VETERANS HEALTH ADMINISTRATION CONTRACTING AND PROCUREMENT PRACTICES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

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

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VETERANS HEALTH ADMINISTRATION CONTRACTING AND PROCUREMENT PRACTICES

THURSDAY, SEPTEMBER 23, 2010

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:01 a.m., in Room 334, Cannon House Office Building, Hon. Michael Michaud [Chairman of the Subcommittee] presiding.

Present: Representatives Michaud, Brown of Florida, Donnelly, Perriello, Brown of South Carolina, and Boozman.

Also Present: Representative Carnahan.

OPENING STATEMENT OF CHAIRMAN MICHAUD

Mr. MICHAUD. As we get started, would the first panel please come forward? Good morning. The Subcommittee on Health will now come to order. I would like to thank everyone for attending this hearing. The purpose of today's hearing is to investigate potential weaknesses in the Veterans Health Administration's (VHA's) contracting and procurement practices, and explore ways that we can strengthen how VHA contracts and procures medical equipment and health care products for our veterans.

In recent years, we have seen many reports and studies on the contracting and procurement activities of the U.S. Department of Veterans Affairs (VA). These reports have identified the need for increased transparency and fiscal responsibility, as well as highlighted problems of inadequate competition and lack of accountability and oversight. As a result of these deficiencies in VHA's contracting and procurement practices, veterans may not be getting the latest innovation in health care products. This was also made evident in our June Health Subcommittee hearing on wireless health care technology, which revealed the difficulties that many private companies face in informing VA about their products and getting their products in the hands of our veterans. Furthermore, we are all aware of the problems of dirty reusable medical equipment at certain VA medical centers.

Today, we will hear from the U.S. Government Accountability Office (GAO) about a study that they are conducting on the purchasing and tracking of supplies and medical equipment. Their preliminary observations include the potential risk to our veterans' safety when VA is in noncompliance with VA purchasing and track-

ing requirements. Finally, internal control weaknesses with VHA's use of billions in miscellaneous obligation continues to be a problem because VA contracting officials do not have sufficient control over the authorization and use of miscellaneous obligations. It is unclear whether these obligations were for legitimate needs.

I have been very supportive of increasing funding for the VA. However, I think we must also make sure that they are using our dollars wisely. For instance, the VA does a great job in negotiating for lower cost prescription drugs. The cost is estimated in 2011 to be $4.8 billion. Even though we are able to negotiate for the lower cost prescription drugs, my concern is whether or not the utilization for those prescription drugs are the most cost effective way that the VA should be moving forward. And I look forward to hearing from today's witnesses as we aim to better understand the challenges that face the VHA contracting and procurement practices, and work together to find potential solutions to these challenges.

I want to now recognize my good friend and colleague Mr. Brown for any opening statement that he may have.

[The prepared statement of Chairman Michaud appears on p. 46.]

OPENING STATEMENT OF HON. HENRY E. BROWN, JR.

Mr. BROWN OF SOUTH CAROLINA. Thank you, Mr. Chairman, and I appreciate you calling this hearing today. I am pleased to be here to discuss contracting and procurement issues within the Veterans Health Administration. VA's troubled contracting and procurement processes have long been an issue of great concern to this Committee and the subject of various Government Accountability Office and VA Office of Inspector General (OIG) reports that continue to cite major deficiencies and material weaknesses. Given the wide scope of VA's reach and budget, it is particularly important that we ensure that they have the proper procedures and oversight mechanisms in place to ensure that VA's procurement and contracting is done responsibly, appropriately, and with proper oversight.

In that vein, I am particularly concerned about testimony we will hear from the Office of Inspector General that "data in VA and VHA acquisition support information systems is incomplete and unreliable." Without accurate data, we have no idea what we are doing right or what we are doing wrong, where we are, where we are going, or where we need to be. This is unacceptable within a system that is responsible for the care of our Nation's veterans and spent a little over $9 billion on health care goods and services last fiscal year alone.

Streamlining contracting and procurement processes to eliminate the potential for waste, fraud, and abuse, while at the same time improving the cost and comfort of doing business with VA to ensure our veteran heroes have access to the highest quality medical care is and should be at the top of our priority list.

I look forward to hearing from the witnesses on our first panel about the obstacles to doing business with VHA, and from the government witnesses on our second and third panel about the functioning of VHA's acquisition system. Although we are nearing the end of this legislative session, I am hopeful that we will be able to move legislation H.R. 4221, the "Department of Veterans Affairs Acquisition Improvement Act of 2009," introduced by our Ranking

Member Steve Buyer. This bill, that I originally cosponsored, would correct the long-term procurement issues within VA and provide great oversight of VA's contracting and access management processes.

I thank you, Mr. Chairman, for being here for this discussion, and I yield back the balance of my time.

[The prepared statement of Congressman Brown appears on p. 46.]

Mr. MICHAUD. Thank you very much, Mr. Brown. Before I begin I would like to ask unanimous consent that Mr. Carnahan, who will be attending this hearing later, be invited to sit on the dais on the Subcommittee on Health today. Hearing no objections, so ordered. I also would like unanimous consent to include all the written testimony in the record. Hearing none, so ordered.

At this time I would like to introduce the panel. Our first panel includes Mark Munroe, who is the Senior Vice President of Sales and Marketing for the Mobile Medical International Corporation. We have Derek Newell, President of Robert Bosch Healthcare; Linc Moss, who is the Senior Vice President and Chief Operating Officer for Ramtech Building Systems, Inc. We have Jay Wise, who is from Wise Knowledge System, and Jim Clair who is Chief Executive Officer of Goold Health System (GHS). Jim is also accompanied in the audience by Lorraine Lachappelle, who is an R.N., and is the Director of Community Assessment. And it is my understanding that Lorraine also served in the Army. I want to thank you very much for your service on behalf of this great Nation of ours.

Without any further ado, we will start off with Mr. Munroe.

