressed. I am a surgeon and I have worked in a lot of hospitals, a lot of different systems, there are so many errors in judgment in the implementation of this that it takes your breath away.

I want to start with a concept. The concept I want to start with is, you may delegate authority, but you may not delegate responsibility. Now, that is true in the military, it is also true in business, and it is certainly true in surgery. You know, the surgeon is the captain of the ship, he can authorize people to help him do different things in the operation and around the room, but he takes responsibility for it. And that certainly is true in any system of business and the VA included.

So, remember, please remember that when we start talking about these super prime vendors and prime vendors and we are pretending like they are the ones whose responsibility it is to make this system work, it is your responsibility to make it work, and they are set up for failure. And they also set up and inveigled to do things that I think were certainly odious and bad behavior, but maybe illegal, and I want to ask you specifically about that.

It was said that some prime vendors improperly, improperly substituted their own products for products that were offered by the contracted suppliers. In this context, does improper mean illegal, or does it just mean odious and wrong and bad behavior? Certainly there is a tort there; is there a crime?

Mr. Waldron, maybe you can answer that best.

Mr. WALDRON. That is a tough question. I think it would go back and depend on the nature of the transaction, and the agreement between the prime vendor and the hospital and what was actually ordered. If items are substituted for a brand name that was specifically ordered, then that would be an issue and that would be a problem under that particular contract.

Mr. DUNN. Yeah, we can't litigate it here, but you—

Mr. WALDRON. Right.

Mr. DUNN [continued]. —get the sense, this is wrong. I mean, it is very wrong behavior. And to then turn around and suggest that what we do is to concentrate all of this power in one of these super, super prime vendors is an appalling idea.

Ms. Oakley has said she thought that the MSPV Next Gen, I guess, is a good idea, but failed in execution. Do you agree with that, Mr. Waldron?

Mr. WALDRON. I do believe that the prime vendor program is foundationally a solid approach. DHS and DLA are successfully managing prime vendor programs right now. On the pharmaceutical side, the VA has run a very successful prime vendor program. It goes back to execution and it goes back to people. You can't underestimate the importance of people.

And the last thing I would just make that is kind of interesting. When I read the GAO report, one thing that struck me that just is the terminology used, for example, to identify the program office responsible for the formulary, it was the Health Care Commodity

Executive Program Office. That term “commodity” I think again sends a message that these things are all interchangeable, that it is like pens and paper.

Mr. DUNN. Well, we know as clinicians that they aren’t interchangeable.

Mr. WALDRON. Right.

Mr. DUNN. There are very, very subtle, but important differences in many of the different medicines and tools we use.

Is the VA capable of implementing another prime vendor program, this one that would work, your opinion, Mr. Waldron?

Mr. WALDRON. They have a long way to go. They need to put in place a clinician-led program office with medical supply chain experts to execute this, that is first and foremost. It boils down to requirements development: if you don’t have sound requirements development, you can’t support the health care providers who are serving our veterans. They need to put the people in place.

I think the jury is out. We have spent—our members have spent the last two years, you know, trying to execute—

Mr. DUNN. But the timeline on this is years, it is always years and years, and veterans are dying and being injured by us in each of those years. I mean, we can’t be measuring time in years.

And I want to ask you one more in the few seconds left to me. We are all familiar with group purchasing organizations; in what way is this very different from a GPO, the MSPV?

Mr. WALDRON. In a certain sense, it is similar with their idea of they are trying to leverage their requirements across hospitals and get better pricing, and consistency and tiered pricing. In that sense it is very similar, from my perspective; it again goes back to the execution. I think there is a way forward, we do believe there is a way of forward, but it starts with putting clinicians in place to manage the formulary—

Mr. DUNN. Well, thank you for ending it, because my time is expired, ending with the clinicians, though. And, please, I beg you, go back and talk to your doctors, I mean, you have to do that.

Mr. Chairman, thank you. I yield back.

Mr. BILIRAKIS. Thank you, Dr. Dunn.

Mr. Takano, you are recognized for 5 minutes.

Mr. TAKANO. Thank you, Mr. Chairman.

Mr. Lemmon, the GAO report highlighted challenges with staffing and I want to associate myself with Ranking Member Walz’s comments about the hiring freeze. As we know, President Trump’s hiring freeze did not exempt acquisition and logistics personnel. And I want to just drill down into how this hiring freeze affected staffing at the Medical Surgical Prime Vendor Program Office, and staffing in the Procurement and Logistics Office, and in key logistics and leadership positions at the facility and network level.

What actions—I want to get into this—what actions have been taken to fill the 16 unfilled positions at the MSPV Office, Program Office?

Mr. LEMMON. Well, many of the positions we have received exemptions where we can recruit those positions and are working to do that. At the network level in the field—

Mr. TAKANO. How many of those positions have you received waivers to fill, waivers from the hiring freeze out of the 16?

Mr. LEMMON. I would have to get back to you.

Mr. TAKANO. So you don't know that number, you will get back to us on that. Thank you.

And how many of those positions have been filled of the 16?

Mr. LEMMON. I would have to get with you with that number.

Mr. TAKANO. Okay. And can you tell me, is there a timeline on when these positions will be filled, is there a goal? And how many of them would we intend to fill? Well, you don't know how many have been exempted, so you really can't answer that, right?

Mr. LEMMON. I can't answer it today.

Mr. TAKANO. Okay. I want to clarify, did the hiring freeze adversely affect patient care, in this particular instance?

Mr. LEMMON. You know, having an inefficient supply chain does impact logistics in the hospitals as far as their ability to order the products efficiently. Certainly, they do have ways to do purchases outside of the Med-Surge Prime Vendor, but I won't say there has not been any negative impact to veteran care, because this does touch veterans' care.

Mr. TAKANO. So at the very least it could have significantly affected veterans, patient care of our veterans.

Now, I want to expand upon, I mean, I appreciate Dr. Dunn's question, I wish he hadn't used the acronyms, because what I think he was asking is can you compare the VA's Pharmacy Prime Vendor Program, I think he used the acronym, to its Medical Surgical Prime Vendor Program? So these two programs, one is the vaunted pharmacy program. And we know the VA has the ability to negotiate, unlike Medicare, I mean, this huge volume, the VA is able to negotiate with the pharmaceuticals, unlike other Government programs, right?

So the question was, is there a comparison between the two, because we are obviously purchasing medical surgical supplies through also a similar situation? Can best practices from the pharmacy prime vendor program be applied to the MSPV Program?

Mr. LEMMON. We believe they can, particularly in the area of program management and developing the requirements area. Pharmaceuticals are different in some respects than med-surge items, but there are certainly lessons that we can learn from our prime vendor program.

Mr. TAKANO. Well, is the development of a medical surgical supply formulary potentially more complex, is it more complex than a pharmacy procurement?

Mr. LEMMON. I believe that it is.

Mr. TAKANO. Therefore, it would mean that we would have to have very good managers, very good personnel, and these are the vacancies that I am alluding to. If it is more complex, even more important to have people staffing the program.

Mr. LEMMON. I agree with that.

Mr. TAKANO. I am puzzled as to why it has not been a bigger priority, especially when we talk about surgical supplies and the timeliness of acquiring them, you know, impacting on when these surgeries can be scheduled. And it would seem to me that this is kind of an all-hands-on-deck emergency situation, that these positions should be filled and they should have been filled a long time ago.

All right, that is all the questions I have, sir. I yield back.

The CHAIRMAN. I thank the gentleman for yielding.
General Bergman, you are recognized for 5 minutes.

Mr. BERGMAN. Thank you, Mr. Chairman.

I will get to the point very quickly and I will keep my questions short, you keep your answers short. How's that?

Mr. Lemmon, does a strategy document exist for developing the Med-Surge Prime Vendor Program?

Mr. LEMMON. The—

Mr. BERGMAN. Does the document exist? Do you have a strategy? Did somebody within the VA develop a strategic plan, with a mission statement and the strategy that follows?

Mr. LEMMON. There were documents—

Mr. BERGMAN. Is there a document that exists that you are working from today? Yes or no?

Mr. LEMMON. Is there one document that lays out succinctly—

Mr. BERGMAN. Is anybody in charge—

Mr. LEMMON. Yes.

Mr. BERGMAN [continued]. —of this over there? Who?

Mr. LEMMON. We do have—

Mr. BERGMAN. Who?

Mr. LEMMON. We do have acting people in charge.

Mr. BERGMAN. If you are acting, you are still in charge.

Mr. LEMMON. Right.

Mr. BERGMAN. Are you in charge?

Mr. LEMMON. I am.

Mr. BERGMAN. Okay. Does a document exist that you use on your desk, a reference when you are making sure those under your charge who you are leading and making progress in this programs, that there is a reference document that guides you in your decisions in your leadership role?

Mr. LEMMON. We do have a supply chain transformation document that touches multiple areas, but if you are talking about MSPV—

Mr. BERGMAN. We are talking about a specific program here that does not exist, because it hasn't been developed. Is there a document?

Mr. LEMMON. I am not going to say there is a specific document—

Mr. BERGMAN. Okay. Well, I would suggest maybe you consider it if you are going to be successful in creating one. All right?

Now, I am going to give you an example. By the way, in a former life before Congress—is this uncomfortable? It is, isn't it? It is uncomfortable for me too. It is uncomfortable for all of us here, because there are a lot of veterans in the room who potentially could suffer the consequences of bad decisions at the administrative and deliverables level. Okay? We have great clinicians doing the job, we are not backing them up on the business side of it, not the clinical side. All right? So that is, if you sense a little edge on my part, your sense is correct.

Let me just give you an example. Okay? Because a lot of things are near and dear to my heart, and I just a couple of weeks ago was up at Walter Reed for a, you know, procedure that gentlemen and ladies of my age are recommended to get. Okay? And it is a little uncomfortable at times. You know, in the medical business,

we look for new products. I was in the medical products business for a long time and have dealt with the VA. But, for example, there is a product available that is used throughout the industry for colon-rectal screening, VA doesn't use it. It makes things simpler.

Can you give me an idea for new products, without guidelines driven by clinicians and validated through the industry through others that are already using the products outside the VA system, so any other hospital, have we created a barrier to introducing quality products that are going to allow our veterans to get better care?

Mr. LEMMON. Well, we certainly have to have a more robust involvement with clinicians, so they can inform our decisions on what products would be on a formulary and available for ease of purchase in the hospitals. Certainly at the hospital level there are ways to procure items that any doctor may feel like they would like to have.

So, you know, I wouldn't say we have a barrier, but we can certainly—

Mr. BERGMAN. Okay. Do you have a sense of urgency?

Mr. LEMMON. We do.

Mr. BERGMAN. When are we going to see it?

Mr. LEMMON. We are developing a plan.

Mr. BERGMAN. Is anybody in the hierarchy, the wire diagram—and I know my time is running out here—in the wire diagram who has been responsible for developing this new program, has anybody in that, again, wire diagram been paid a bonus?

Mr. LEMMON. I don't know.

Mr. BERGMAN. I would like to find—I would like to know.

Mr. Chairman, I yield back.

The CHAIRMAN. I thank you the gentleman for yielding back.

Ms. Kuster, you are recognized for 5 minutes.

Ms. KUSTER. Thank you, Mr. Chairman. And thank you to our panel for being with us today.

With my colleague General Bergman, who is the chair of the Oversight and Investigation Subcommittee, I am the Ranking Member, you can imagine that we take this role very seriously. I am sorry that you are the person in the hot seat today, but I do have to remind you that you are under oath and these questions are very serious for us.

We are here to represent the balance of the well-being of our veterans and the well-being of our taxpayers, and we constantly are faced with this dilemma. But I have to say, joining the comments on both sides of the aisle from our colleagues, that we swung and missed in a big way on this project, because not only have we put veterans' care at risk, which is our first and foremost goal, it sounds to me as though we have also cost the taxpayers. And you have talked about these purchase cards that are used. I know for a fact that that is not the most efficient, effective, or frugal way to go about making these decisions.

So my concern—and you have had a lot of people ask you if veteran care was compromised—in my view, I want you to include when you come back with that answer to this Committee veteran care that was delayed was likely compromised, because treatment that is delayed is treatment that may be denied, and I think that

is our concern. And you can tell it is not partisan, but this is simply unacceptable.

And what I want to focus in on is the impact of the hiring freeze, because this may be the first time that this Committee has heard that veterans' care is compromised, the quality of care, the timeliness of care, based on that hiring freeze. So could you just state for the record how the hiring freeze has affected staffing at the MSPV Program Office, staffing in the Procurement and Logistics Office, and in key logistics and leadership positions at the facility. And once, for the record, could you state has patient care been compromised due to a hiring freeze?

Mr. LEMMON. Well, certainly over the past year there have been delays in hiring because of the freeze. Certainly we don't have as an efficient of a supply chain as we need right now and not having key leadership positions or a more robust staff has impacted that.

I do believe that hospitals have ways to get the products they need, we need to make it easier for them to get the products and assure taxpayers are getting good value when those—

Ms. KUSTER. And would you agree—and I am sorry to interrupt, I want to hear the rest of your answer, but would you agree that using these purchase cards is not the most effective, efficient, and frugal way to go about making those purchases?

Mr. LEMMON. I completely agree with that. It is really more of a last-resort approach. We need a very robust catalog of products that can be efficiently ordered by an ordering officer at a hospital and delivered through the prime vendor program for med-surge supplies.

Ms. KUSTER. So, Mr. Lemmon, can I ask you, what is the next step for dealing with this hiring freeze? And I would like to work with our Committee chair, I am asking our Committee chair to work with the Trump administration, how are we going to guarantee that our veterans receive the highest quality of care in the timely manner that they deserve and how are we going to get around this hiring freeze to make sure that that gets accomplished?

Mr. LEMMON. Well, we do have a process to request waivers, which we have done and we have received—

Ms. KUSTER. Would it take legislation for you to—I mean, the waiver doesn't seem to be an effective process here. I am trying to look at how we could make sure that this procurement is included—or excluded from the hiring freeze. This is important; this is the quality of care that our veterans receive and it is being compromised. Would that take legislation?

Mr. LEMMON. I don't believe so. I believe that those positions can be approved for hire.

Ms. KUSTER. My time is up. I would direct that question to the chair, if I could, for a response going forward on how we get around this problem.

Thank you.

The CHAIRMAN. I will try to get that response to you by tomorrow. How's that?

Ms. KUSTER. Thank you, Mr. Chair. I yield back.

The CHAIRMAN. I thank the gentlelady for yielding.

Mr. Banks, you are recognized.

Mr. BANKS. Thank you, Mr. Chairman.

Ms. Oakley, the GAO report mentions a, quote, “lack of leadership stability,” end quote, at the VHA program office, but no mention of what actual qualifications VHA leaders need to possess in order to be able to effectively lead a medical surgical program office. So what is your vision on the qualifications and experience for the MSPV director that was recommended in the report?

Ms. OAKLEY. I think you need someone that has both clinical experience as well as acquisition and procurement experience.

One of the things that we found during the course of our review is, you know, this effort requires collaboration across a number of different types of offices—procurement, logistics, clinicians—and they all speak different languages. So getting somebody in there that has experience on both sides that would be able to bridge that gap and translate, would be an ideal person to put in place. But frankly, at the very minimum, getting somebody in there for the long term. Getting somebody who is going to be there and be able to establish relationships all across VA to be able to implement this big change is what should be the priority.

Mr. BANKS. Okay, that is very helpful.