STATEMENTS OF MARK T. MUNROE, SENIOR VICE PRESIDENT, SALES AND MARKETING, MOBILE MEDICAL INTERNATIONAL CORPORATION, ST. JOHNSBURY, VT; DEREK NEWELL, M.P.A., MPH, PRESIDENT, ROBERT BOSCH HEALTHCARE, PALO ALTO, CA; LINCOLN MOSS, SENIOR VICE PRESIDENT AND CHIEF OPERATING OFFICER, RAMTECH BUILDING SYSTEMS, INC., MANSFIELD, TX, ON BEHALF OF MODULAR BUILDING INSTITUTE (MBI); JAY WISE, PH.D., CHIEF EXECUTIVE OFFICER, WISE KNOWLEDGE SYSTEMS, INC., PIPER CREEK, TX; AND JAMES A. CLAIR, M.P.A., M.S., CHIEF EXECUTIVE OFFICER, GOOLD HEALTH SYSTEMS, AUGUSTA, ME

STATEMENT OF MARK T. MUNROE

Mr. MUNROE. My name is Mark Munroe, Senior Vice President of Sales and Marketing for Mobile Medical. Mobile Medical is an international company that develops and manufactures commercial and military mobile surgical hospitals, which meet all U.S. health care standards. These mobile health care solutions are rapidly deployable, fully integrated, self-contained, and present innovative solutions for today's health care delivery needs. My purpose here today is to explain how Mobile Medical has worked with VA medical centers throughout the country while describing some of the challenges associated with those experiences, and pointing out some of our exciting success stories.

Let us begin with the New Orleans VA Medical Center. As we are all aware, Hurricane Katrina struck New Orleans 5 years ago. Since Katrina, the New Orleans VA Medical Center has not provided surgical or endoscopic services to the veterans of New Orleans. Veterans in the New Orleans region must seek health care at other facilities within the system. This often causes veterans to wait for needed procedures, or travel greater distances to receive the care they need. In January 2008, Mobile Medical moved to mitigate this disruption of services by responding to a request from the New Orleans VA Medical Center leadership for a proposal involving mobile surgery units.

These units were to be used to meet a variety of needs and to serve as a temporary surgical facility during the hospital rebuilding process. You will notice on your screen I have brought up an image of the mobile surgery unit in what we call transportation mode. The New Orleans VA issued a solicitation on FedBizOpps in May 2009 for mobile surgery units. This solicitation was subsequently canceled and redirected to the General Services Administration (GSA) Schedule. It should be noted that while Mobile Medical was in the process of contracting with GSA, code compliant mobile surgery units did not exist on the GSA Schedule. As a result of this action, companies with GSA contracts responded but none of them, including the one to whom the GSA solicitation was ultimately awarded, met the VA criteria for a history of producing and deploying regulatory compliant mobile surgery units.

In addition, Mobile Medical learned that its proprietary company confidential information provided as part of its January proposal had been released to over 70 GSA Schedule holders. Quoting from the attached summary of Mobile Medical's Federal legal action, which is in your packet, "Judge Horn clearly found that the VA's actions were improper and the attempted modification was beyond the scope of the GSA Schedule program. An agency placing an order under the GSA schedule program may not simply send out a request for quotation (RFQ) as, in her words, a 'solicitation feeler,' evaluate quotes for items that do not exist on anyone's GSA schedule contract, and then hope a selected contractor can convince the GSA a modification is within the scope of their existing contract by the time the agency places an order. Such an end run, which occurred in the case, violates even the most basic requirements of fair and open competition for Federal contracts."

As a small business working in a HUBZone during difficult economic times, the last thing our company ever expected would be the need to sue the U.S. Government for actions taken during a procurement process. It should be noted that the legal costs alone with this process have run Mobile Medical in excess of $300,000. Clearly, oversight is necessary to ensure that other small businesses, like Mobile Medical, do not encounter this type of situation.

Standing in stark contrast to Mobile Medical's experience in New Orleans is our very positive experience serving the needs of veterans at the VA Medical Center in Muskogee, Oklahoma. I am going to bring up a few images as we kind of go through that will represent some of the interior of the mobile surgery unit as well as some of these projects.

The leadership at the Muskogee VA Medical Center from the Director to the Contracting Officer, Facilities Engineering, and surgical teams, should be commended for their work on this model project. In this forum I am happy to do that today. During a recent customer visit, a member of Mobile Medical's Board of Directors, Retired Air Force Surgeon General Paul K. Carlton, learned from VA officials that this facility is saving over $9 million in construction costs by closing their operating rooms for the duration of the renovation period rather than phasing in their renovation. Quoting Dr. Carlton in his report to Mobile Medical, "the renovation project began in 2008 with strong leadership. After researching alternative options, the medical center closed five operating rooms and the project began using two mobile surgery units," which you see being delivered and installed at the facility on your screen. "By doing this they are shaving $9.3 million off the original construction quote for the project, even after spending $3.6 million to lease the mobile surgery units." The medical center is also avoiding another $14 million that would have gone to local hospitals to carry the surgical center's case load during the renovation, for a total savings of just over $23 million. Included in your packet is that full report. Those savings are attached in the executive summary and we urge Members to note that the Senate Military Construction Veterans Affairs Subcommittee has also included language in its report to the Senate, Report 111–115, urging the VA to utilize qualified mobile surgical units in OR renovation projects where such utilization clearly offers savings.

A final example of a successful project is the VA Medical Center in Miami, Florida. Miami is currently utilizing six mobile surgery units during a full operating room renovation project. And this will just give you a quick summary of the actual images from Muskogee, and now into the Miami project.

While the Miami project was also challenged through the contracting process, again strong leadership was the key. Dr. Seth Spector, Chief of Surgery, has kept the project moving forward and in August of this year, Miami was able to turn their operating rooms over to the Army Corps of Engineers for renovation, while continuing to provide full surgical services to the veterans of the Miami service area.

While 5 minutes, and I apologize for running a bit over, is a short time to share with you all of the successes and weaknesses in the VA contracting process, I am sure you will find our supporting documentation compelling. I look forward to any questions you may have, and thank you for your time this morning.

[The prepared statement of Mr. Munroe appears on p. 47.]

Mr. MICHAUD. Thank you very much. Mr. Newell.

STATEMENT OF DEREK NEWELL, M.P.A., MPH

Mr. NEWELL. Mr. Chairman and other Members of the Subcommittee, on behalf of Robert Bosch Healthcare, I thank you for the opportunity to provide testimony. I am the President of Robert Bosch Healthcare, and Bosch which makes the T–400 and the Health Buddy systems, provides remote patient monitoring services to the Veterans Administration, which allows veterans to remain at home and get adequate care while they are in their homes. We

have been doing this since 2003 and currently we have over 30,000 veterans who use our systems, which represents about 70 percent of the total telehealth and remote patient monitoring systems used by the VA. The population we serve suffers from chronic illnesses like congestive heart failure, diabetes, hypertension, and post-traumatic stress disorder. The Health Buddy and the T–400 systems collect patient data and vital signs, send those back to clinicians. They check for, the system automatically checks for, out of bounds indicators and alerts physicians and nurses to possible deterioration and veterans' health status. And that prevents the exacerbation of the veterans' systems and alleviates high levels of usage of the emergency room by some of these veterans.

These technologies have demonstrated positive results in improving the health care of our Nation's veterans population and in reducing costs. There was a study published last year that showed a 25-percent reduction in inpatient days and a 19-percent reduction in hospital admissions for those veterans that were using our system compared to similar veterans who were not using our systems. The VA has been a visionary in building this technology, and improving it, and working with the vendor community to ensure that this segment of the health care delivery system within the VA is expanded.

Regarding improvements in the procurement process, between the time I was invited to this Committee and today, the VA has published a request for procurement (RFP) for the procurement of our devices and for remote patient monitoring devices. And we applaud the transition of the procurement to the Denver Acquisition Center. So there have been some improvements that I was going to recommend that have already occurred, so I am applauding the folks within the VA for doing that. This move will integrate and mainstream procurement practices for home monitoring technologies, including ours as well as our competitors. The purchasing was previously done through individual Veterans Integrated Service Networks (VISNs) through a national contract, through the prosthetic center at the VISNs, which results in a high degree of variability between the facilities and how they would procure and their purchasing practices. Another challenge that has been rectified was that our devices, while prosthetics is good at buying wheelchairs and other types of devices that are not connected to technology systems and not connected to the Internet, the purchasing practices did not allow for the payment of services and other technologies required to operate our systems, such as the servers that exist within the VA's firewall. They buy a computer and they want it to connect but they do not want to pay for the back end. Or they have, they do not have a mechanism to pay for that. They did not, they do now.

While we compliment the VA's innovation to date, we believe there are a number of ways that Congress could assist the agency in improving the procurement process to expedite greater use of remote patient monitoring technology. Based on our experience, I suggest the following enhancements that would improve contract and procurement processes in the VA. These apply specifically to remote patient monitoring but may be able to be used in other areas.

One is preferred partners. In our particular situation often increased numbers of vendors would increase competition and reduce prices for the VA, which is a State objective of the procurement process. However, when each vendor must comply with installing duplicate sets of servers and security requirements to make our systems work, but there is no guarantee of volume in terms of purchase of the devices, having too many vendors may actually cause them to amortize the cost of the back end over too few units which would have the opposite effect of raising prices. So we would suggest that the VA pick a fewer number of partners, preferred partners, maybe two or three, in areas where there are fixed cost infrastructure requirements associated with technologies that get deployed to the home. Currently in the contract they are going to pick up to six vendors. I think that three would probably be more appropriate.

Targeted innovation. Recently the VA has started communicating to partners about its vision of veterans' health needs and priorities. However, this could still be improved. Better education and funding, targeted innovation with preferred partners, would enable us to respond in a more timely manner to the VA's needs and to be partners in finding solutions. At present, a majority of our information comes to us when there is a solicitation, which is once every 5 years. Only then do we have concrete knowledge of their vision, and their plans and their goals, and the specific number of units that they might buy. And as you can imagine, in a company we would need to know what kind of volumes before we would make significant investments.

Two more smaller elements that could help the contracting process and the Federal Supply Schedule (FSS) contracting process, moving back to a single point of contact for contract partners would allow more efficiency. Currently we interact with a variety of FSS contract staff which creates a constant learning curve for them and is a challenge for us. Greater sharing of information between the VHA and other Federal health care agencies would expedite the adoption of telehealth as well as expedite the adoption of best practices, not just for our technology but for other technology. Keeping information about the quality of care improvements and cost savings that can be made under wraps can present a challenge when you are trying to disseminate effective best practices.

Mr. Chairman and Members of the Committee, we believe these few but concrete specific actions would go a great distance to support the VA's efforts to expand the use of our technologies and other innovative technologies. In this regard, we admire the VA's efforts to date and hope that our years of experience in interacting with the agency as a private vendor will be useful to the Committee. We are proud to be partnered with the VA in improving the quality of care and reducing the costs of health care for our veterans. I appreciate this opportunity to testify and would be happy to answer any questions you may have.

[The prepared statement of Mr. Newell appears on p. 59.]

Mr. MICHAUD. Thank you very much, Mr. Newell. Mr. Moss.

STATEMENT OF LINCOLN MOSS

Mr. MOSS. Good morning. Chairman Michaud, Ranking Member Brown, and Members of the Committee, my name is Linc Moss. I am Senior Vice President and Chief Operating Officer of Ramtech Building Systems. Ramtech is a vertically integrated design-build commercial modular building construction firm based in Mansfield, Texas. I am testifying today on behalf of the Modular Building Institute. MBI is a not-for-profit trade association that was established in 1983 that serves companies involved in the manufacturing and distribution of commercial factory-built structures.

I appreciate the opportunity to speak to the Committee on ways to improve contracting with the Department of Veterans Affairs. Throughout the construction industry, there is a concern with the VA as to the solicitation of construction projects that call for a delivery system referred to as Design-Bid-Build. This traditional project delivery method is often more costly and less efficient than other delivery methods and its restrictive nature prohibits alternate forms of construction, such as permanent modular, from being able to participate in the bidding process.

Over the past decade, the use of Design-Build has greatly increased in the United States making it one of the significant changes in the construction industry. The Design-Build method streamlines project delivery through a single contract between the government agency and the contractor. This simple but fundamental difference not only saves money and time, it improves communication between the stakeholders and delivers a project more consistent with the agency's needs. It also allows for all sectors of the construction industry to participate.