Now, Mr. Lemmon, now that I gave you a break, back to you for a moment. It was brought to our attention at a recent roundtable that you participated in that the Department was in the final stages of determining a, quote, “way forward,” as you called it, to address the backlog by implementing business process reforms in Section 8123 of Title 38 through administrative means via a rulemaking.

Can you provide us with a more specific update of the status of this effort and a better understanding why the potential exists for a rulemaking? It would seem that you already have the authority for this and it would likely be better if this was done administratively.

So what is the timing for such a decision and when do you think it would be implemented if we have to do it administratively? If it has to be done via a rulemaking, as you said, what authority do you need from the Committee to do that?

Mr. LEMMON. Okay. The question you posed is in regards to prosthetic implants, which is covered by the special authority VA has under 8123. A business process has been drafted, it is being circulated amongst the Department for concurrence. At that time, once that is finalized, our Office of General Counsel will determine whether we can implement administratively or go through rulemaking. And that decision has not been made yet, but we anticipate that that will happen quickly, probably within the next 30 to 60 days we will have a decision on that.

Mr. BANKS. Okay. We will follow up with you in the next 30 to 60 days.

On another note, how is the new process for purchasing the surgical implants different from the existing prosthetics and sensory aids services process?

Mr. LEMMON. Well, the proposed process really, essentially relies on having a national contracts where we have leveraged our spend, but the contracts are with the major suppliers. The portion where we have to depend on the authority in 8123 is really the timing of

the orders, because a physician would actually choose exactly what they are going to use in the surgery, we would issue those orders after the products are consumed, and that is where we need the authority that is outside of the FAR.

Mr. BANKS. Okay. Thank you.

Ms. Oakley, since I have a minute left, the GAO report stated that the recent reforms did not meet the needs of medical centers and as the end user in caring for the patient. It would seem that for the arrows in determining the formulary items are more likely not points up from the clinical needs perspective and instead down to the physician or surgeon, do you see any of this—if that makes sense—do you see any of this changing in the 2.0 effort?

Ms. OAKLEY. I think that VA has come to the recognition that having a clinically-driven program is vital to success. I think it was a late recognition and I think that they are, at least on paper and what I have seen, indicating that this would be the way forward. And so I find that as a positive development; again, though, it all comes back to execution.

Mr. BANKS. Okay. Thank you. My time has expired.

The CHAIRMAN. I thank the gentleman for yielding.

Mr. Coffman, you are recognized.

Mr. COFFMAN. Thank you, Mr. Chairman.

First of all, Mr. Lemmon, can you tell me, Ms. Stella Fiotes, what position does she have right now?

Mr. LEMMON. I believe that she is the Acting Chief Acquisition Officer after Greg Giddens retired.

Mr. COFFMAN. So she is in charge right now, temporarily, until a decision can be made. That is interesting, because she was in charge, she was one of those in charge of the—she was the Office of Construction Projects, Office of—and so under the Office of Acquisition Logistics and Construction. And so we had a project in the State of Colorado that she was in a leadership on that was supposed to cost \$600 million, a little over \$600 million, it cost 1.67 billion, is where we are right now, because it was so badly mismanaged, and yet she has been promoted in terms of the hierarchy at the VA. And so you can guess why there is not a change. This Administration made so many promises about how they were going to clean up the VA, but if they are keeping people like this around, they are obviously not that interested in cleaning up the VA.

So one of the problems that we had before when we had a briefing, I think it was probably a couple years ago, on procurement, a year or 2 years ago—last September, was that they were—and, Ms. Oakley, maybe this is to you—they were taking the purchase cards to get around the contracting process and just adding them all up. So just to—but part of the problem was is that patient safety was compromised, because they were able to get around all the procurement rules and with some of those regarding patient safety, particularly in the purchase of tissues and things like that, human tissues.

And so could you comment on that?

Ms. OAKLEY. I can't directly comment on patient safety, but I would say that purchase cards were definitely seen as the way to meet the needs of the medical centers because of the limited formulary and the formulary that didn't meet their needs. And so VA

has seen an increase in purchase card purchases, you know, during the course of the past year with the rollout of MSPV-NG.

Mr. COFFMAN. Okay. Anybody else? Mr. Lemmon?

Mr. LEMMON. Certainly the greater use of purchase cards has not been good for VHA.

Mr. COFFMAN. Well, how can you—I mean, so we have known this problem for so long, we have identified it, and identified it that people are using it to get around procurement rules, get around contracting rules, because that is much more involved and, you know, they want to take a shortcut. And that is not good for the taxpayers and that is not good for the VA patients, but yet you continue to do it, I mean, your organization continues to do that. Can you tell me why?

Mr. LEMMON. Well, the reason they are doing it at the field is because we haven't provided a robust enough prime vendor program for med-surge supplies to meet their needs, quite frankly, and that is what has to be corrected to reduce the purchase card spend.

Mr. COFFMAN. Okay. Well, I can say I am very disappointed, I don't see changes from the last Administration to this Administration in the VA and that is very disappointing.

I yield back.

The CHAIRMAN. Dr. Wenstrup, you are recognized for 5 minutes.

Mr. WENSTRUP. Thank you, Dr. Roe.

Mr. Lemmon, who is the MSPV Program leader at this time?

Mr. LEMMON. Currently, we have Dan Harris, and he is supported by John Miller in our office.

Mr. WENSTRUP. Can I ask what their qualifications are? Do they have any clinical background, you know, RN, MD, where they fit in that?

Mr. LEMMON. They have logistics background, they are not doctors or nurses.

Mr. WENSTRUP. So who at VHA is the clinical leader overall?

Mr. LEMMON. My boss is Tammy Czarnecki and she is certainly involved in the program, Assistant Deputy Under Secretary for Health, for Operations and Management, and she has a nursing background.

Mr. WENSTRUP. Okay. VHA has said they plan to utilize about 130 clinical program offices to provide clinical input going forward, which makes sense. Can you tell me how this will work and give me some specifics?

Mr. LEMMON. We have developed a very structured, clinically-driven sourcing program that is being routed for concurrence at this juncture, but it does involve the program leaders and clinical leaders, and they would identify those clinicians in the field and actually take responsibility for the product areas that falls under their responsibility.

It is recognized, I think, across VHA how important having a very robust and in-depth clinical program is to support our med-surge program, and that is what we are trying to build.

One of the weaknesses or failures in our prior attempt at this is that we didn't have the structure behind it that we needed. So it was always a challenge to the clinicians and get the input. And it has been recognized within the Department that to fix this, we have to have a very structured, clinically-driven sourcing program

where these department heads fully understand their responsibilities and obtain the services of the clinical experts in the field to bring to bear to the decisions on our formulary.

Mr. WENSTRUP. Yeah, I am just curious how far down the line you go. If you have one person who is in a certain field and maybe they have some input, that may be fine.

And I can tell you how big the VA is, but I can tell you at every hospital I worked, every year, every hearing when it comes to budgeting and planning and everything else, every individual surgeon would get asked, is there anything that you need? Is there something now out there that you need to do your job better?

How far down do you take this? I know Ms. Oakley talked about execution, right? How are we executing his?

And this pertains a lot to the retention of those that we are trying to recruit, because if you come in and you want to take care of veterans, but your hands are tied because you can't get the things you need to take care of them the best way that you know how, and they say, well, that is the system or we can't do that, guess what? You leave, because your name is on the line. And that doesn't mean you get everything you want whenever you ask for it, you know, but you have to have a process all the way down to each and every individual, in my opinion.

So I would like some comment on that, and maybe some advice from Ms. Oakley as well.

Mr. LEMMON. Well, I completely agree with you, and that is why at the hospitals we have clinical product review committees that can actually push requirements up, in addition to trying to establish this clinically-driven source of—

Mr. WENSTRUP. So that is at a committee level, but I am asking, are you getting down to the nitty-gritty to those that are actually doing the work, currently?

Mr. LEMMON. We definitely need to do a better job of that—

Mr. WENSTRUP. Thank you.

Mr. LEMMON [continued]. —there is no question.

Mr. WENSTRUP. Ms. Oakley?

Ms. OAKLEY. That was one of the things that we found in our review is that VA didn't really outline a process for how to get something onto the formulary that would meet the needs of a physician-identified need. And so one of the things we recommended, because the formulary is a living, breathing thing, right, I mean, it is going to be changing all the time, is laying out how does one, how does one working-level physician go about getting something on the formulary, so that they can actually have the things that they need in their day-to-day life.

And so that is right in line with one of our recommendations in saying that they should lay out this process and communicate it through all levels of VA.

Mr. WENSTRUP. Thank you.

I yield back.

The CHAIRMAN. I thank the gentleman for yielding.

Mr. Poliquin, you are recognized.

Mr. POLIQUIN. Thank you, Mr. Chairman, very much. I appreciate it.

I am a little taken aback here, to be very blunt with you, so let me just get right to it. You folks over at the VA have about 170 veteran's medical centers around the country, right? Is that right, Mr. Lemmon? Okay, about 170. About 40,000 doctors, practitioners, and 170 medical centers around the country. And you are taking care of about 7 million of our veterans, our veterans who stood up for this country and fought for our country and gave us our freedom, is that right? Okay.

Now, you would think with that kind of horsepower you folks would be able to get your act together, use the volume that you folks represent, and go out to these different folks that manufacture catheters and stethoscopes and scalpels and buy this stuff in volume, such that the folks up at Togus, Maine, when they need to operate on one of our heroes, they will have the stuff that they need. And now we are hearing from Mr. Bergman a minute ago, you said you don't even have a plan to execute this process.

Number two, I just heard a minute ago that because you folks are unable to get the equipment that we need in our operating rooms or what have you, you folks are using credit cards or some sort of Government credit card to get what you need before they go in the OR and take care of one of our veterans.

And you know what I think? I think you have had 12 years to do this. The last time I asked my staffer, she said, yeah, this process started in 1995. This is 2017 on December 7, Pearl Harbor Day, it is almost 2018. This is the third time you guys have tried to do this.

I don't know. Neal and I are new here, along with Jodey and Clay, and Jim and Jim—and Jack and Jim. I will tell you, if I am here 12 years from now, I don't want to hear you folks come in and say, well, this is our sixth time trying this, we can't quite get it right. I don't think you guys are competent.

You have 340,000, 345,000 employees, your budget has gone from 120 billion a year to 190 billion a year over eight years. You have got plenty of dough, plenty of people, and you are saying you can't find the people to run this. Give me one day, I will go over there, I will find you someone to run this.

So I don't want to be around for the next few years having you folks come back in saying, well, we couldn't quite get it right.

Mrs. Oakley, you are involved in the part of the Government that is supposed to oversee these folks and analyze if they can do it, right? Okay. Have you ever heard of this outfit over at the DoD called the Defense Logistics Agency?

Ms. OAKLEY. I have.

Mr. POLIQUIN. Okay, good. And they have a similar process, right? They are trying to do what you guys are trying to do, which is to buy in bulk to make sure the folks that are providing health care for our heroes can do it cheaply and save the taxpayers money, right? How are they doing?

Ms. OAKLEY. As far as I know, the DLA has a fairly successful program.

Mr. POLIQUIN. Good. How are we doing over at the VA? Poorly, right?

Ms. OAKLEY. Yes.

Mr. POLIQUIN. Good. I am trying to save you some breath here.

Have you saved any money, Mr. Lemmon, over the last 12 years trying to do this? Have you saved any money?

Mr. LEMMON. Well, we have saved—

Mr. POLIQUIN. How much have you saved?

Mr. LEMMON. Under the supply chain initiatives, it was approximately \$300 million.

Mr. POLIQUIN. What percent have you saved?

Mr. LEMMON. What—

Mr. POLIQUIN. What percent have you saved? You are buying a scalpel, you are buying a thousand of them instead of two of them on a credit card, you would think you would be able to save a little bit of money.

Mr. LEMMON. You would. I don't know what the—

Mr. POLIQUIN. Okay, fine.

For the record, I have a couple questions for Mr. Lemmon. Number one, you talk about distribution-of-pricing agreements. They are different from contracts, right?

Mr. LEMMON. They are.

Mr. POLIQUIN. Are the prices binding in a distribution-of-pricing agreement? Yes or no?

Mr. LEMMON. I don't believe they are.

Mr. POLIQUIN. Okay, so that is a no?

Mr. LEMMON. No.

Mr. POLIQUIN. That is a no. Okay, thank you, Mr. Lemmon. Is there any competition when you are dealing with a distribution-of-pricing agreement?

Mr. LEMMON. Not normally.

Mr. POLIQUIN. Oh, okay. So it is sole source, right? Okay.

Let's see. How about any conflicts of interest? Ms. Oakley, have you seen any potential conflicts of interest? These folks have been trying to do this for 12 years, now they have the third try, they are coming back to us, they are trying to do this? Any potential conflicts of interest in what they are trying to do, which I have no confidence they are going to be able to do?

Ms. OAKLEY. I didn't see any apparent conflicts of interest in our work.

Mr. POLIQUIN. Good.

Mr. Chairman, I have 30 seconds, I have to do this, but I am going to yield back the 30 seconds, so I can give Mr. Lemmon break here.

[Laughter.]

Mr. POLIQUIN. Thank you.

The CHAIRMAN. I may have the big one here that Mr. Poliquin yielded back some time, that is amazing. Thank you, sir.

Mr. Arrington, you are recognized.

Mr. ARRINGTON. Thank you, Mr. Chairman.

I don't think there is enough outrage on this Committee, quite frankly, with what we hear day in and day out. The last Oversight Committee that I sat under the leadership of Chairman Bergman was about a GAO report that basically said that the VHA is not investigating bad doctors, they are not disciplining bad doctors, and they are not reporting bad doctors to a database, so that those bad doctors can't continue to practice in the VHA and in other places, and it was just astonishing. And so I want to associate myself with

the indignation of Ranking Member Walz and of my colleague Bruce Poliquin.

I don't even know where to begin. I think I would first say for the record, thank God our veterans have a choice now. And we can't do enough, Mr. Chairman, to give them more choice and flexibility to get out of this broken Government-run, single-payor health care system that they are trapped in, and it is shameful that we do that. And so we need to do everything we can to continue to enhance that Choice Program.

Ms. Oakley, I appreciate your clarity and your definitiveness in your answers. You seem very confident, so I am going to start with you. And I appreciate that; that is sincere.

You said there is an execution problem; that the model is a good model, but that we are not executing. Is that because there is not enough staff, there is not the right staff, there is not continuity in staff? Is it leadership? Is it poor planning? Break that down for me, if you would.

Ms. OAKLEY. Okay. Well, the short answer is, it is all of the above.

Mr. ARRINGTON. Okay.

Ms. OAKLEY. I think any—

Mr. ARRINGTON. Rank order the top two or three for me.

Ms. OAKLEY. Well, if you look at organizational transformation-leading practices, the bottom line is it all starts with solid leadership and tone from the top.

Mr. ARRINGTON. Can I stop you just right there? Because it is my understanding we invited some of the medical leadership from the VHA to come and testify today; are you aware of that?

Ms. OAKLEY. I am not.

Mr. ARRINGTON. Mr. Lemmon, are you aware of that?

Mr. LEMMON. I heard that earlier today.

Mr. ARRINGTON. Yeah, we asked your bosses to come and they decided to send you all. And it tells me that there is a leadership problem; they ought to be here. I can't think of anything more important to veteran patient care than what you are doing and they refused to come. I don't know the reason, maybe there is a good reason.

So, leadership, tell me the chain of command. Give me the three or four layers up. Start with the top and work your way to yourself.

Ms. OAKLEY. It is actually complicated within VA, right?

Mr. ARRINGTON. Well, there is problem number one.

Ms. OAKLEY. Yeah, which we have reported on before, within the organization. And so, you know, the Chief Acquisition Officer is a key role in all of this. It is the person that is advising the Secretary of VA on how to accomplish VA's mission through its acquisition management function, and it has been somebody in an acting position and has turned over multiple times since at least 2009.

Mr. ARRINGTON. So I have heard a lot about hiring freezes from my colleagues today. Were there vacancy problems before the hiring freeze?

Ms. OAKLEY. There were.

Mr. ARRINGTON. So the continuity in leadership existed or preexisted—

Ms. OAKLEY. Yes.

Mr. ARRINGTON [continued]. —this hiring freeze?

Ms. OAKLEY. Yeah, absolutely.

Mr. ARRINGTON. And by the way, I am for hiring freezes, I am for cutting this Government, I think you could cut a third of it and we could continue to provide—it is about cutting the right parts of it, and being smart and strategic about it.

And I am willing to work with the Ranking Member and anyone else to send a letter to the leadership, whether it is the Secretary or if it is Ms. Clancy or Czarnecki, and express our serious concern that they aren't here at this hearing to explain why this program is not working for our veterans, and to tell them that they need to get in gear in hiring people and getting their operation fully functioning.

Ms. OAKLEY. Absolutely.

Mr. ARRINGTON. But that is something that I would be willing to do, Mr. Ranking Member, and anyone else. But, again, this seems to pre—this continuity or lack thereof seems to preexist this hiring freeze—

Ms. OAKLEY. Absolutely.

Mr. ARRINGTON [continued]. —is that accurate?

Ms. OAKLEY. Yeah, and at all levels, from the CAO on down to key logistics positions within the medical centers. They are not easy positions to fill. So it is not necessarily, you know, that you would be able to hire somebody off the street. And competition from private hospitals, as I understand it, is pretty fierce for skilled, experienced logistics individuals, as well as the acquisition workforce related to contracting skills.

So these kind of vacancies and lack of skill sets are pervasive throughout VA and also other agencies.

Mr. ARRINGTON. Thank you, Ms. Oakley. My time has expired. I yield back.

The CHAIRMAN. I thank the gentleman for yielding.

Mr. Peters, you are recognized for 5 minutes.

Mr. PETERS. Thank you, Mr. Chairman. As you know, we co-hosted a roundtable with Mr. Banks, which brought together the VA and stakeholders from the medical device community who could participate in the program to discuss what is occurring and what we could do to make it better, and I appreciate the Chairman having the hearing today.

We also had the GAO and Coalition for Government Procurement in attendance, we also had the Chairman, and I am very interested in continuing to work to improve this program.

At this time, though, I have not been able to attend most of the hearings. I am going to yield my time, remaining time to the Ranking Member, Mr. Walz.

Mr. WALZ. Thank you, Mr. Peters.

And I would just like to say—and I appreciate the gentleman's willingness to work together on this—I would like to say, though, using a fully-functional VA is a choice, it is a choice that 94 percent of VFW members who were surveyed would like to make. So as I said in my opening statements, should I be a conspiracy theorist on this, continuing to undermine the VA's capacity to do what it is going to do under the guise of then you will have to go to the private sector is not providing a full range of choices. Those of us

who use VA services and find it quite adequate are very frustrated when the reason we are not getting that care is, is because we haven't filled the positions.

And I don't disagree that may have extended before, but I want to be very clear, under oath, a VA person said the hiring freeze has precluded us from filling these positions and it has adversely affected veterans' care. That should sink in to all of us that we do have a responsibility to get that together, we do have a responsibility to find this.

And I would like to say, Mr. Lemmon, I think the questions were right about asking other folks to attend here, because the buck does stop somewhere. And again, for years I heard it, it stops with the President and it stops with the Secretary.

I want to be thankful for you, your honesty and candor, and I also want to make it clear in a public setting, should there be any retaliation for stating factually what you see, that will pay with a heavy price in this Committee. This idea of making sure VA employees are able to come up here, speak candidly about what is going to improve our veterans' care, I am appreciative of that. I know you are taking a lot of this, it is systemwide. GAO is here to help us do that. There are certainly things out there.

There aren't necessarily, as we heard, if you send this over to the private sector, who is going to do it? Who can do it?

And as the Chairman and I were talking about here, the Defense Logistics Agency might not be the best example of how everything is supposed to work, and the F-35 certainly comes to mind and other things, that these are complex issues trying to get care. But if we are looking for the easy fix or we are looking to pass the buck on this, that is simply unacceptable.

I am with—the Chairman said it right, we are not trying to launch Voyager III here, we are trying to order surgical supplies that they had, the suggestion is made and this is why this Committee is so strong. These physicians speak with experience, they speak with let them into that. GAO put out a chart we have been up here referencing and looking at that said follow this and you will get this right.

And so I thank the gentleman for yielding his time. I want to be clear that I am a supporter of Choice, I was there when Choice was created, I was part of that, as was Mr. Takano and Mr. Roe, but part of the Choice is a fully functional. And again, if it is hyperbole that it is a Government—no, it is our responsibility. And we have said this, you give them that card and tell them go somewhere, what hearing are we going to have with hospital executives from the private sector who get to do it the way they want to? These are the only people that we can capture, bring in here, swear under oath, and get some results.

This should not be that difficult. This is not the fight of privatization, Choice, community-based care or whatever, this is basic logistics of functioning of a medical institution that is being accomplished. I represent the Mayo Clinic, they have to order a lot of supplies for their institutions and they are able to do that.

So I have full confidence we can do this. We just need to again—now I have come full circle and been back here from that 11 years ago starting and I have been convinced of this, almost every single

problem can be fixed by proper leadership, by accountability and what is there, and this is no different.

I yield back.

The CHAIRMAN. I thank the gentleman for yielding.

There are many private sector systems, HCA comes to mind. It is a large system, about the size of VA as far as number of hospitals, and they don't have these problems.

Mr. Higgins, you are recognized for five minutes.

Mr. HIGGINS. Thank you, Mr. Chairman.

Mr. Chairman, Mr. Ranking Member, this hearing is reflective of exactly the type of exasperation that we the people, we just don't get it, so we shake our head. Any attempted savings for money from bulk purchasing is certainly wasted on bureaucracy. I don't have confidence in this entire MSPV system.

VA operates I believe 1233 medical facilities, including hospitals and CBOCs, we are spending a billion dollars a year, that would be about 4 million per facility. There are distinguished doctors and surgeons on this panel. I have certainly had my surgeries based upon traumatic injury, including my entire right eye socket to be reassembled, but I just presumed that the surgeons and doctors and surgical staff had the tools and the facilities that they needed in order to perform that surgery. And I would expect that we can do a better job by allowing the money to follow the veteran.

I think that the money we are spending on this program is wasted. We already have oversight over the command and control and chain of command over every VA facility and the directors thereof. I think the doctors and surgeons and medical professionals that work within the VA and the VHA should be able to order what they feel they need.

And I think that the Members of this panel that are testifying today are quite courageous to have appeared, you know, because it is virtually indefensible the waste of the people's treasure to accomplish nothing.

I represent the LAC group in Louisiana. They operate in 26 states, they have 13,000 employees and 60 hospitals. They don't have this problem, but they don't have the bureaucracy that we deal with in this town.

With the Chairman's permission, I would like to yield my remaining time to my friend and colleague Dr. Dunn, an accomplished surgeon.

The CHAIRMAN. Two minutes, Dr. Dunn.

Mr. DUNN. Thank you very much, Mr. Chairman. Thank you, Congressman Higgins.

I am a bit of a supply site kind of guy, I want to turn to the suppliers. There is a great sense of dissatisfaction among the suppliers to this program and I want to ask Mr. Waldron if you would characterize that dissatisfaction briefly.

Mr. WALDRON. Our members have been frustrated with the roll-out of the Prime Vendor Next Generation. We have seen, you know, RFPs and solicitations that have not accurately described products that to be acquired—

Mr. DUNN. We have information that some of them are actually considering just not dealing with the VA, it is just not worth their trouble; is that accurate?

Mr. WALDRON. I think there is bid fatigue out there right now, because we have had a cycle, so to speak, where solicitations were put out, then they were cancelled, now the VA is attempting to put them back out again. And all this bid-and-proposal costs are part of the business when you are dealing with the Government and those funds are not unlimited for a private entity.

Mr. DUNN. That is right. So these are businesses, I just want to underscore this for everybody, these are businesses that literally exist to make and sell products, and the VA is making it so painful to do business with them that they will walk away from the business. That really is just a huge statement against the process that they are faced with.

One more question I want to bring up, because this one also is a little frightening from a clinician's point of view, and that is the gray market items that we see. These are really dangerous for patients, because a lot of the things that we use have to be handled very carefully, very sterile, and I see that the gray market has somehow entered into the VA purchasing system. Can anybody make sense out of that for me? Tell me how that happens or that it won't happen anymore? Give me some comfort. Gray market items being bought by our Government.

Mr. Lemmon?

Mr. LEMMON. I have heard of a few examples of that. I don't think we generally have that problem on any scale, but, again, I think it goes back to our supply chain system. When we don't have the breadth of products we should have available that is on national contract with reputable manufacturers and—

Mr. DUNN. My time has expired, but I would like you to assure us, in fact I am going to ask you to get back to our Committee, send something back that says what are you doing to address this problem so that it doesn't continue to be a problem.

Thank you very much, Mr. Chairman.

The CHAIRMAN. I thank the gentleman for yielding.

And I thank the witnesses today for being here and sharing your testimony. I know this has been a difficult hearing today.

And I will see if Mr. Walz has any closing comments.

Mr. WALZ. Thank you, Mr. Chairman.

Thank you all for being here and helping. And in lieu of a closing statement, I would like to yield 30 seconds to Mr. Takano.

Mr. TAKANO. Thank you, Ranking Member Walz.

I just want to make sure that we don't rush to a conclusion or make a wrong conclusion from today's testimony that the answer is to put everyone into the private sector or that the Choice program is somehow going to alleviate what is going on here. What I heard today is we have a lot of unfilled positions, and those positions have been vacant and possibly attributed to an unwise hiring freeze.

Second, I was also at that Oversight hearing and my line of questioning focused on whether or not private sector health organizations were just as guilty or just as lax in terms of their reporting about practitioners, and the questioners were either unable to answer that question or were actually saying that they probably weren't any better than the VA.

So the answer is not necessarily that the private sector health medicine is a panacea or an answer to the challenges we have at the VA. And I would say that we have to do our best to make sure that the positions we have at the VA are filled, that we staff the 40, the 45,000 unfilled positions in the health arena here at the VA, that these are some of the things that we need to focus on just as much, rather than rush to the conclusion that people are trapped, so-called trapped in this system, rather than making the VA the very best VA that it can be.

The CHAIRMAN. I thank the gentleman for yielding.

I will point out that in my 9 years finishing up this month on the VA, I looked at the first budget that I showed up on in 2009, it was 93.5 billion and about 250,000 employees, and now VA has a budget that we are trying to work to, it is \$186.5 billion. And I do want to point out to people that because of the Budget Control Act in 2011, essentially, until we changed the caps this year, those numbers were almost level.

So we got that money from the military, from education, from other programs and put it in the VA, because this Congress, both Republicans and Democrats, felt that was important. And I think when it is not being spent wisely, it is frustrating to us here and to those other people that we took the money from. Basically, that is what we did.

And just to make it very clear, it is not a money problem. It is not a hiring freeze that is doing this, I can tell you right now it is not. It is leadership and that is absolutely what it is.

And so when you good leaders in places—I got a letter that I wish I had time to read on here, from a veteran in Albuquerque, New Mexico that six years ago wouldn't go to the VA there, and he walked through every bit of his visit and then he wrote me a letter—I called the guy yesterday—he wrote me a letter about how much better it is. So he walked me through his next visit, which was absolutely a great visit to the health care.

So things are not all doom and gloom. I want to make sure that is out there. There's a lot of good things going on at the VA. Right now this is not one of them, though, I will have to say. And it has got to get corrected.

Because, Mr. Takano, in my career I don't remember having to go out and walk and tell a patient's family I don't have the equipment and tools to do the operation on your wife today, that never happened. I have worked in VA hospitals, I have worked in private not-for-profit hospitals, I have worked in for-profits, I worked the whole gamut, it has never happened to me before, but it is happening in VA because of this procurement problem.

And, as Ms. Kuster said, this ultimately will affect quality of care. Putting the hernia off for a day or a week, that doesn't matter. Putting a bypass off or a stent or something that really matters, or a cancer operation might really matter.

And I know our witnesses today, many of you in the audience also, none of the MSPV trials and travails are just not news to you, but you work with the program every day. And I get the impression that when many of the decisions that we have discussed were made causing problems that we are still grappling with today, some of you probably felt that they were questionable. For example, setting

a 6,000-item formulary when the industry standard is 30 to 50,000 items, trying to establish the formulary all at once in a little more than a year, initially. They are not insisting on clinical leadership involvement or deliberately sidelining them. You are professionals and I believe these decisions must have made you uneasy.

I ask that you use this GAO report and this hearing as a catalyst to take a hard look at the situation and decide what really makes sense. What kind of MSPV Program, whatever you want to call it, I don't care, are you truly prepared to live with for years in the future. This is critically important to providing quality health care for people. What is best for our veterans?

Unfortunately, it seems the desire to gloss over difficulties and declare victory and move on may have contributed to MSPV's problems in the past. If it takes longer to get it right, so be it, get it right.

I appreciate your participation today and I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and include extraneous material.

Without objection, so ordered.

I do before I finish want to thank the Committee, both sides of the aisle, for a very, very productive year from this Committee and what we have accomplished for our Nation's veterans, many times we don't—the Accountability and Whistleblower Act, the Choice Act we have done, the Forever GI Bill, the claims appeal, and we are going to continue. This Committee is going to continue to work to try to get things right and provide, as Mr. Takano said, the best quality care for our Nation's heroes.

And I again want to wish everyone here in the audience and on this Committee a very, very merry Christmas with your family, and a happy holiday season for all of you.

Mr. TAKANO. Mr. Chairman, as a point of personal privilege, I just want to acknowledge that our colleague Ms. Brownley is not with us today because she is in her home district because of the fires in California. And I appreciate your holiday wishes and I take them to heart, and I too enjoyed this year of productivity.

The CHAIRMAN. Thank you all very much. And with nothing further, the meeting is adjourned.

[Whereupon, at 11:39 a.m., the Committee was adjourned.]

A P P E N D I X

Prepared Statement of Ricky L. Lemmon

Good morning Chairman Roe, Ranking Member Walz and Members of the Committee. Thank you for the opportunity to discuss VA's Medical/Surgical Prime Vendor (MSPV) program and the related Government Accountability Office (GAO) draft report. I am accompanied by Mr. Philip Christy, Associate Executive Director, Strategic Acquisition Center.

Introduction and History of MSPV

VA is committed to providing our Veterans the best care available while being good stewards of taxpayers' dollars. Part of meeting these commitments is making sure that our medical centers have the right supplies and equipment to deliver the care our Veterans need.

The Department once relied on its own procurement, storage and transportation system to distribute relatively low cost and frequently demanded medical and surgical supplies until the mid-1990s. VA then did away with this in-house system and converted to a commercially sourced MSPV program to provide this capability. Since then, the MSPV program has been the primary method used to provide our medical centers these kinds of supplies.