The Design-Build project delivery system offers the VA a variety of advantages that other construction delivery systems cannot. Typically under the Design-Build approach, an agency will contract with one entity for both design and construction of the project. By greater utilization of the Design-Build delivery system, the VA can achieve these goals: faster delivery, greater cost savings, improved quality, a single source of responsibility, and reduction in administrative burden.

As our Nation prepares for an influx of returning warriors, it is imperative that we are able to provide them with the services and facilities that will help them assimilate into civilian life. By adopting the Design-Build approach, the VA could provide various facilities in a compressed time frame while ensuring that the product delivered meets the missions and various quality expectations.

Design-Build also allows for other sectors of the construction industry that are often excluded from Design-Bid-Build projects to compete and bid on VA projects. Alternate design offerings, such as modular construction, tilt wall, pre-engineered steel, would be able to participate in VA solicitations if they were issued using a Design-Build delivery system. Numerous permanent modular contractors such as Ramtech have performed services for the VA in the past, but because of the limited amount of Design-Build solicitations the opportunities are severely restricted. However, in those cases where Ramtech did perform on projects the customers were extremely satisfied as our building met mission requirements and

exceeded quality expectations. In fact, one of the projects was in Congressman Brown's area, and it was a clinic at Myrtle Beach.

By greater utilizing the Design-Build delivery system in the Department of Veterans Affairs construction policy, the VA would greatly increase the amount of projects that alternative construction contractors could participate in. Let me emphasize that alternative construction methods, such a permanent modular are not always the solution, as there is no one perfect building system for every application. However, by expanding opportunities for them to be part of the process, the Federal Government could be assured that it gets the best value by seeing all options before awarding a contract.

Another possible advantage is the fact that one of the missions within the Department of Veterans Affairs is the ability for the VA to support service-disabled veteran-owned small businesses. Because the Design-Build methodology typically relies on a single source for both design and construction of the project, Design-Build contractors often partner with architectural and engineering firms to assist in the design of the project. This fact facilitates partnering between service-disabled veteran-owned small business (SDVOBs) and construction firms similar to Ramtech. In the permanent modular construction field, the relationship with a contractor such as Ramtech means the SDVOB partner will get approximately 60 percent to 70 percent of the building delivered and installed by the Design-Build firm while the SDVOB partner performs the site work, utility connections. Often SDVOBs do not have the logistical capabilities to site build the entire building, but have the ability to perform other critical functions that comprise 30 percent to 40 percent of the overall construction project.

In conclusion, contractors that rely on Design-Build delivery system have, and continue to overcome, obstacles when it comes to working with the Department of Veterans Affairs. While businesses such as Ramtech are anxious to compete, the current trend of Design-Bid-Build projects issued by the VA severely prohibit that participation.

On behalf of MBI as well as Ramtech Building Systems, I thank you for your time. We will be happy to answer questions.

[The prepared statement of Mr. Moss appears on p. 60.]

Mr. MICHAUD. Thank you very much, Mr. Moss. Mr. Wise.

STATEMENT OF JAY WISE, PH.D.

Dr. WISE. Thank you for the opportunity to speak this morning. My name is Jay Wise, Dr. Jay Wise. I am the President and CEO of Wise Knowledge Systems. Wise Knowledge Systems has produced and deployed the medical technology called Knowledge Based Expert Systems, KBES. We call it KBES. I am going to abbreviate this to save some time. I am going to have to leave at 11:00, Mr. Chairman, period, so I have to go. But I want to share with you some things that have to do with acquisition in my experience almost daily for the last 6 years with the VA.

The KBES technology is an interesting tool. It is a decision support technology that keys on entire domains of knowledge. Our cardiac model can assimilate knowledge instantly from 10,000 cardiac surgeons and put it on a particular patient. This has resulted in

extraordinary savings in cost and some extraordinary care improvements down the road. I am going to kind of zip ahead a little bit.

Dr. Paul Tibbits, Deputy Chief Information Officer of the VA, we met with him and he said that he was aware of the success of Wise Knowledge Systems Smart Tool deployed in active military operations for the Navy and the Marine Corps and wanted to find a place for it at the VA. I was then sent to visit with a Ms. Lloyd at VHA. Ms. Lloyd's remarks were, "The VA is broken. KBES might be a very good thing for the VA, but that would mean we would have to work and people at the VA will not work." Dr. Tibbits then said that yes, Ms. Lloyd is right, the VA is broken, and nobody around here wants to work.

Dr. Tibbits then edited and published with our group a very detailed capability assessment of Knowledge Based Expert Systems for his office, for the VA, for the medical mission of the VA. It was altogether the most glowing analysis we have ever had, and we have been tested, quite literally we are on permanent exhibit at the Smithsonian. So this is not a new thing.

Following that, Dr. Tibbits said that Ms. Wendy McCutcheon, a person working in one of the acquisition offices, was now the sole authority to acquire medical things for the VA, this one person. And Ms. McCutcheon said that, "She did not see any particular value in it," and we should start the whole process over. I asked them if the fact that I was a veteran-owned small business had any bearing on any of this with the GSA. They said, "No, we will not use the GSA, they are not helping us." That is a direct quote.

On February 23 I spoke again with Chairman Filner, and he invited me to this hearing. That is my testimony. It is quite short. I will give you my summary now, all right?

Since 2004 Wise Knowledge Systems has attempted to provide Knowledge Based Expert Systems to the VA. KBES has received very positive technical reviews as an advanced modeling and simulation decision support technology from each and every point of assessment and testing that it has been sent. That would be all of them. In the Navy, in the Marine Corps, at the U.S. Department of Defense (DoD), at VA, and in the private sector. Wise Knowledge Systems believe there is an important ethical issue for the health and medical care of American veterans being crippled by arrogant leadership, thus, making the VA fail in part to keep its promise to deliver state-of-the-art medicine and health care to American veterans.

Once a medical technology has been tested, evaluated, praised, deployed, and what else, nonresponse is unacceptable. One does not do that. And one does not say that the reason we are not going to have some is because the VA is broke and nobody around here wants to work.