The primary source of supplies for previous generations of MSPV contracts was the Federal Supply Schedule (FSS). Use of FSS, when combined with local and regional contracts, resulted in our hospitals having access to a clinically viable selection of supplies. However, this operational model did not facilitate clinical product decisions on a national level that would allow VHA to leverage its purchasing power.

Adoption of clinically driven strategic sourcing was, and continues to be, envisioned to leverage VA enterprise-wide purchase volume in order to drive lower prices and improve product quality. The MSPV-Next Generation (MSPV-NG) contract was conceived, in part, to address these issues through the development and use of a mandated national catalog or formulary.

Current Medical/Surgical Prime Vendor

In 2016, the Office of Acquisition Operations, Strategic Acquisition Center, in partnership with VHA, announced the award of four Indefinite Delivery Indefinite Quantity (IDIQ) contracts in support of MSPV-NG. The program was mandatory for all VA medical centers. Medical centers pay prime vendors a distribution fee plus the product price. Product prices were primarily established by negotiated blanket purchase agreements against FSS contracts, VA national indefinite delivery contracts, and local contracts to support Veterans Integrated Service Networks. The distribution fee was a markup to the product prices intended to cover prime vendor costs for managing customer inventories and ensuring the timely delivery of needed products to customers. As documented in the GAO report, this contract has not been as successful as we would have liked, due to the time required to solicit and award enough medical and surgical products to meet the needs of our medical centers. Accordingly, VHA has decided to move forward with modifying the current contracts or developing replacement contracts to rectify the issues identified in the GAO audit. In determining how to potentially improve the availability of items under the current MSPV contract, we are considering the contracting process used by the Defense Logistics Agency (DLA) to efficiently establish pricing agreements that enable over 100,000 medical and surgical items to be available through DLA's MSPV contract.

An acquisition plan has not been finalized for replacement of MSPV. VA is exploring a different approach to MSPV, where potential prime vendors can propose a full catalog of medical and surgical products. This would depart from the current approach to MSPV where individual contracts are negotiated with each supplier to form a book of contracts that MSPVs can distribute against. The potential benefits

of MSPV 2.0 would be a more robust catalog of items than we have today that could be available from the beginning of the contract and lower prices. VA is conducting market research to identify the best commercial solutions to meet its mission needs in this area. Additionally, the administrative resources and time required to negotiate thousands of individual contracts would be reduced if VA only negotiated with the prime vendors for both medical and surgical products and distribution services. There have been multiple meetings with industry leaders to obtain feedback regarding the proposed approach to MSPV 2.0 and that feedback is currently being considered. Feedback will also be obtained from VA clinicians before VA makes any final decisions regarding a new MSPV. This is why our efforts to make the current MSPV contracts more robust are important. We want to make sure the needs of our medical centers are met while we develop a better approach to MSPV.

GAO Report

GAO recently released the report, "Veterans Affairs Contracting: Improvements in Buying Medical and Surgical Supplies Could Yield Cost Savings and Efficiency." GAO made 10 recommendations concerning our current MSPV management processes, and VA has already begun to institute each of them:

- VHA is developing an implementation plan that clearly articulates our strategy for the MSPV program. The plan will include how to prioritize categories of supplies for future requirement development and contracting. This document will also serve as a communication tool for all stakeholders involved in MSPV. We expect the first draft to be completed by the end of calendar year (CY) 2017.
- Hiring a permanent program office director for MSPV is a high priority. We expect a vacancy announcement to be posted by the end of CY 2017.
- VA acknowledges that the role of Chief Acquisition Officer should be assigned to a non-career employee, per the third GAO recommendation, but our flexibility is limited by restrictions on non-career positions within the Department.
- To ensure we are providing complete guidance for matching equivalent supply items, VHA has replaced the MSPV Item Conversion Tracker Tool with the Medical Product Data Bank eZSave program, which collects product information from over 80 government and private sources. We will conduct a review by the end of this CY to measure our success.
- Similarly, we are developing a communication plan to ensure frequent and effective outreach to the medical centers concerning the criteria and processes for changing items of the formulary. We fully expect that several modes of communication will be in use by the end of this CY.
- VHA is developing a new metric for MSPV cost avoidance. The implementation of this metric is contingent upon the completion of a separate data standardization project, but we anticipate this new metric will take effect by June 2018.
- VHA plans to replace or modify the current MSPV contract and formulary process with a contract which will facilitate greater access to a wider variety of products, using best commercial and government practices. This plan includes providing improved service until the current contract is modified or replaced.
- VHA will emphasize the importance of clinical program offices' involvement in MSPV requirements development and standardization efforts. Proposed guidance is being finalized, enabling clinical program offices to directly manage the selection of items in the formulary related to their clinical expertise. By the end of CY 2018, clinical program offices will prioritize their requirements and will emphasize standardization where clinically acceptable.
- VHA is formalizing guidance for contracting offices, the Supply Chain Data and Informatics Office, and medical centers to ensure they work together to identify opportunities for strategically obtaining goods and services on an emergency basis. The target completion date is June 2018.
- VHA will establish a process to identify commodities and supplies that are frequently purchased using emergency procurement methods. These items will be evaluated for inclusion in the MSPV formulary, if appropriate, by June 2018.

Conclusion

VA seeks to continue to provide our Veterans with the timely care they have earned and deserve. At the same time, we are seeking new and innovative ways to be more responsible stewards of the taxpayers' dollars. We are grateful to GAO for their report and to the Committee for their commitment to helping the Department improve. I look forward to responding to any questions you may have.

Prepared Statement of Shelby S. Oakley

VETERANS AFFAIRS CONTRACTING

IMPROVEMENTS IN BUYING MEDICAL AND SURGICAL SUPPLIES COULD YIELD COST SAVINGS AND EFFICIENCY

Chairman Roe, Ranking Member Walz, and Members of the Committee:

In December 2016, the Department of Veterans Affairs (VA) launched the Medical Surgical Prime Vendor-Next Generation (MSPV-NG) program as its primary means for purchasing supplies, such as bandages and scalpels, for 170 VA medical centers. These supplies are intended to meet the health care needs of about 7 million veterans. In fiscal year 2015, VA obligated \$465 million for these types of supplies, and, in 2016, it stated that it planned to achieve \$150 million in cost avoidance through a supply chain transformation effort, which includes MSPV-NG. This transition represents a significant change to how medical and surgical supplies are purchased, which has raised questions about whether MSPV-NG will appropriately balance medical needs with logistical efficiency, and whether VA can achieve its planned cost avoidance. Effective supply chain management is an essential part of delivering quality health care to veterans—for instance, an April 2017 interim report issued by the VA Inspector General detailed supply management issues at the District of Columbia VA Medical Center that posed risks to patient care.¹

My remarks today are based on our recently issued report on the MSPV-NG program, and I will summarize a few key findings from that report.² Specifically, I will address the extent to which VA's implementation of MSPV-NG has been effective in meeting program goals.

As part of our work for our November 2017 report, we reviewed VA policy, communications, briefings, and other documents, prior GAO reports on best practices for organizational transformation, and internal control standards.³ We interviewed Veterans Health Administration (VHA)- and VA-wide procurement leaders, program office managers, and members of three integrated product teams who helped develop the product descriptions for supply items (known as requirements). We also interviewed supply chain managers from four leading hospital networks regarding their medical supply management practices and compared them to those used by VA when implementing the MSPV-NG program.⁴ To assess VA's MSPV-NG contracting process, we analyzed the contents of the formulary (a list of specific items that medical centers are allowed to purchase) to determine what acquisition instrument was used to add the items. We determined that the MSPV-NG formulary data were sufficiently reliable by tracing data to a sample of source documents, among other steps. We selected three VHA regional networks based on those with the highest total contract obligations in fiscal years 2014 through 2016, geographic diversity, and other factors. We conducted site visits to six medical centers within these three regional networks, interviewing contracting and clinical officials. Finally, we obtained and analyzed data on VA's metrics for the program and determined the data were sufficiently reliable for our purpose of measuring utilization by interviewing officials responsible for maintaining the data and other measures.

More detailed information on our objectives, scope, and methodology for our work can be found in our November 9, 2017 report.⁵ We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

MSPV-NG Program

¹ Department of Veterans Affairs Office of Inspector General, Interim Summary Report (Washington, D.C.: Apr. 12, 2017).

² GAO, Veterans Affairs Contracting: Improvements in Buying Medical and Surgical Supplies Could Yield Cost Savings and Efficiency, GAO 18 34 (Washington, D.C.: Nov. 9, 2017).

³ GAO, Standards for Internal Control in the Federal Government, GAO 14 704G (Washington, D.C.: Sept. 10, 2014).

⁴ We selected these hospital networks because they were identified by an industry study as having leading supply chain practices. See Gartner, Inc., The Healthcare Supply Chain Top 25 for 2015 (Nov. 18, 2015).

⁵ See GAO 18 34.

For over a decade, each of VA's 170 medical centers used VHA's legacy MSPV program to order medical supplies, such as bandages and scalpels. Many of those items were purchased using the Federal Supply Schedules, which provided medical centers with a great deal of flexibility.⁶ However, as we reported in 2016, this legacy program prevented VHA from standardizing items used across its medical centers and affected its ability to leverage its buying power to achieve greater cost avoidance.⁷ Standardization is a process of narrowing the range of items purchased to meet a given need, such as buying 10 varieties of bandages instead of 100, in order to improve buying power, simplify supply chain management, and provide clinical consistency. In part because of the legacy MSPV program's limited standardization, VHA decided to transition to a new iteration, called MSPV-NG.

The transition to MSPV-NG has been a major effort, involving the MSPV-NG program office, stakeholders from the VHA's Procurement and Logistics Office and VA's Strategic Acquisition Center (SAC)-a VA-wide contracting organization-and logistics and clinical personnel at every medical center. The program also includes hundreds of new contracts with individual supply vendors and a new set of prime vendor contracts to distribute the supplies.

VA's goals for the MSPV-NG program include (1) standardizing requirements for supply items for greater clinical consistency; (2) demonstrating cost avoidance by leveraging VA's substantial buying power when making competitive awards; (3) achieving greater efficiency in ordering and supply chain management, including a metric of ordering 40 percent of medical centers' supplies from the MSPV-NG formulary; and (4) involving clinicians in requirements development to ensure uniform clinical review of medical supplies.

VHA launched the MSPV-NG program in December 2016, but allowed a 4-month transition period. After April 2017, medical centers could no longer use the legacy program. MSPV-NG now restricts ordering to a narrow formulary. VHA policy requires medical centers to use MSPV-NG-as opposed to other means such as open market purchase card transactions-when purchasing items that are available in the formulary.

Supply Chain Practices Identified by Selected Leading Hospital Networks

Leading hospital networks we spoke with have similar goals to VA in managing their supply chains, including clinical standardization and reduced costs. These hospital networks reported they analyze their spending to identify items purchased most frequently, and which ones would be the best candidates to standardize first to yield cost savings. The hospitals' supply chain managers reported establishing consensus with clinicians through early and frequent collaboration, understanding that clinician involvement is critical to the success of any effort to standardize their medical supply chain. By following these practices, these hospital networks have reported they have achieved significant cost savings in some cases, and the potential for improved patient care, while maintaining buy-in from their clinicians.

VHA's Implementation of MSPV-NG Program Has Not Yet Achieved Its Goals

VHA's implementation of the MSPV-NG program-from its initial work to identify a list of supply requirements in early 2015, through its roll-out of the formulary to medical centers in December 2016-was not executed in line with leading practices. Specifically, VHA lacked a documented program strategy, leadership stability, and workforce capacity for the transition that, if in place, could have facilitated buy-in for the change throughout the organization. Further, the initial requirements development process and tight timeframes contributed to ineffective contracting processes. As a result, VHA developed an initial formulary that did not meet the needs of the medical centers and has yet to achieve utilization and cost avoidance goals. VA made some changes in the second phase of requirements development to address deficiencies identified in the initial roll out. Key among these was to increase the level of clinical involvement, that is, to obtain input from the doctors and nurses at VA's individual medical facilities. Despite changes aimed at improving implementation, the agency continues to face challenges that prevent the program from fully achieving its goals.

⁶The Federal Supply Schedules program, managed by the General Services Administration, provides federal agencies a simplified method of purchasing commercial products and services at prices associated with volume buying. The General Services Administration has delegated authority to VA to manage health-care-related supplies and services. For more details on the legacy MSPV program, see GAO, Veterans Affairs Contracting: Improvements in Policies and Processes Could Yield Cost Savings and Efficiency, GAO 16 810 (Washington, D.C.: Sept. 16, 2016).

⁷See GAO 16 810.

VA's Lack of an Overarching Strategy and Leadership Instability Were Obstacles to Effective Implementation of MSPV-NG

VA did not document a clear overall strategy for the MSPV-NG program at the start and has not done so to date. About 6 months after our initial requests for a strategy or plan, a VHA official provided us with an October 2015 plan focusing on the mechanics of establishing the MSPV-NG formulary. However, this plan was used only within the VHA Procurement and Logistics Office and had not been approved by VHA or VA leadership. Leading practices for organizational transformation state that agencies must have well-documented plans and strategies for major initiatives (such as MSPV-NG) and communicate them clearly and consistently to all involved—which included VHA headquarters, the SAC, and all 170 medical centers.⁸ Without such a strategy, VA could not reasonably ensure that all stakeholders understood VHA's approach for MSPV-NG and worked together in a coordinated manner to achieve program goals. In our November 2017 report, we recommended that the Director of the MSPV-NG program office should, with input from SAC, develop, document, and communicate to stakeholders an overarching strategy for the program, including how the program office will prioritize categories of supplies for future phases of requirement development and contracting. VA agreed with this recommendation and reported it would have a strategy in place by December 2017.

Leadership instability and workforce challenges also made it difficult for VA to execute its transition to MSPV-NG. Our work has shown that leadership buy-in is necessary to ensure that major programs like MSPV-NG have the resources and support they need to execute their missions.⁹ Due to a combination of budget and hiring constraints, and lack of prioritization within VA, the MSPV-NG program office has never been fully staffed and has experienced instability in its leadership. As of January 2017, 24 of the office's 40 positions were filled, and program office officials stated that this lack of staff affected their ability to implement certain aspects of the program within the planned timeframes. In addition, since the inception of MSPV-NG, the program office has had four directors, two of whom were acting and two of whom were fulfilling the director position while performing other collateral duties. For instance, one of the acting MSPV-NG program office directors was on detail from a regional health network to fulfill the position, but had to abruptly leave and return to her prior position due to a federal hiring freeze. In our November 2017 report, we recommended that VHA prioritize the hiring of a MSPV-NG program director on a permanent basis. VA agreed with this recommendation and indicated a vacancy announcement will be posted by the end of 2017.

The MSPV-NG Initial Requirements Development Process Had Limited Clinician Involvement and Did Not Prioritize Categories of Supplies

The MSPV-NG program office initially developed requirements for items to be included in the formulary based almost exclusively on prior supply purchases, with limited clinician involvement. The program office included in its October 2015 formulary plan that relying on data from previous clinician purchases would be a good representation of medical centers' needs and that clinician input would not be required for identifying which items to include in the initial formulary.¹⁰ Further, rather than standardizing purchases of specific categories of supplies—such as bandages or scalpels—program officials told us they identified medical and surgical items on which VA had spent \$16,000 or more annually and ordered at least 12 times per year, and made those items the basis for the formulary. Officials said this analysis initially yielded a list of about 18,000 items, which the program office further refined to about 6,000 items by removing duplicate items or those that were not considered consumable commodities, such as medical equipment. This approach to requirements development stood in sharp contrast to those of the leading hospital networks we met with, which rely heavily on clinician input to help drive the standardization process and focus on individual categories of supplies that provide the best opportunities for cost savings.