It is an unfortunate part of our American history that our government made and intentionally broke virtually every treaty with American Indian tribes. These treaties or agreements were made by our government knowing they would not be kept. The explanation for this fraudulent manipulation was often Indians were not people, they are not quite human beings. One wonders if some of the VA leadership, and that is in my written testimony, you can read who is what, one wonders if some of the VA leadership main-

taining the status quo of failing to provide these tools when they know and have published that it is state of the art, feel that our young people in uniform are also not quite people, not quite human beings, that their families are not quite human beings. I do not know.

It is clear to me and to my team that the vast majority of individuals at the VA are sincerely dedicated to American veterans and do want to work and work hard. Wise Knowledge Systems recommends installing and supporting qualified individuals who have the experience and expertise to actually evaluate these sorts of things for our veterans. We recommend the VA do the right thing, honor your contract with the veterans.

I want to thank all of you all for having this hearing and giving our experience a voice. I am here for a little while to answer any questions you may have. I am sorry, Chairman, but I must leave at 11:00. I have an engagement, so.

[The prepared statement of Dr. Wise appears on p. 63.]

Mr. MICHAUD. Thank you very much, Mr. Wise, for your testimony. And we should be done by then, but if not, feel free to just get up and leave. Mr. Clair.

STATEMENT OF JAMES A. CLAIR, M.P.A., M.S.

Mr. CLAIR. To Chairman Michaud, to Ranking Member Brown, and Members of the Subcommittee, thank you for your kind invitation to discuss the Department of Veterans Affairs procurement practices and specifically how the VA might benefit by incorporating certain cost containment strategies within their pharmacy benefit management and nursing home care programs. My name is Jim Clair, I am the Cheif Executive Officer of Goold Health Systems, and I am accompanied today by Lorraine Lachappelle, a registered nurse, and Goold Health Systems' Director of Community Assessments.

Goold is a national health care management company that specializes in meeting our clients' specific health care objectives with a special emphasis on cost containment. However, at all times, we are driven by evidence-based medicine and achieving clinically effective outcomes. In the interests of time, I am skipping forward to page three of my prepared remarks and will concentrate on three specific cost containment strategies that we think would benefit the VA.

Number one, medication management. The U.S. Department of Health and Human Services recommends medication therapy management (MTM), a program that sets out to ensure optimum therapeutic outcomes, reduce the risks of side effects when using medications, and must be coordinated as part of a care management plan. Goold Health Systems expands upon MTM by using predictive modeling to analyze pharmacy and medical claims data to measure the probability of exceeding set cost parameters for high cost users and complex medical conditions. Problematic patients are ultimately placed in an intensive benefit management program or a chronic pain management program. We utilize regression analyses that correlate chronic conditions with total drug cost. We then identify individuals who would benefit from our targeted interventions. Once in IBM or chronic pain management the patient is

linked to one physician prescriber and one pharmacy dispenser for management of complex medical conditions and chronic pain issues, ensuring that those patients receive appropriate drug therapies. We provide educational materials and monitoring services to those individuals to help them better understand their medical conditions as well as work with them on medication adherence and potential drug interactions.

We also work with their providers to help ensure that optimum clinical outcomes are achieved. Savings accrue to our clients because of the intensive involvement of the provider, the patient, and the GHS clinical team. Examples would be narcotics use, asthma, and COPD.

Other examples of medical management strategies that we believe would benefit the VA are formulary management, including 15-day supply limits. GHS performs extensive analyses to identify drugs that have high discontinuation rates shortly after the onset of therapy. It was reasoned that limiting the number of day supply of these first scripts would result in savings from reducing waste. About 30 drugs were identified that meet our criteria. These drugs tend to have high discontinuation rates due to either significant side effects or relative lack of efficacy. Targeted drugs for this effort include long acting narcotic stimulants, psychiatric medicines, urinary and continence products, and smoking cessation drugs.

Another example of formulary management is dose consolidation. Many existing drugs now only need to be taken once per day. There is a considerable amount of savings available if these drugs are not allowed to be used more frequently without good clinical cause. Examples of targeted dose consolidation are Zyprexa and Risperdal, two anti-psychotic drugs that have allowed our State clients to save over 1 percent of their pre-rebate expenditures annually by aggressively pursuing dose consolidation.

The second cost containment strategy I would like to discuss is pharmacy program integrity, the definition being that it should ensure that our tax dollars are not put at risk through fraudulent violations of the rules or abuses of the system. It should ensure that appropriate payments are paid only to legitimate providers for services only to eligible beneficiaries. Like many other health care managers, Goold Health Systems has significantly expanded our program integrity efforts over the last few years. The National Healthcare Anti-Fraud Association recently estimated that 3 percent of the health care industry's expenditures in the United States are due to fraudulent activities. This calculates to an annual amount of approximately $51 billion.

In a recent analysis for one of our clients we created a "monthly outlier report" on pharmacy expenditures and trends. The analysis was performed for each drug filled in the previous month. A review of the average amount spent per drug, and the average quantity per day supply based on quantity limits was undertaken. Those drug claims that fell outside of established guidelines were flagged for audit. This resulted in claims being reviewed as a result of improper use of override codes and subsequently many of these outlier claims were reversed. For this one client with a pharmacy budget of approximately $200 million, small certainly by VA stand-

ards, we expect the results of the specific audit to yield between $500,000 to $1 million in savings.

Two other examples of pharmacy program integrity review would include automatic early refills. The VA is heavily reliant on mail order. It is important that the mail order provider be monitored to ensure that mail order pharmacies wait to ask for the patient to ask for their medication to be refilled. This does not preclude a mail order pharmacy from making outgoing calls to a patient if they would like their next dose of medication sent. But it would not allow a mail order pharmacy from automatically sending the prescription to them in all cases.

A second example being something called near duplicates. Each medication intended for human use is assigned a number called an NDC, a national drug code. It is a unique product identifier that, for example, distinguishes an oxycodone 10 milligram tablet from an oxycodone 20 milligram tablet, a generic medication. Near duplicates can occur with generics with a different NDC of the same drug, same strength, is used a few days after that patient's first prescription was filled. In many cases, this is an appropriate fill due to the legitimate loss of medication. However, there can also be billing errors or inappropriate dispensing such that these claims should be reversed. Monitoring utilization at this level, this granular level, can yield additional savings to the VA if it is not being done now.