⁸GAO, *Organizational Transformation: A Framework for Assessing and Improving Enterprise Architecture Management*, GAO 10 846G (Washington, D.C.: August 2010); and *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, GAO 03 669 (Washington, D.C.: July 2, 2003).

⁹GAO, *High-Risk Series: An Update*, GAO 15 290 (Washington, D.C.: Feb. 11, 2015).

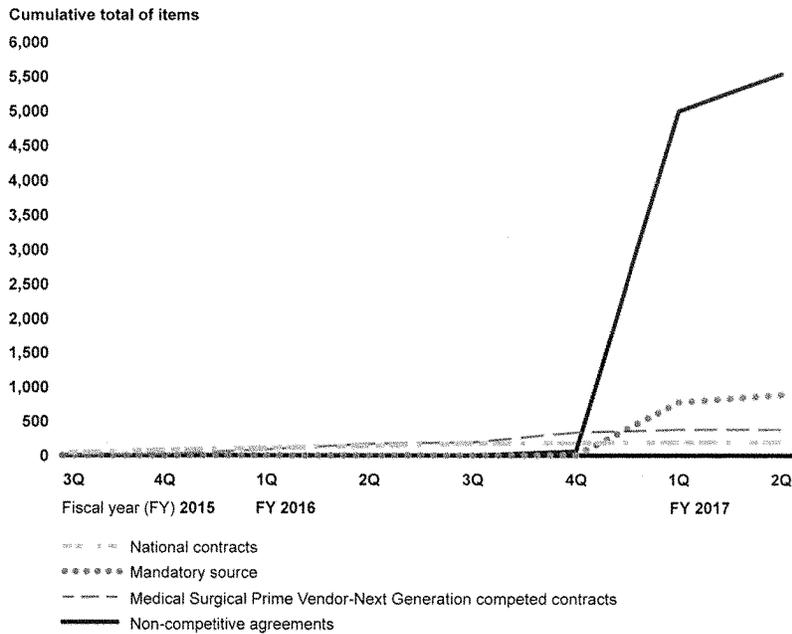
¹⁰The fiscal year 2014 data on historical purchasing by medical centers came from the Medical Product Data Bank database, jointly funded by VA and the Department of Defense, and was the principal source for identifying potential items to include on the initial version of the MSPV-NG formulary.

Requirements Development and Tight Time Frames Contributed to Ineffective Contracting Practices for Initial Formulary

Based on the requirements developed by the program office, SAC began to issue competitive solicitations for the 6,000 items on the initial formulary in June 2015. Medical supply companies had responded to about 30 percent of the solicitations as of January 2016. As a result, according to SAC officials, they conducted outreach and some of these companies responded that VHA’s requirements did not appear to be based on clinical input and instead consisted of manufacturer-specific requirements that favored particular products instead of broader descriptions. Furthermore, SAC did not solicit large groups of related items, but rather issued separate solicitations for small groups of supply items-consisting of three or fewer items. This is contrary to industry practices of soliciting large groups of related supplies together. Therefore, according to SAC officials, some medical supply companies told them that submitting responses to SAC’s solicitations required more time and resources than they were willing to commit.

By its April 2016 deadline for having 6,000 items on the formulary, SAC had been working on the effort for over a year and had established competitive agreements for about 200 items, representing about 3 percent of the planned items. Without contracts for the items on the formulary in place, VA delayed the launch of the MSPV-NG program until December 2016 and SAC began establishing non-competitive agreements in the last few months before the launch of MSPV-NG. As shown in figure 1, these non-competitive agreements accounted for approximately 79 percent of the items on the January 2017 version of the formulary. While this approach enabled the MSPV-NG program office to establish the formulary more quickly, it did so at the expense of one of the primary goals of the MSPV-NG program-leveraging VA’s buying power to obtain cost avoidance through competition.

Figure 1: VA’s Use of Non-Competitive Agreements Spiked Late in 2016



Source: GAO analysis of Veterans Affairs formulary data. | GAO-13-274T

Initial Formulary Did Not Meet Medical Center Needs, Resulting in Low Utilization of MSPV-NG and a Missed Opportunity to Leverage VA’s Large Buying Power

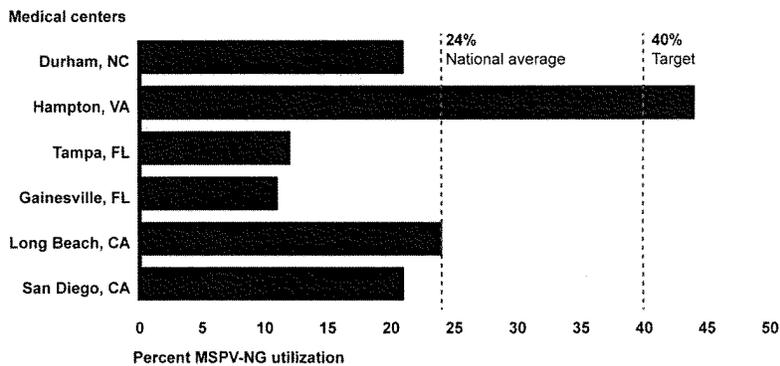
Once VA’s MSPV-NG initial formulary was established in December 2016, each medical center was charged with implementing it. According to logistics officials we

spoke with at selected medical centers, they had varying levels of success due, in part, to incomplete guidance from the program office. Without clear guidance, many medical centers reported they were unable to find direct matches or substitutes on the MSPV-NG formulary for a substantial number of items they routinely used, which negatively impacted utilization rates for the initial formulary. In our November 2017 report, we recommended that the Director of the MSPV-NG program office provide complete guidance to medical centers for matching equivalent supply items. VA agreed with this recommendation and indicated it would provide this guidance to medical centers by December 2017.

According to SAC, as of June 2017, only about a third of the items on the initial version of the formulary were being ordered in any significant quantity by medical centers, indicating that many items on the formulary were not those that are needed by medical centers. Senior VHA acquisition officials attributed this mismatch to shortcomings in their initial requirements development process as well as with VA's purchase data.

VA had set a target that medical centers would order 40 percent of their supplies from the MSPV-NG formulary, but utilization rates were below this target with a nationwide average utilization rate across medical centers of about 24 percent as of May 2017. Specifically, Chief Supply Chain Officers—who are responsible for managing the ordering and stocking of medical supplies at six selected medical centers—told us that many items they needed were not included in the MSPV-NG formulary. As such, we found that these six medical centers generally fell below VA's stated utilization target. As shown in figure 2, among the six selected medical centers we reviewed, one met the target, while the remaining five were below 25 percent utilization.¹¹

Figure 2: Utilization of Medical Surgical Prime Vendor-Next Generation (MSPV-NG) Program at Six Selected Medical Centers (May 2017)



Source: Veterans Health Administration Office of Procurement and Logistics. | GAO-18-274T

Instead of fully using MSPV-NG, the selected medical centers are purchasing many items through other means, such as purchase cards or new contracts awarded by their local contracting office, in part, because they said the formulary does not meet their needs. These approaches run counter to the goals of the MSPV-NG program and contribute to VA not making the best use of taxpayer dollars.

Greater utilization of MSPV-NG is essential to VA achieving the cost avoidance goal of \$150 million for its supply chain transformation effort. Under the legacy MSPV program, the National Acquisition Center tracked cost avoidance achieved by comparing prices for competitively-awarded MSPV supply contracts with prices available elsewhere. However, VHA officials stated that they are not currently tracking cost avoidance related specifically to MSPV-NG. In our November 2017 report, we recommended that the VHA Chief Procurement and Logistics Officer, in coordination with SAC, should calculate cost avoidance achieved by MSPV-NG on an ongoing basis. VA agreed with this recommendation and reported it would develop a new metric to measure cost avoidance by June 2018.

¹¹The one facility that met the target, Hampton VA Medical Center, is categorized by VA as a smaller, less complex facility, and had fewer items to match, which could contribute to its higher utilization.

VA Continues to Encounter Requirements Development and Contracting Challenges as It Works to Address MSPV-NG Shortcomings

In Phase 2 of MSPV-NG, the program office has taken some steps to incorporate greater clinical involvement in subsequent requirements development, but both its requirements development and SAC's contracting efforts have been hampered by staffing and schedule constraints.¹² In the fall of 2016, the program office began to establish panels of clinicians to serve on MSPV-NG integrated product teams (IPT) assigned to the task of developing updated requirements for the second phase of the formulary. Program officials said they had difficulty recruiting clinicians to participate. We found that slightly more than half (20 of the 38) of the IPTs had begun their work to review items and develop updated requirements by the time the MSPV-NG program launched in December 2016. Staff on the IPTs had to complete their responsibilities by the end of March 2017 while simultaneously managing their regular workload as physicians, surgeons, or nurses.

By early March 2017, the IPTs still had about 4,200 items to review. Faced with meeting this unrealistic timeframe, the MSPV-NG program office had 9 IPT members travel to one location-with an additional 10 members participating virtually-to meet for 5 days to review the remaining items. Members told us that this time pressure limited the extent to which they were able to pursue the goal of standardizing supplies, and that their review ended up being more of a data validation exercise than a standardization review. VHA ultimately met this compressed timeline, but in a rushed manner that limited the impact of clinician involvement.

In our November 2017 report, we recommended that the VHA Chief Procurement and Logistics Officer use input from national clinical program offices to prioritize its requirements development and standardization efforts beyond Phase 2 to focus on supply categories that offer the best opportunity for standardization and cost avoidance. VA agreed with this recommendation and stated it is in the process of finalizing guidance that will detail the importance of involving the national clinical program offices in MSPV-NG requirements development and standardization efforts.

The SAC plans to replace the existing Phase 1 non-competitive agreements with competitive awards based on the Phase 2 requirements generated by the IPTs, but it may not be able to keep up with expiring agreements due to an unrealistic schedule.¹³ Because they were made on a non-competitive basis, the Phase 1 agreements were established for a period of 1 year. In order to keep the full formulary available, the SAC director said the staff must award 200 to 250 contracts before the Phase 1 agreements expire later this year. SAC officials acknowledged that it is unlikely that they will be able to award the contracts by the time the existing agreements expire. According to SAC officials, they are in the process of hiring more staff to deal with the increased workload. Further, the SAC division director told us that they canceled all outstanding Phase 2 solicitations in September 2017 due to low response rates, protests from service-disabled veteran-owned small businesses, and changes in overall MSPV-NG strategy.

In our November 2017 report, we recommended that the MSPV-NG program office and SAC should establish a plan for how to mitigate the potential risk of gaps in contract coverage while SAC is still working to make competitive Phase 2 awards, which could include prioritizing supply categories that are most likely to yield cost avoidance. VA agreed with this recommendation and indicated it has developed a plan to mitigate the risk of gaps in contract coverage with short- and mid-term procurement strategies to ensure continued provision of medical and surgical supplies to VHA facilities. The department also stated that it plans to replace the current MSPV-NG contract and formulary process with a new approach where the prime vendor would develop the formulary. However, VA will likely face challenges in this new approach until it fully addresses the existing shortcomings in the MSPV-NG program.

Chairman Roe, Ranking Member Walz, and Members of the Committee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contacts and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact Shelby S. Oakley at 202-512-4841 or OakleyS@gao.gov. In addition, contact points for

¹²Work on Phase 2 began while medical centers were implementing Phase 1 and beginning to order from the MSPV-NG formulary.

¹³According to VA, the agency plans to use indefinite delivery/indefinite quantity contracts in addition to blanket purchase agreements for Phase 2.

our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals who made key contributions to the report on which this testimony is based are Lisa Gardner, Assistant Director; Emily Bond; Matthew T. Crosby; Lorraine Ettaro; Michael Grogan; Jeff Hartnett; Katherine Lenane; Teague Lyons; Roxanna Sun; and Colleen Taylor.

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Prepared Statement of Roger D. Waldron

Good Morning Chairman Roe, Ranking Member Walz and Members of the House Committee on Veterans Affairs. Thank you for the opportunity to appear before you to address the VA Medical/Surgical Prime Vendor (MSPV) program, including its “Next Generation” and “2.0” iterations.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than \$145 billion dollars of the sales generated annually through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWACs), and agency-specific multiple award contracts (MACs). Coalition members include small, medium, and large business concerns that provide more than \$12 billion worth of medical/surgical products and pharmaceuticals to support the health care needs of veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and to support our veterans.

As you know, the VA uses several strategies to acquire medical/surgical equipment and supplies including national contracts, federal supply schedules and the Medical/Surgical Prime Vendor (MSPV) program. It is critical that these programs work together consistently and effectively to create a high value acquisition and distribution system. The VA faces numerous challenges associated with the management of its hospitals and supply chain. Studies, reports, and analyses have been published about these challenges and possible solutions. In September 2016, the Government Accountability Office (GAO) made 10 recommendations to improve the efficiency and effectiveness of VA acquisitions.¹ On Monday GAO released a new report, GAO -18-34, “Veterans Affairs Contracting: Improvements in Buying Medical and Surgical Supplies Could Yield Cost Saving and Efficiency” which documents many of the challenges and impacts the of the MSPV-NG on the VHA customer and the VA’s industry partners over the last two years.

Earlier this year, the Coalition was pleased to have submitted recommendations to the VA to reform its procurement operations in connection with the VA modernization program. Attachment 1 to this statement contains our detailed recommendations for:

1. Establishing Clinician Leadership/Program Management
2. Centralizing VA Procurement Operations
3. Streamlining Unnecessary and Duplicative Regulations
4. Improving IT Systems
5. Reorganizing Pharmacy Benefits Program
6. Reforming the Role of the VA Office of the Inspector General in Contracting

The Coalition also has been privileged to prepare comments in response to the VA’s proposed MSPV 2.0. The MSPV program seeks to deliver a national strategic sourcing solution that combines a formulary approach with electronic cataloging and ordering to support the Veterans Administration Medical Centers. VA’s version 2.0 would outsource the program to a single commercial contractor. The contractor would determine what the agency would buy, and how the items would be sourced, managed and distributed; administer contracts; and ensure quality control. Nationwide electronic ordering and invoicing would be facilitated using the commercial contractor’s e-commerce platform.

Coalition members support VA’s objectives related to aligning the acquisition of medical/surgical products more with commercial best practices and increased efficiency. The current MSPV 2.0 proposal, however, leaves so many questions unanswered that, at this time, we are unable to make a realistic evaluation of its impact on veteran’s health, VA suppliers or the contracting process. Our questions and areas of concern are described in detail in Attachment 4 to this statement.

The Coalition has several fundamental concerns that our members believe must be addressed to ensure the success of the MSPV program and/or any future VA program for the application of medical/surgical equipment and supplies. Specifically, we believe that the VA needs to:

1. Establish a strong program office, led and managed by clinicians

¹ GAO-16-810, Improvements in Policies and Processes Could Yield Cost Savings and Efficiency, September 2016

2. Be clear that best value for the veteran, not price, will drive program requirements

3. Maximize alignment with commercial practice

4. Leverage competition to benefit the prime vendor program

A Clinically Led and Managed Program Management Office

Our members continue to emphasize that a program office led and managed by clinicians is a commercial best practice and is critical to implementation of a successful prime vendor program that supports President Lincoln's promise "To care for him who shall have borne the battle, and for his widow, and his orphan". The foundation for an effective and efficient VA medical supply program, focused squarely on the needs of veterans, is a VHA program office that is led by health care professionals with both clinical and medical supply chain expertise. A clinically led program office possesses the breadth of skills and experience to make effective and efficient evaluation of medical devices and overall product decisions that result in optimal outcomes and best value for patients and practitioners across the VA health care system. Our experience with MSPV-NG has shown that without clinical program leadership and management, VA is destined to have MSPV strategies and decisions that are focused on, and driven by, the government "procurement process," potentially compromising the health care needs of veterans.