The third cost containment strategy I would like to discuss is something called long-term care assessments, and it is the reason that Ms. Lachappelle is with me. Through the early 1990's, nursing facility costs in one of our client's States were increasing at annual rates far exceeding the general inflation rate, or even the health care cost inflation rate. Eligibility determinations for Medicaid nursing facility care were determined by the provider, leading to much higher utilization rates than otherwise supported by independent review. As a result, Maine State government instituted an independent, objective Maine Medicaid eligibility screening process with the following objectives: to create a single entry point for medical functional eligibility assessments for long-term care programs; to increase consumer participation and control; to educate consumers about in home long-term care programs and other alternatives to nursing and residential facility care, the most expensive level of care; and to identify and address caregiver needs; to reduce the long-term cost of services by requiring greater emphasis on rehab and health promotion; and to reduce the number of unnecessary admissions to increase the number of discharges from and decrease the length of stay in nursing facilities.

Within strict time parameters set by our client, the GHS screener's job is to provide an accurate prescreening to determine the need for medical functional assessment, maintain the waiting list, and refer consumers to appropriate nurses. More importantly, when an evaluation is indicated the Goold Health Systems registered nurse conducts an accurate, objective medical functional eligibility assessment using the automated medical eligibility determination tool in a way that is always based on sound clinical judgment and in compliance with appropriate policy. We employ about

35 nurses Statewide to do this work, who work with a laptop, portable printer, and cell phone.

In State fiscal year 2010, we performed over 15,000 assessments. The State share of the medical nursing home expenses in 2010 are more than 35 percent lower than their State fiscal year 1994 in nominal non-inflation adjusted dollars. This is a result of policy changes made by the government and the long-term assessment process that we conduct. Comparing where the unmanaged nursing facility budget was headed to where it actually is today has yielded annual State savings that exceed $100 million.

Mr. Chairman, the VA is a very effective provider of important pharmacy and medical benefits to our country's veterans. The cost strategies that I have discussed above have been proven to be very effective in containing health care costs for our Medicaid clients. We believe that these clinical management approaches can assist the VA in further containing costs. Thank you again for the opportunity to testify. My colleague and I would be pleased to answer questions you or the Committee may have.

[The prepared statement of Mr. Clair appears on p. 70.]

Mr. MICHAUD. Thank you very much, Mr. Clair. I want to thank all the panelists for your testimony this morning. It has been very enlightening and I look forward to your answering some of the questions. I know Mr. Wise has to leave at 11:00. I do not know if anyone has any questions for Mr. Wise? So any time you want to leave, feel free. We might have questions once we get going, but I just wanted to check first.

Once again, I want to thank everyone for coming. I have a couple of questions. Mr. Newell, you mentioned, the Buddy and the components that you have at your company and how you are working with the VA system. Do you work also with Federally-qualified health care clinics and rural hospitals? And if you do, are there any problems associated with rural areas, such as that system not working in very rural areas where they might not have cell phone service? Or can you expound on that a little bit?

Mr. NEWELL. Yes, I can. Our systems work great in rural areas. There is a challenge in a rural area with getting the system to the person and getting it set up at times, because it is a rural area. So by definition the logistical challenges of getting the systems to the location and set up are still there. But we have solved those. Our system works on a plain old telephone line. So as long as there is POTS (plain old telephone service) line availability we can deploy the system, and most areas have POTS lines. We also have a cellular modem, which we can attach externally to the Health Buddy or to the T–400 system, and that will allow it to communicate via whatever cellular network is available in the area. So if there is any cellular network available at all, we can connect to it.

It is very effective for rural health. It is being used, our T–400 system especially is being used for the home-based primary care project within the VA. We also have a video system, which allows veterans in rural areas to have a video camera in their home and allows the doctors to assess them without bringing them in to the VA medical center. Not for obviously extremely serious conditions, but as part of their home-based primary care initiative, they are allowed to do that. So it has had huge success. We have a project

in Alaska, which is not with the Veterans Administration with our T–400 system that has been exceedingly successful. And the biggest success in rural areas is the cost of transport of getting somebody who does have an exacerbation from the location to the facility, and that can save tens of thousands of dollars, especially in cases like Alaska where they have to be flown in.

So we have had a huge amount of success in rural areas. And it is a huge application for rural areas. I would say we are very under-penetrated in terms of the number of people who could benefit from it. Thank you.

Mr. MICHAUD. Thank you. My next question is, Mr. Clair, you mentioned that by utilizing some of the work that you have done in different States, VA may be able to save money. The estimated cost for prescription drugs in 2011 is $4.8 billion. That is a good deal, the VA negotiated for lower cost prescriptions. My concern, however, is on utilization within the VA on the drug system. How the VA is bigger than a lot of the States. How would you be able to help the VA? Can you narrow that down? Or in a small pilot program? And what potential do you think there might be for cost savings within the VA pharmacy benefits program?

Mr. CLAIR. Thank you, Mr. Chairman. The first thing that we do when we work with one of our clients is get the actual drug utilization data. It is very important, as I think all of the Members of the Subcommittee know, that the VA has a very effective pricing strategy. They purchase very well. They have very good network and communications and distribution systems. But reviewing the utilization data is very important. And what we would be interested in doing is some, is getting some subset, a region, a State, an area, to be defined by the VA in which we would get pharmacy claims and medical claims over a period of time. Hopefully, at least 12 months worth of data. Load that in and start to have my clinical team of doctors and pharmacists and nurses and data analysts reviewing that in order to identify savings opportunities specifically.

Mr. MICHAUD. Thank you. I do not want to elaborate on nursing homes because of my displeasure with VA on how they deal with reimbursement for State Veterans Nursing Homes. It is my understanding that the cost of nursing homes within the VA system is much higher than at Veterans Nursing Homes. When you have worked with nursing homes, how much savings were you able to achieve?