The lack of clinician and medical supply chain experience within the VHA medical/surgical Program Office has led what appears to be the view that medical and surgical products are simple and interchangeable commodities. This view simply is not the case; these acquisitions cover highly regulated and complex medical products with unique characteristics that directly impact patient outcomes in VA facilities. Under the current program, there have been several issues which seem to be contract-driven, rather than clinician-driven. For example, the practice of awarding a limited number of line items, rather than the standard commercial practice of awarding contracts for coordinated suites of products. This practice:

1. Leads to inefficiencies at VA facilities. The unavailability of certain products can impact the ability to perform medical procedures, often resulting in cancellations, and it consumes valuable nursing time to find and source products;

2. Challenges industry in the solicitation process to recognize individual product codes that may be buried in unfamiliar groupings, increasing the potential misalignment of expectations and performance; and

3. Raises concerns for the practice of medical care by end-users. Awarding different medical products within a suite of products may require additional training for VA medical staff to ensure appropriate use, increasing time pressures on already stressed medical staff, and potentially introducing safety risks through the expansion of product variation.

The proposed MSPV 2.0 does not address the imperative of a clinically-led, successful program office. In fact, MSPV 2.0, as we understand the vision, likely will exacerbate the clinician vacuum by vesting in a commercial entity, the responsibility and authority to develop, determine and manage what products are included on the MSPV formulary and how such products are sourced. Coalition members have raised questions as to how the VA will ensure that this "super" prime vendor will ensure an appropriate clinical role when making formulary decisions that prioritize patient outcomes for our nation's veterans. Moreover, they are concerned that there is no assurance that formulary items are NOT selected by the MSPV 2.0 contractor based on competing business interests/decisions rather than the health care needs of veterans. The establishment of a program office with strong leadership by clinicians who have medical supply chain expertise is necessary to assure well-developed technical requirements that address these concerns. Best value outcomes start with sound, effective and clear customer requirements in this regard.

Coalition members continue to report a lack of clinician input in developing technical requirements. For example, in connection with MSPV-NG, the Strategic Acquisition Center (SAC) establishes IDIQs and BPAs based on requirements developed in consultation with the procurement and logistics arm of the VHA. Clinicians apparently provide input in some instances, though there is a lack of transparency regarding these decisions. Under these circumstances, members are concerned that award decisions are based on price and not best value for veterans' health care. It is their experience that a lack of clinical input has led to an incomplete formulary, which causes supply shortages and may require facilities to purchase items via the open market, often at a high cost, on government purchase cards. Robust clinical leadership during the requirements development process would avoid such prob-

lems. It is not enough to formalize the current “clinical input” process (the VHA’s Integrated Product Teams) being utilized under MSPV–NG for the future 2.0 program. See Attachment 2 providing additional background and recommendations on creating a clinician led program office.

Best Value

Veterans cannot be relegated to “low price technically acceptable” health care, and for this reason, the VA must clearly assert that value, i.e., the facilitation of the most positive health care outcomes for veterans, not raw low price, is the objective when acquiring medical equipment and supplies for our nation’s veterans. Value drives positive health care outcomes for veterans. Coalition members understand that a significant objective for the MSPV 2.0 is cost savings. The MSPV 2.0 vision, to date, however, provides little-to-no detail regarding how cost savings will be measured and considered in the context of medical outcomes, supply chain efficiencies, or the like. Further, there is no detail as to whether the responsibility for making these important decisions will rest with the MSPV 2.0 contractor or the government. Without a clear articulation of a VA position that value, not price is the driving force, there is little incentive for a contractor to offer the latest innovative, but perhaps more expensive new, life-saving technology for our veterans. Given this lack of clarity, coupled with the absence of a clinician led and managed program office, the Coalition members are concerned that financial incentives, rather than a focus on patient outcomes, will drive the program. Clinical expertise is essential to making best value selections of medical and surgical products.

Attachment 3 includes a letter from the Coalition to the VAC SAC regarding low price technically acceptable evaluation methodology for medical/surgical items.

Commercial Practice

To assure streamlined processes and reasonable prices, we strongly urge the VA to align with best commercial practices. In issuing the RFI for MSPV 2.0, VA stated that alignment with commercial practice was a key objective. Paragraph 2.0 of the Scope section of the RFI, however, provides that one contractor will be responsible for “developing a medical surgical supply and equipment formulary for each facility in the VA., [and will] provide strategic sourcing, life cycle management, distribution, inventory management and analysis services, quality control/quality assurance support services, and warranty management services for materials they are responsible for providing.” This approach is inconsistent with commercial practice. Indeed, Coalition members report that there is no comparable commercial model that provides for a super prime vendor essentially responsible for developing, designing, and managing a formulary while at the same time distributing, delivering, and managing all the products listed on that formulary.

In particular, as noted in Attachments 2 and 4, the RFI’s approach does not reflect the complexity associated with establishing, competing, and managing the requirements for a medical/surgical prime vendor catalog world-wide. As currently constructed, the RFI proposes the execution of a competition within a few months. For comparison, our members have explained to the VA that pursuant to the commercial model, which represents 98–99% of the US market for medical devices, a commercial organization, with a clinically led program office, typically takes approximately four years to successfully compete such a catalogue.

In addition, our experience with MSPV–NG has shown that the VA does not utilize the established medical product categories that are used in the commercial market. Although VHA has attempted to create product categories, an improvement upon the current line item competitions, these categories are government-unique and not recognized by industry. Following product categories that are well known in the commercial market increases the likelihood of developing a comprehensive scope of formulary products that meet the needs of clinicians in the VA medical system. To do otherwise risks suffering significant gaps in the availability of medical and surgical products on the Formulary, similar to the experience under the current MSPV–NG contracts

Further, MSPV 2.0 should allow companies to distribute their products to the VA as they do for commercial hospitals. Specifically, although many medical products are available through medical/surgical distributors, a considerable number of medical devices are only available through direct acquisition from manufacturers. Direct ordering from manufacturers for certain products is a standard commercial practice typically driven by medical safety requirements and the corresponding chain of custody tracking to ensure traceability of product. In these circumstances it is neither appropriate nor efficient to stock these through distributors. Thus, the VA should look to other alternatives such as separate IDIQ contracts of the Schedules program, as appropriate.

In sum, prior to launching MSPV 2.0, the Coalition recommends that the VA take the time to identify commercial best practices for the medical supply chain and align the VA's purchasing strategy accordingly.

Competition

Finally, VA's proposal for MSPV 2.0 in the RFI assigns one commercial entity responsibility for making critical decisions that, generally are reserved to the government, specifically, what to buy, how to buy, and contract administration. The Coalition cannot emphasize enough its recommendations that the VA establish the MSPV 2.0 formulary, based on requirements developed by a clinically led program office, rather than outsourcing this function to a contractor. The establishment of the formulary for veterans is an inherently governmental function that should be conducted by the government and not a private entity. It is the VA's responsibility to identify the medical and surgical products that meet the health care needs of veterans at best value to taxpayers, as the VA possesses unparalleled expertise and intimate understanding of the panoply of needs of this client base. A private entity does not, and thus to allow that private entity to do so would risk formulary decisions being made based on an individual contractor's business and financial incentives, rather than the best interest of veterans. It is also a direct business conflict of interest for a single contractor to both manage and perform the requirement. Here, the contractor would be responsible for the overall development/management of the formulary and delivery of all the items listed on that formulary.

The VA's proposal also would allow a single 2.0 prime vendor to have total control over the program, without any readily discernible checks, and it assumes that further consolidation of the MSPV program is desirable. The Coalition believes that this approach is flawed because it fails to recognize the value to competition and having multiple prime vendors to supply VA health care facilities world-wide. For instance, distribution is a commercial activity, with many competent players at a regional or sub-regional level. Rather than leverage competition among those players, VA's MSPV 2.0 vision cedes disproportionate market power to one firm. Over time, vesting too much authority into a single contractor is not good for government or its supplier base because it enables the contractor to control not only the federal market, but also federal suppliers in ways that may be detrimental to the government and the ultimate customer, veterans. By way of example, this disproportionate market power can affect:

- VA's ability to replace a non-performing prime vendor
- A supplier's ability to access VA procurement through a single point of entry
- Continual performance improvement over the life of the contract due to competition
- The ability of small/small disabled veteran businesses to either contract with VA directly as prime contractors or successfully participate in the prime vendor program.

VA is still in the process of creating its vision for MSPV 2.0. Program development and implementation will likely occur over an extended period of time. Given the millions of veterans impacted by the program, the Coalition strongly urges VA to stabilize the current program while it takes the time to explore future options.

We recommend that VA immediately launch a clinician led management program office that will lead initiatives to both shore up the current MSPV-NG program, and help build future programs. The program office should have a clinical leader and clinical staff, mixed with experienced medical supply chain professionals. We also recommend that VA reinvigorate use of the VA Federal Supply Schedule contracts (Schedules) to help stabilize the current program and streamline procedures at the VA National Acquisition Center to support the MSPV-NG program. In the past the VA and its prime vendors relied heavily on Schedules to supply medical/surgical equipment and supplies. The Schedules feature:

- Established contract relationships with major suppliers;
- A broad representation of small and large contractors;
- Extensive choices among commercial products; and
- Streamlined ordering that allows VA to leverage its volume.

With an anticipated rise in the micro-purchase threshold, the Schedules should become easier to use than they are now. The Coalition has submitted to VA a number of recommendations to streamline the Schedules contracting process and enhance the government's ability to add new and innovative products and services. We have attached those recommendations to this statement.

Thank you for the opportunity to submit this statement. I will be happy to answer questions.

Attachment 1

August 2, 2017

Mr. Greg Giddens
 Modernization Lead
 Department of Veterans Affairs
 810 Vermont Ave, NW
 Washington, DC 20420

Subject: Department of Veterans Affairs Modernization

Dear Mr. Giddens,

The Coalition for Government Procurement (Coalition) appreciates the opportunity to submit comments regarding the reorganization and modernization efforts at the Department of Veterans Affairs (VA).

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than \$145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than \$12 billion worth of pharmaceuticals and medical/surgical products to support health care needs of our nation's veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and support for our veterans.

The Coalition is submitting these comments on behalf of our members in response to the "Executive Order on a Comprehensive Plan for Reorganizing the Executive Branch," directing agencies to enhance efficiency, effectiveness, and accountability by reorganizing and eliminating unnecessary agencies, components, and programs. The Coalition sincerely appreciates the opportunity to provide input regarding opportunities to increase efficiencies in VA's acquisition functions. If there are any questions I may be reached at (202) 331-0975 or rwaldron@thecgp.org.

Sincerely,

Roger Waldron
 President

VA Modernization Recommendations

In Fiscal Year 2016, the VA obligated more than \$23.2 billion to prime contractors-more than a third of the VA's total discretionary budget. Contractors are essential to the VA's mission, providing pharmaceuticals, services, and medical supplies and equipment that are required for the care for our Nation's veterans. The VA faces numerous challenges associated with the management of its hospitals and supply chain. Studies, reports, and analyses have been published about these challenges and possible solutions. Instead of duplicating this work, the Coalition's comments solely focus on recommendations for reforming the VA's procurement operations in order to maximize quality health care services for veterans. The Coalition recommends:

1. Increasing Clinician Input
2. Centralizing VA Procurement Operations
3. Streamlining Unnecessary and Duplicative Regulations
4. Improving IT Systems
5. Reorganizing Pharmacy Benefits Program
6. Reforming the Role of the VA Office of the Inspector General in Contracting

1. Increasing Clinician Input

Coalition members report that there is a lack of clinician input in the VA procurement process. For example, for MSPV-NG, the Strategic Acquisition Center (SAC) establishes IDIQs and BPAs based on requirements developed in consultation with the procurement and logistics arm of the Veterans Health Administration (VHA). Clinicians apparently provide input in some instances, though there is a lack of transparency regarding these decisions and members are concerned that the awards are primarily based on price, rather than best value for veterans' health care. A lack of clinical input will lead to an incomplete formulary, which causes supply shortages and may require facilities to directly purchase items. Likewise, input by clinicians

into the selection of drugs and biologics for the National Formulary is not transparent and there are impediments to drug company representatives providing information to VA medical professionals regarding clinical aspects of non-formulary drugs. By comparison, as discussed below, the Department of Defense (DoD) has a process for formulary decision-making that includes input from manufacturers and representatives of Tricare beneficiaries and publication of the basis for the Pharmacy and Therapeutics Committee recommendations. Additionally, there is no visibility into the process for transitioning care from DoD to the VA, including integration with DoD clinicians, to ensure the VA is providing access to products based on their effectiveness and appropriateness and not just low cost.

Recommendations:

- Create an office (similar in function to Pharmacy Benefits Management (PBM) and Prosthetics and Sensory Aids Service) which is responsible for providing clinician input to the MSPV-NG
- Streamline the VHA procurement bureaucracy to allow clinicians to have more input in ordering-including, as suggested below, streamlining and merging the acquisition functions of the VHA and OALC.
- Provide greater transparency in clinician's product recommendations similar to the PBM

2. Centralizing VA Procurement Operations

The decentralized nature of the VA's procurement operations at the VA headquarters level and within the Veterans Health Administration (VHA) leads to significant inefficiencies and delays in the delivery of health care products and services to veterans compared to the commercial market.

VA procurement offices, like the Strategic Acquisition Center and National Acquisition Center, report to different management offices at VA headquarters leading to duplication, and a lack of coordination and consistency in how health care products and services are purchased by the VA. Currently, many VA suppliers invest in contracting with the VA through both the Federal Supply Schedules (FSS) program and the Medical/Surgical Prime Vendor (MSPV) program for the same products. Consolidating the operations and leadership of these programs would lead to greater consistency and drive process improvements that would reduce costs for contractors. Reduced operational costs will allow for increased health care services for veterans.

Recommendations:

- Streamline and centralize the VA's acquisition operations—move the NAC and the SAC into the same organization. Additionally, the VA should merge the acquisition functions of the OALC and the VHA in order to streamline the procurement process. Coalition members remain concerned that clinician input (which comes from VHA) is divorced from contracting decisions made by the NAC and the SAC.
- Develop standard operating procedures for the MSPV-NG and VAFSS programs with the goal of reducing acquisition lead times, developing greater consistency in requirements and interpretations of policies/procedures, adding new products to contract, streamlining solicitations and awards
- Increase transparency and communications by:
- Improving coordination and shared internal and external communications from the NAC and SAC
- Establishing an Industry Liaison or ombudsman within each program to respond to general questions, refer contractors to appropriate VA resources, raise issues of concern with leadership
- Establish standard processing times for the completion of modifications
- Update the Priority for Use of Government Supply Sources to provide greater clarity to both VA purchasers and contractors
- Extend VAFSS contract term to 5-year contracts with three 5-year option periods consistent with GSA Schedules to streamline processes for government and industry
- Additionally, the VA's should establish additional national contracts with Ordering Officer Delegation (OOD). Currently, only two national contracts have OOD; the lack of this capability forces contracting to a local level resulting in a slow process.