Mr. CLAIR. It is significant. The issue specifically is that if you do not have, in effect what we are employed to do is be a gatekeeper into the nursing home facility itself. And if there can be a support system that allows one to stay in their home based on their acuity and their emotional state, etcetera, you are diverting people away from the nursing home level of care and that saves appreciable amounts of money. My calculation in State fiscal year 2010 is that the savings to one State client was over $100 million. So in effect, nursing home expenditures go down. You reinvest some of those savings into the community level of care, but overall your net savings to the VA would be significant.

Mr. MICHAUD. Thank you. Mr. Brown.

Mr. BROWN OF SOUTH CAROLINA. Thank you, Mr. Chairman. Thank you, gentlemen, for being here today. Mr. Munroe, in your

testimony you state that the New Orleans VA solicitation was redirected through the GSA schedule. What reason did VA give you for this move?

Mr. MUNROE. As you know, there are a number of different procurement methods that the VA can use. The original redirect was to facilitate supposedly ease of contracting. And certainly a VA contracting officer's discretion is to use whatever contracting method he or she feels best serves. The challenge that we have with that is when you redirect to a method that does not have a solution, you cannot then go try to create that solution on the GSA, for example. So there were a number of things that happened in that process. Our biggest concern in that process is, if you are going to use the GSA schedule, use it for what it is worth, or for what it is supposed to be used for. Go there, identify the product that exists on a Federal Supply Schedule, and procure it. If it does not exist on the Federal Supply Schedule, you cannot then go back to GSA and say, "Here are all the requirements that I have. Let us solicit in an open forum everybody who has a GSA contract and see if they can try to do this."

So there are a number of different ways that the procurement process can happen. The answer that we were given as to why it was redirected through the GSA schedule was for pure ease of contracting. Which we are in full support of. If products exist on the GSA schedule then an easier process obviously is to use that schedule. But when they do not exist, as you saw from the comments that Judge Horn provided, you cannot then go into open solicitation and try to convince GSA that that product can exist there as a vendor.

Mr. BROWN OF SOUTH CAROLINA. So how many units do you have now in operation?

Mr. MUNROE. I am sorry?

Mr. BROWN OF SOUTH CAROLINA. How many units do you have in operation?

Mr. MUNROE. We have, now we have 12 units within the VA and the government health care system. We also provide services to the U.S. Navy in their hospitals as well, that use the product for exactly the same reason.

Mr. BROWN OF SOUTH CAROLINA. But you do not have any in New Orleans?

Mr. MUNROE. We do not, there is nothing in New Orleans right now.

Mr. BROWN OF SOUTH CAROLINA. Where do they get their service?

Mr. MUNROE. If you are a veteran right now in New Orleans and you need endoscopic services, you have to travel 2 hours for those services. You have to travel outside of the New Orleans service area to another VA service area.

Mr. BROWN OF SOUTH CAROLINA. What reason did they give you for not using your service?

Mr. MUNROE. Well the intent there was to use the service. They started that process. But through an incorrect procurement procedure they stopped. That contract has been awarded to another company. The problem is, that other company does not meet the standards of care that the VA has in all of their medical centers. And

you cannot take, you know, our contention with that is, in Miami, for example, in Muskogee, in Martinsburg, facilities that members have seen and actually gone to, those facilities require the same standard of care in a mobile unit as they do in their fixed based facility.

Mr. BROWN OF SOUTH CAROLINA. So when you bring the unit, do you bring the medical support staff, too?

Mr. MUNROE. We do not bring the medical support staff, and that is probably the most important part of what we do with the VA. In Muskogee what we were told—and let me answer your question. We do not bring them because the utilization of the existing medical staff is the key to the project. So the surgeons, the nurses, the technicians, the facility is supplying both their equipment, which they know how to use, and they are supplying their staff, which keeps them productive. In Muskogee, for example, the operating room nurse manager told me that if they had to move their patients to the community to render services, she would have lost 80 percent of her nursing staff. Because they would have not stayed. They would have gone to where the patients would have gone. And that is part of that overall savings that comes into play. Those are the intangibles. They did not lose 80 percent of their staff because they are doing it this way. But if they had, what would have been both the financial impacts to the VA health system? And more importantly, the service impact to the veterans in that service area?

Mr. BROWN OF SOUTH CAROLINA. Do you lease the equipment or do you sell it?

Mr. MUNROE. We lease, we do both. But in the VA network, we lease. It is an operating lease. So if the renovation project is a 12-month, 24-month, 36-month project, it is an operating lease and then we remove the equipment at the end. So if you do not mind I can just—can you bring that back up for me?

Mr. BROWN OF SOUTH CAROLINA. Could you tell me how many vendors are in the market?

Mr. MUNROE. Well our, it is my understanding that over the next 10 years, and I will be curious when some of the other panelists come up, over the next 10 years the VA is estimating that there will be over a hundred facilities that will go through an operating room renovation project. The average number of units that we see is around four units in order to be able to service a medical center.

Mr. BROWN OF SOUTH CAROLINA. But how many vendors are out there providing those units?

Mr. MUNROE. How many VISNs are we in currently?

Mr. BROWN OF SOUTH CAROLINA. No, how many vendors? How many people like you are selling——

Mr. MUNROE. Oh, vendors. I am sorry, I thought you were selling VISNs.

Mr. BROWN OF SOUTH CAROLINA. It is a southern thing.

Mr. MUNROE. That provide a—that is the difference between the southern and the Vermont piece of it. So sorry, Chairman Michaud, for those of us up in the Northeast.

Mr. MICHAUD. It took me a while to get used to his accent as well, so.

Mr. BROWN OF SOUTH CAROLINA. Sometimes we have to have an interpreter.

Mr. MUNROE. VISNs and vendors just got too close there. So there are no other vendors in the market today that provide a State licensed, and this is the key, State licensed, Medicare certified, JCAHO accredited, mobile surgery unit. So there are no other vendors in the United States that provide that level of certification. Does that answer your question?

Mr. BROWN OF SOUTH CAROLINA. Sure.