3. Streamlining Unnecessary and Duplicative Regulations

The current VA regulatory environment for procurement is overly burdensome and complex. Coalition members report that contract actions on the VA Schedules can take as much as three times longer than comparable actions on the GSA Sched-

ules. While these regulations and long delays represent a significant burden for industry (including Veteran-Owned Small Businesses), the VA's contracting workforce must also devote significant resources to compliance with certain regulatory requirements. Most importantly lack of a streamlined process fails to ensure that high quality products and services are available to veterans as quickly and efficiently as possible.

Recommendations:

- Eliminate the Price Reductions Clause (PRC). While the Coalition has consistently advocated for the removal of the PRC from the Schedules program, the need to remove the PRC is particularly evident for Schedule 65 I B Drugs, Pharmaceuticals, & Hematology Related Products, since the Veterans Health Care Act already controls the price of covered drugs. Ultimately, the PRC's only one regulation which is unnecessary and duplicative. The VA Regulatory Reform Officer, in compliance with Executive Order 13777 "Enforcing the Regulatory Reform Agenda," should be given the appropriate resources, particularly staff, to complete a thorough review to identify other unnecessary practices to eliminate and/or reform.
- Create a FSS Program Office housed within GSA which would include VA acquisition professionals on detail. The office would ensure the alignment of GSA and VA/MAS policies, increase productivity, and reduce cycle time. The FSS Program Office would also be responsible for resolving differences between the VA and GSA on key regulatory and policy matters. The Coalition has identified several areas where the VA and GSA have different policy interpretations including: (i) negotiating for lowest price, considering terms and conditions, (ii) negotiating for products versus product lines, and (iii) the approach to resellers.

4. Improving IT Systems

There has been significant attention given to the VA's electronic health records, but there are other IT systems which are in dire need of updates to support a better health care system for veterans. For example, the VA needs updates to its IT systems that handle basic business functions such as billing, claims, payment, and contract administration. An IT system that collects information on the VA's supply chain utilization is also essential to identifying what the VA is purchasing, and how improvements can be made over time. Outdated IT systems and manual processes lead to unnecessary delays and inefficiencies in the VA health care system.

Recommendations:

- For the FSS program, leverage existing resources of the GSA such as e-offer and e-mod, which will reduce contracting time at the NAC. When administering the VA Schedules, the VA should focus on health care for veterans and leave FSS administrative matters to GSA.
- The VA should establish an integrated IT system to support supply chain management. This system would be essential to resolving issues such as late payments and product shortages and better inform the VA about purchasing trends and behaviors.

5. Reorganizing the Pharmacy Benefits Program

DoD, in managing its pharmaceutical benefits program, permits clinical input from industry and beneficiaries during a transparent decision-making process that considers clinical and cost effectiveness of products. Ultimately, decisions focus on clinical/therapeutic attributes, as well as price. Additionally, DoD posts the basis for its decisions on a public website. Further, a Beneficiary Advisory Panel holds public meetings to comment on formulary recommendations before they are finalized including the effect on patients if prescribed medication will no longer be as accessible, for example if conditions are imposed on their use. New drugs are considered for formulary placement within a set time after coming on the market to ensure products are timely reviewed and those available through military treatment facilities are purchased. Additionally, DoD manages blanket purchase agreements (BPA) for pharmaceutical agents on its formulary through a class review process in order to leverage market forces. Coalition members remain concerned about the VA's formulary process, which is less structured than in DoD. The VA's process could be strengthened by implementing a similar process, while increasing clinician input and improving outcomes for veterans. Finally, veterans receiving care remotely may not be able to easily travel to a VA facility to receive a prescription. Integrating retail pharmacies would resolve this issue and provide a better outcome for veterans.

Recommendations:

- The VA should modify their formulary process by creating an effective, efficient, and integrated pharmacy benefits program modeled after the DoD program (see 31 CFR § 199.21). Additionally, the VA should allow for manufacturer input and engage in frequent and effective communication with industry—for example DoD allows for manufacturer input in the decision-making process, will post the minutes from its meetings on their website, and has defined decision-making criteria.
- Another important aspect of DoD's process for procuring pharmaceuticals is that they will compete BPAs for agents that are added to the formulary, thereby taking advantage of volume discounts and market forces. The VA should adopt this model and issue a class deviation on the Multiple Award Schedule ordering procedures in FAR 8.405-3 to streamline the process for creating single award BPAs for pharmaceutical agents on the formulary. The Coalition raised this issue in 2011 when the MAS ordering procedures were proposed, and we believe that the VA would benefit from revisiting it.
- New drugs should be reviewed for addition to the formulary within six months after they are available commercially.
- Veterans receiving care remotely should not have to obtain their initial prescriptions from a VA facility, which could be many miles away, or through mail order, which could take two weeks. Allowing retail pharmacies to dispense initial prescriptions of 30-days while requiring refills of maintenance drugs through mail order. VA should implement a process that complies with Veterans Choice and ensures immediate access to needed medication without overburdening the beneficiary.

6. Reforming the Role of the VA Office of the Inspector General in Contracting

The VA OIG plays a crucial role in detecting waste, fraud, abuse within the VA and is essential to protecting the interests of veterans in the VA's care. However, the OIG's role in contracting is overly expansive, which, ultimately, leads to significant delays. Veterans may wait months in order to receive innovative products and pharmaceuticals. This is particularly true in the case of mandatory pre-award audits, which often must be repeated. GSA, which administers the Schedules program, does not require pre-award audits.

Recommendations:

- Eliminate the OIG's pre-award and post-award audit functions for the VA Federal Supply Schedules (FSS). The administrative and pricing review functions can be completed by the contracting officer. The OIG should focus its efforts on investigating cases of suspected fraud related to the VA supply chain. Additionally, this would eliminate any potential conflicts of interest.
- Transfer pricing support staff to the National Acquisition Center (NAC). Members report that contract award and modification times at the NAC are at an all-time high—preventing veterans from accessing new and innovative products and discouraging veteran-owned companies from participating in the FSS. Transferring these staff to the NAC and removing the OIG's audits function will significantly speed up the process.

Attachment 2

The Core Issue: VHA needs a Clinically Led and Managed VHA Program Office

Background:

- Medical devices are highly regulated and frequently very complex devices, which lead to specific medical outcomes in the hands of the surgeon or clinicians and often have variations in cost of use. Commercial hospital systems recognize these complexities, and create oversight organizations that are permanently staffed with individuals with both clinical and medical supply chain expertise to evaluate medical devices and make product decisions that result in optimal outcomes and best value for their patients and clinicians across their hospital system.
- Industry supports and encourages VHA to follow the commercial models which represents 98–99% of the US market vs 1–2% for VHA, and make enterprise level decisions through their Program Office for medical devices to improve efficiencies for both VA and industry, however the overwhelming concern of the medical device industry as well as VAMCs 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

Problems that the current VHA Program Office creates:

- The absence of relevant expertise to lead the program has led to many challenging issues:
- The NG–MSPV program was created without proper leadership from VHA, and instead was created by individuals unfamiliar with medical devices. It has been recognized as a total failure and costly to VA. Examples include:
- Naive to sheer size and effort of task: VHA did not recognize the level of complexity and the challenge of competing requirements for a med-surg PV catalog. A process that a commercial organization (like the GPO Premier) with all the key experienced clinical staff in place, would take four years to execute, was approached by VHA to complete in only a few months
- Poor procurement strategy by VHA: VHA Program Office was unfamiliar with established medical product categories, and elected to compete individual line items rather than recognized product category suites, resulting in significant product suite gaps and confusing product mixes that did not meet the needs of VHA clinicians. When VHA later attempted to create product categories, they developed ones that were hospital departments (Exam Rooms, OR Supplies, Central Supplies, etc) rather than product categories industry would recognize and respond to
- Unrealistic goal to restrict medical products to only highest volume products: VHA decided to severely restrict the number of lines on formulary that did not adequately support clinical care, eliminating critical product sizes needed by clinicians
- Low price approach: VA used a single award based on lowest price for most of the MSPV awards, resulting in products that were not acceptable to clinical users and also awards that did not take into consideration other factors such as:
 - Award for medical disposables that were lowest price but did not function with existing medical equipment at VAMCs
 - Award for medical disposables that did not factor that VAMCs would incur additional costs as other disposable products would need to be used with the awarded product, resulting in higher cost in use for VA
 - Award for medical product that did not factor total costs to VAMCs, such as construction costs for the change
- Lack basic understanding of medical supply chain: VHA was unaware of very basic medical supply chain structure that while many medical products are available through med-surg distributors, there is a significant number of medical devices that are only available direct from manufacturers, which led to VA SAC spending significant contracting time, dollars, and effort to create solicitations for the direct only products that manufacturers would not respond to as it was inconsistent with the commercial model. VA also created unrealistic goals for procurement through MSPV based on this lack of knowledge that VAMCs could never meet
- Confused by medical products: Many solicitations were posted that reflected that medical products confuse VHA, such as an ENT catheters posted in a Urology Supply solicitation.

Negative Impact to VA and Industry

- VHA clinician satisfaction: Clinicians at VAMCs are very unhappy with current product availability and access, as it impacts the ability to perform medical procedures, often resulting in cancellations, and also consumes valuable VHA nursing time trying to find and source products. This impacts veteran access and satisfaction with VA Medical Centers, and physician/nurse retention
- VAMCs opinion of the VHA Program Office and their decisions is very low: VAMCs are very aware and vocal that the VHA Program Office lacks the clinical and medical supply chain experience, which they view as being less than exists at their own VAMCs, and consequently ignore many of the decisions from Program Office as it fails to meet their needs
- Purchase card use: VAMCs are using government purchase cards at an increasing rate as needed products are no longer available from the MSPV, increasing costs but also increasing the very real risk of gray market and/or counterfeit medical device purchases outside of the secure medical supply chain (MSPV), and ongoing problem for VHA for a number of years

- Industry opinion of VHA: Industry is experiencing “bid fatigue”, and has occurred significant costs in trying to respond to solicitations that are poorly developed and then cancelled. Industry extremely concerned about lack of resolve from VHA leadership to correct and lead the program

The Solution

- Create an Effective VHA Program Office: 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 DHA MedLog, which is the med-surg equivalent for DoD and is led by a critical care nurse, and staffed with seasoned medical logisticians and nurses who have actually worked in Military Treatment Facilities. The VA PBM is a good VA example of what a program office should look like, led by a pharmacist and staffed with clinicians who have experience working in VAMCs. Common elements of a good federal medical program office:
 - Leader is a clinician (RN, pharmacist, or MD) who has also worked in a VA/DoD medical center and familiar with VA/DoD medical supply chains
 - Staffed full-time with other clinicians and medical supply chain professionals (logisticians), who have also worked in a VA/DoD medical center
 - VHA needs to create career paths for medical supply professionals to insure VHA has a bench of qualified individuals to work at the national Program Office level, similar to how DoD develops medical supply professionals

Attachment 3

August 8, 2017

Phil Christy
Acting Executive Director, Office of
Acquisition Operations
Department of Veterans Affairs
810 Vermont Ave NW
Washington, DC 20420

Subject: Solicitation for MSPV- Next Generation

Dear Mr. Christy,

The Coalition for Government Procurement appreciates the Strategic Acquisition Center (SAC) publication of draft solicitations for the Next Generation Medical/Surgical Prime Vendor (MPSV) program and the opportunity for industry to provide feedback in response. We would like to submit the following comments on the MSPV solicitations on behalf of our member companies.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than \$145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than \$12 billion worth of pharmaceuticals and medical/surgical products to support health care needs of our nation’s warfighter and veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and support for our veterans.

Based on our member companies extensive experience with medical device supply chains in both the government and commercial sectors, and also consistent with feedback member companies have heard from VA Medical Centers, many believe the current MSPV-NG program formulary is being driven through a process that may actually result in significantly less use of the MSPV. Rather than the VA developing a program designed to meet the clinical end-users needs which creates efficiencies and reduces VA system costs, the NG-MSPV program is being driven by government contracting goals that do not reflect the reality of effectively managing medical devices. Our concerns include the following:

- Lowest price technically acceptable (LPTA) source selection
- A lack of consistent and effective clinician input
- Risks associated with grey market items

We appreciate your attention to these matters impacting the efficiency and effectiveness of the medical and surgical supply chain and the quality of health care for veterans.

Lowest Price Technically Acceptable Source Selection

The MSPV program seeks to deliver a national strategic sourcing solution that combines a formulary approach with electronic cataloging and ordering to support the Veterans Administration Medical Centers. The program relies on four Prime Vendor Contracts and supporting Indefinite Delivery-Indefinite Quantity (IDIQ) contracts with suppliers. Additionally, Section E.14 of the Request for Proposals (RFP) notes that the contract award for the IDIQ's will be determined in accordance with FAR 15.101-2, LPTA Source Selection Process. LPTA source selection procedures are being used in the RFP's for Patient Care Products, Urology, Respiratory Products, Medical Imaging Products, and many other hospital department level groupings.

Given the nature of these procurements, a LPTA source selection raises significant concerns. LPTA source selections are most effective in situations where unsuccessful contractor performance is minimal and where there is little value or need to pay for higher performance. Those criteria are not met in this situation. The SAC is procuring products that will be used in the care and treatment of our Nation's veterans—these are situations where the quality of the products is integral to the health care outcomes for our veterans. As such, an LPTA source selection is inappropriate. Further, products within these categories may be complex devices with unique features that differentiate them from a clinical perspective, or that reduce overall cost of care, making comparative clinical and cost effectiveness a more appropriate standard.

Section E.14 of the RFP's for Patient Care Products, Urology, Respiratory Products, and Medical Imaging Products also directs offerors to provide tiered pricing information based on unit volume. Additionally, offerors may be subject to a Unit of Measure adjustment (calculated at 4.4%) based on the Unit of Issue. This pricing approach ignores commercial practices where vendors usually sell products as packages or cases, rather than individual units.

We recommend that the VA reconsider its use of LPTA selection criteria for these and future MSPV solicitations, and instead focus on a program that is based on best value decisions with clinician input.

Clinician Input in the MSPV

Coalition members remain concerned about the level of clinician input in the MSPV program. There have been several issues which seem to be contract-driven, rather than clinician-driven.

The practice of awarding by line item rather than the standard commercial practice of awarding contracts by a coordinated suite of products 1) leads to inefficiencies with VA and industry contracting, 2) challenges industry with the basic recognition of the solicitations as individual product codes are buried in unfamiliar groupings, and most important, 3) concerns for the practice of medical care by end-users. Awarding different medical products within a suite of products may require additional training for VA medical staff for each product code to ensure appropriate use, increasing time on already stressed medical staff and potentially increasing safety risks by increasing variation. Robust clinical oversight during the requirements development would correct this issue and be aligned with the best practice of contracting by a coordinated suite of products.

Many products that are proprietary were posted under the Brand Name or Equal solicitations, even though there are no equivalents. These will include a number of products that are disposable components for capital equipment located at VAMCs, and using other disposables will typically not work with that equipment, may invalidate the equipment warrantee, or could cause patient harm. We believe that these items, if there was robust clinical input, would have been placed in the Brand Name Only designation.

Additionally, products are being placed under improper categories. For example, a Coalition member identified an ear, nose, and throat product was posted under the urology category. Although this issue has been rectified, the Coalition remains concerned that the products and categories of the contract are not properly aligned. Duplicate product codes are also being uncovered in totally different solicitations (example: same product code listed in Medical Imaging and also in OR Supplies). This would be resolved if contracted by coordinated suites and product categories, rather than line item by hospital department.

We recommend that the SAC immediately incorporate clinician input into their contracting process, including individuals with robust medical supply chain experi-

ence. A model that the SAC could emulate is the Department of Defense (DoD) pharmaceutical formulary process (see 31 CFR § 199.21). The DoD Pharmacy and Therapeutics Committee assures that the selection of agents for the formulary is based on broadly representative professional expertise concerning clinical and cost effectiveness of products within the pharmaceutical agent class. The Committee's decisions and minutes are posted publicly, and industry is given the chance to provide their input and feedback to the Committee. This process ensures sufficient clinical input for the DoD formulary in assessing clinical differentiators and cost trade-offs as well as identifying errors in category assignments. There should be a permanent organization in the VA responsible for ensuring clinician input, which is crucial to the MSPV's success.

Grey Market Items

The Coalition supports the SAC's efforts to prohibit grey market items from being sold through the MSPV-NG via unauthorized resellers. The MSPV solicitations include a definition of grey market goods that we recommend be modified consistent with commercial practice. Section B of the solicitation defines a grey market good as, "genuine branded goods sold outside of an authorized sales-territory (or by non-authorized dealers in an authorized territory) at prices lower than being charged in authorized sales territories [emphasis added] (or by authorized dealers)." Instead, we recommend the following:

The Contractor shall provide only new equipment and new parts for the required products described herein. ABSOLUTELY NO "GREY MARKET GOODS" shall be provided under any Delivery Order. Grey Market Goods are defined as genuine branded goods sold outside of the manufacturer's authorized. Grey market goods purchased from unauthorized sources have left the authorized supply chain and may not be stored in conditions that meet the manufacturer's specifications, and medical devices could be counterfeit or adulterated which pose a threat to patient safety. Grey market items will typically invalidate a manufacturer's warranty. All Equipment must be covered by the manufacturer's warranty.

We recommend that the "grey market good" definition be modified to remove the reference to price and to provide some rationale as to why grey market items are prohibited for delivery orders. Grey market items may have a lower price or a higher price than the price of items sold within the authorized medical supply chain. Unauthorized resellers could purchase the product from an authorized distributor and then resell to the government at a higher price. The price of an item does not relate to whether it is a grey market good or not. The revised "grey market goods" definition above also emphasizes the risk to patient safety of purchasing outside of an authorized distributor network and potential invalidation of the manufacturer's warranty.

In summary, the Coalition recommends that the SAC:

- 1) Reconsider use of LPTA source selection criteria for the MPSV RFP's. Instead we recommend a program based on best value decisions and clinician input.
- 2) Incorporate more clinician review into the MSPV RFP's. The Coalition has identified several aspects of the RFP's including the unit of measure adjustment and the groups that may not be supported by clinicians.
- 3) Host a meeting between the SAC, VHA, and industry, so that stakeholders can discuss the process for clinician input and identify solutions.
- 4) Create a permanent office that is responsible for delivering clinician input. This process could be modeled on DoD's pharmaceutical formulary process.
- 5) Revise the definition of grey market items as proposed.

Thank you for considering the Coalition's comments concerning the Next Generation MSPV. If there are any questions, please contact me at (202) 331-0975 or rwaldron@thecgp.org.

Sincerely,

Roger Waldron
President

Attachment 4

November 9, 2017

Brian C. Love
Contracting Officer, MSPV 2.0

Strategic Acquisition Center (SAC)
 Department of Veterans Affairs
 10300 Spotsylvania Ave, Suite 400
 Fredericksburg, VA 22408

Dear Mr. Love,

The Coalition for Government Procurement appreciates the opportunity to respond to the Department of Veteran Affairs (VA) October 19, 2017, Request for Information and Statement of Objectives (SOO) seeking information about the capability, capacity, and viability of US businesses that provide product supply chain end-to-end management. VA is considering options for the next iteration of its current Prime Vendor program for medical surgical supplies and equipment.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than \$145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than \$12 billion worth of pharmaceuticals and medical/surgical products to support health care needs of our nation's warfighters and veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and support for our veterans.

VA would like to improve the quality, effectiveness and efficiency of its medical/surgical prime vendor program by using best commercial practices and technology. To achieve these objectives, the Department is examining the possibility of a single contractor that would provide VA worldwide, a turn- key solution, for a one-stop-shop acquisition platform for medical supplies, equipment, and related products. As we read the notice, VA is anticipating that the potential contractor would:

A. Determine what the agency would buy

i."be responsible for developing a medical surgical supply and equipment formulary for each facility in VA ."

B. Acquire the items

i."provide strategic sourcing..."

C. Manage and distribute the items

i." life cycle management, distribution, inventory management."

D. Administer contracts and assure quality control

i."analysis services, quality control/quality assurance support services, warranty management services, and

E. Provide for electronic ordering, invoicing, and real-time status.

These services would be provided using an e-commerce platform that incorporates best business practices.

Coalition members support VA's objectives related to aligning the acquisition of medical/surgical products more with commercial best practices and increased efficiency. Before, however, we can realistically assess MSPV 2.0, there are a number of important questions that VA must address. Those questions are set forth below. Without answers to these questions, Coalition members are concerned that VA's vision could negatively impact the ability of government suppliers to adequately respond to the health care needs of veterans. The Coalition values opportunities for continued discussion with VA on these questions.

1. Is the MSPV 2.0 vision based on a viable commercial model?

Despite the expansive involvement of our member companies in the market for commercial items, our members question whether there is an existing commercial provider that can deliver the extensive scope of services described in the FBO notice for medical supplies and equipment.

VA's current prime vendor program supports more than 9 million veterans. An initiative that moves to a new, commercially untested e-commerce platform should be undertaken only in increments, after a series of periodic evaluations, over a period to time. To do otherwise risks failing the health care needs of veterans.

Prior to launching MSPV 2.0, the Coalition recommends that the SAC:

a. Identify through what channels the medical and surgical products considered for the program are purchased in the commercial market (recognizing that they are bought through different pathways, not just one)

b. Align the VA's purchasing strategy with these commercial practices

c. Coordinate with the program offices that are already contracting for these products, ensuring that there is no duplication of effort

We also recommend that the VA consider following the VHA's pharmacy/prosthetics/logistics working group as a model, which determines the responsibility and management for specific products. A MSPV/equipment/direct working group could be established to coordinate the efforts between the responsible program offices.

2. Does the Veterans Health Administration (VHA) have a clinically led and managed program office that will determine which products will be acquired through MSPV 2.0?

Coalition members note particularly that there is a lack of clinician involvement in determining what products are included on the current MSPV-NG formulary and how such products are sourced. To date, VHA has not taken responsibility for its medical supply chain by establishing a clinician led and managed MSPV program office. Under the proposed model, how would the VA ensure that the prime vendor has the appropriate clinical staff to make formulary decisions that prioritize patient outcomes? How would the VA ensure that formulary items are NOT being selected by business people based on business decisions?

The Coalition is concerned that under the current proposal, financial incentives rather than a focus on patient outcomes will drive the program. There is also concern that without the program being led and managed by clinicians at VHA, many of the same challenges with the current MSPV program will continue into the next iteration.

3. Should "medical equipment" items be excluded from the formulary given that, commercially, they are sold direct from manufacturers and not through distributors?

VA mentions that medical equipment items will be included in the Formulary. These types of products are typically purchased direct from manufacturers and not sold through distributors in the commercial market. Many equipment items such as Ventilators have various software options and accessories that are purchased with the equipment in a customized manner. Meaning that each particular end user customer could ask for a unique configuration of software options and accessory items. In addition, the VA has a Non-Expendable Medical Equipment program that would seem to conflict with including equipment items in a MSPV formulary.

4. Are some of the functions contemplated for the contract, inherently governmental?

The United States has been the long-standing policy that inherently governmental functions shall not be performed by a contractor. FAR 7.5 lists examples of functions that have been considered as inherently governmental. Those examples include processes that VA appears to contemplate contracting out, specifically:

- Determining what supplies or services are to be acquired by the Government
- Approving any contractual documents, to include documents defining requirements, incentive plans, and evaluation criteria
- Awarding contracts
- Administering contracts
- Determining whether contract costs are reasonable, allocable, and allowable

VA should examine its proposal and statement of objectives to assure that it will not outsource inherently government functions to a contractor.

5. Does the VA proposal establish an organizational conflict of interest that cannot be mitigated?

FAR 9.502 states that "[a]n organizational conflict of interest may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential conflict of interest on a future acquisition'.

The vision for MSPV 2.0 assigns one entity responsibility for decisions on what to buy, how to buy and contract administration. As described, the entity has total control over the system without any readily discernible checks. What prevents for

example, a contractor from selecting products for formulary based on its commercial relationships?

The MSPV 2.0 approach presumes that further consolidation of the MSPV program is desirable. There is some thought that this approach is flawed. There is value to competition. Distribution is a commercial activity and there are many competent players at a regional or sub-regional level. Rather than leverage that competition, VA's MSPV 2.0 vision cedes disproportionate market power to one firm. If that contractor has difficulty performing, it would be very difficult to terminate and bring in a new provider. Fewer choices is not in the interest of the VA facilities.

Over time, vesting too much authority into a single contractor is not good for government or its supplier base. The downside of consolidating that much authority into one entity is that it enables the contractor to control not only the federal market, but also to leverage federal suppliers in ways that may be detrimental. Will bargaining power between the suppliers and prime vendor be so distorted that the prime vendor will be able to influence not only federal but commercial business? For example, will the supplier fees be consistent with the 3% rate in the commercial market for medical devices?

6. Will MSPV 2.0 address compliance with underlying procurement policy?

The SOO does not offer guidance as to how fundamental procurement policies will be addressed. For example, must suppliers comply with the requirements of the Trade Agreement and Buy American Acts and who will determine compliance? Must prices be determined fair and reasonable and if so who will do so - VA or the Prime vendor? Will the small business "Rule of Two" be adequately considered?

Would it be the PV's responsibility to comply and how would they do so?

7. How will disputes between suppliers and the prime vendor be resolved?

Our members are concerned that conflict of interest concerns may drive disputes with the prime vendor both in selecting items for formulary and handling future orders. Will a supplier have any ability to challenge these issues or others arising in the acquisition process?

Is the agreement between the supplier and prime vendor a federal or a commercial contract? Does VA envision such matters to be totally between the commercial parties or will the Government have a role?

8. Does the e-commerce platform adequately protect government and contractor data?

The draft SOO includes a requirement for a metrics dashboard and the ability to provide analytics to assess performance, supply chain costs, and forecast market expectations. Who would own the data generated in the electronic system? Will the prime vendor be required to provide sales tracings to suppliers consistent with commercial practices for medical devices? How will this data be protected?

Is the contractor able to also sell product through the program? Can they use/access this data to gain an unfair advantage in the government or commercial marketplace?

9. Is a "requirements" type contract appropriate in this instance?

The SOO (section 5.2.1) states the government intends to issue a single requirements contract using FAR parts 15 and 16. A requirements contract would obligate VA to filling all actual purchase requirements of the government during a specified contract period from one contractor. VA estimates that there will be 86.4 million patient care events in 2018. Given the broad scope of potential users of this acquisition platform, it would seem very difficult for VA to adequately police it users to ensure all orders go to the contractor. "Leakage" from the contract could result in significant liability to the government.

10. Has VA considered the impact of its cost objectives on innovation?

A significant objective for the MSPV 2.0 is cost savings. How will cost savings be measured - lowest price or best value (medical outcomes, supply chain efficiencies, etc.)? Will the contractor or government be responsible for measuring such savings?

There is a potential for the contractor to limit innovation because the innovative product may be more expensive than current technology. Without sufficient clinician input, what incentive does a contractor have to offer more expensive new technology?

11. What does the goal of a 95% usage rate for the “one-stop-shop” acquisition of consumable medical and related commodities described in 5.1.1 mean?

VA has a goal for 95% of medical disposables to come through MSPV program. This goal may be unrealistic depending on what medical products are considered within scope, as a significant portion of these products are available commercially only directly from manufacturers. It is unlikely that those manufacturers are going to change their commercial models for a customer that only represents 1–2% of US sales.

12. Would the VA consider establishing separate contracts for direct only products?

Again, the draft SOO states that there would be a 95% usage goal for the acquisition of consumable medical and related commodities. Much of this industry is direct only. It is not cost effective or efficient to stock them through distributors. VA should follow commercial model of establishing separate contracts. VA could use an Electronic Medical Catalogue (ECAT) like that used by the Department of Defense to facilitate ordering.

13. What will be the drop shipping policy under MSVP 2.0?

Will VA align more with the commercial market and establish contracts with manufacturers for direct- only products.

14. Will prosthetics be excluded from MSPV 2.0?

The variety of products and nature of procedures does not translate to MSPV purchase or delivery infrastructure. Although most cases are templated prior to surgery, the case often requires a change on the spot. As such, multiple sizes and types are made available to the surgeon during each case. This flexibility cannot be achieved by warehousing implants and having a single size/type delivered to the hospital on the date of surgery.

15. The VA SAC would like access to the latest technologies under the formulary. What will the process be to add new products?

Again, more clarification is needed as to how formulary decisions will be made. Members report challenges with the process to add new products under the existing MSPV–NG. What criteria will be used by clinicians to determine which products to add to ensure that veterans have access to the latest technologies?

16. The draft SOO proposes a Period of Performance that could extend 12 to 15 years. What is the rationale for this timeframe?

A performance period of 12 to 15 years far exceeds FAR limitations. Under FAR 17.204(e) the total period of base plus options “shall not exceed 5 years” in the case of services. For supplies, the base plus option quantities shall not exceed 5 years. These limitations do not apply to IT contracts. However, other statutes may further limit the contract term.

The performance period for the Pharmacy Prime Vendor contract is 8 years. Members would like to better understand the SAC’s rationale for a potential performance period of 12 to 15 years for MSPV 2.0.

17. Would the VA further explain Performance Objective 5.1.6, which states, “Allow maximum physician choice in consumable medical commodities, consistent with patient safety and enterprise-wide interoperability and standardization goals, used while maximizing cost saving possibilities?”

Based on this statement, it appears that the VA program office and/or contracting personnel may view many technical medical devices as being commodities without recognizing the differences in brands that can impact patient outcomes. In addition, allowing maximum physician choice and having standardization goals appear to be two completely different initiatives. Further clarification on these points would be helpful.

18. What are the implications of section 6.4 of the SOO that states, “Only FDA approved Medical/surgical supplies that are compliant with Global Standard 1 (GS1), Health Industry Business Communications Council (HIBCC), and/or International Society for Blood Transfusion (ISBT) 28 standards will be available to VHA facilities through the MSPV program?”

It is unclear whether the VA intends to exclude products from the formulary that do not meet these criteria/standards.

Again, the Coalition for Government Procurement sincerely appreciates the SAC's efforts to collect industry's input on the proposed next generation of the Prime Vendor program. We support better aligning the program with commercial best practices and ensuring that it is led and managed by clinicians at the Veterans Health Administration. Significant progress in achieving both objectives will result in more efficiencies and cost savings in the delivery of best value medical and surgical supplies to VA facilities worldwide.

Thank you for considering industry's input in designing MSPV 2.0. We look forward to working with the VA as it continues to explore options for building the next iteration of the Prime Vendor program.

Sincerely,
 Roger Waldron
 President

Statements For The Record

ADVAMED

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 health care 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 reasonable 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.



Material Submitted For The Record

GAO Power Point Chart

Key Steps Selected Leading Hospital Networks' Supply Chain Managers Reported Following in Standardizing Their Medical Supply Chains