Mr. MUNROE. So, you know, when you look at this 400 square foot operating room, it is just over 400, it is 402 square feet, when I travel to the Phoenix VA, which has seven operating rooms and two special procedure rooms, they are embarrassed to bring me into their operating room suites. Because they know that this level of care in these mobile units is higher than what they service, than what they provide for service today in Phoenix.

Mr. BROWN OF SOUTH CAROLINA. What would one cost a month to lease?

Mr. MUNROE. The units are $76,000 per month, per unit.

Mr. BROWN OF SOUTH CAROLINA. To purchase?

Mr. MUNROE. Two point sixty-seven million dollars.

Mr. BROWN OF SOUTH CAROLINA. Okay.

Mr. MUNROE. So if you are doing what I think you are, and you understand how many units we have in service in the VA, it does not take a lot, and you will see in the packet I provided you, it does not take a lot of units to produce a very significant return on investment to the VA. Especially if we believe what they are telling us, which is over the next 10 years, 100 facilities will go through this renovation project. And I truly believe, in Muskogee for example where they have done in depth financial analysis of this, they did the analysis before the units came in. I truly believe the contracting officer when he tells me that they are saving, hard cost savings at that facility, $4 million per unit by doing it this way.

Mr. BROWN OF SOUTH CAROLINA. Okay. Well, I thank you very much.

Mr. MUNROE. Thank you.

Mr. BROWN OF SOUTH CAROLINA. And I know that my time has expired, Mr. Chairman, but I would just like to mention to Mr. Moss, I am grateful for that facility at Myrtle Beach. We have doubled and tripled the size in a fairly short period of time. I know it took a long time to get the project moving, but once it got on board it moved pretty quick. What is the largest facility in which you have been able to use the Design-Build method?

Mr. MOSS. We just completed a 99,000-square foot combined brigade-battalion headquarters building for the Combat Aviation Brigade at Fort Bliss in El Paso. And that was constructed of 100 individual sections in conjunction with site built elements, what we refer to as hybrid construction. So.

Mr. BROWN OF SOUTH CAROLINA. But you do not use modular units?

Mr. MOSS. Pardon me?

Mr. BROWN OF SOUTH CAROLINA. But you do not use modular units?

Mr. MOSS. Well yes sir, they are. They are built off site. They are trucked to the building site and put together, stacked atop one another.

Mr. BROWN OF SOUTH CAROLINA. Very good. Sorry, Mr. Chairman, for taking so much time. But thank you, gentlemen. Sorry I did not get a chance to ask questions of the other two panelists.

Mr. MICHAUD. Thank you very much, Mr. Brown. We gave you a little extra time for interpretation. Mr. Donnelly. Mr. Carnahan. Once again I would like to thank the panel for coming today. I appreciate your testimony, and if there are any additional questions we will definitely get in touch with each of you. So once again, thank you very much. I would like to ask the second panel to come forward. And while they are coming forward I will introduce them. The panel includes Debra Draper, who is the Director of Health Care for the GAO, and Belinda Finn, who is the Assistant Inspector General for Audits and Evaluation within the VA Office of Inspector General. I would like to thank both of you for coming today, and I look forward to your testimony. And we will begin with Ms. Draper.

STATEMENTS OF DEBRA A. DRAPER, PH.D., M.S.H.A., DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; AND BELINDA J. FINN, ASSISTANT INSPECTOR GENERAL FOR AUDITS AND EVALUATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY MAUREEN REGAN, COUNSELOR, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF DEBRA A. DRAPER, PH.D., M.S.H.A.

Ms. DRAPER. Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to be here today as you discuss VA's contracting and procurement practices.

My testimony today focuses on the intersection of some of these activities and veterans' safety.

VA medical centers purchase supplies and equipment that allows them to provide a range of health care services to the 5.5 million veterans served annually. These purchases include expendable medical supplies such as needles, which are used once and discarded and reusable medical equipment such as endoscopes which are reused for multiple patients.

VA has established policies that its medical centers are required to follow when purchasing and tracking medical supplies and equipment. In part, these policies are intended to help ensure the safety of veterans treated in VA facilities.

For example, VA medical centers need information on the reusable medical equipment in their facilities to ensure that they have developed procedures for properly cleaning and disinfecting or sterilizing the equipment prior to reuse.

This information is also critical if a supply item or piece of equipment is the subject of a manufacturer or FDA recall or patient safety alert from VA.

In my testimony today, I will first discuss some preliminary observations from our ongoing work on VA's oversight of compliance with its purchasing and tracking policies for expendable medical supplies or reusable medical equipment.

These observations are based on site visits to five VA medical centers and raised concerns about the safety of veterans receiving care at these facilities. I will then discuss steps that VA Headquarters plans to take to improve its oversight of these activities.

Our initial work has focused on three requirements that we determined were relevant to veterans' safety. These include ensuring Committee review and approval of medical supplies and equipment not previously purchased by the facility, obtaining signatures of ordering and approving officials prior to making purchases, and entering information about supplies and equipment in the VA's inventory management systems.

At the five VA medical centers we visited, our preliminary work identified examples of inconsistent compliance with these three requirements we reviewed. In some cases, noncompliance created potential risk to veterans' safety.

At one VA medical center, for example, officials told us that clinical department staff were allowed to purchase certain reusable medical equipment such as surgical and dental instruments using purchase cards and that these purchases may not have received the required Committee review and approval.

As a result, these purchases may have been made without assurance that they were cost effective and safe for use on veterans.

Officials at another VA medical center discovered that a staff member working in a dialysis department ordered a supply item without obtaining the required signature of an approving official. The staff member ordered an incorrect item which was subsequently used, resulting in the potential exposure of more than 80 veterans to infectious diseases such as HIV, hepatitis B, and hepatitis C.

At a third VA medical center, more than 2,500 veterans were potentially exposed to infectious diseases because according to the facility officials and the VA's Office of the Inspector General a piece of reusable medical equipment was not being properly cleaned and disinfected.

After receiving a patient safety alert from VA, the medical center incorrectly concluded that the item was not being used in part because it was not listed in the facility's inventory. The delayed identification resulted in the item's continued use and potential exposure of veterans.

With regard to VA's plans to improve its oversight of VA medical centers' purchasing and tracking of medical supplies and equipment, VA Headquarters officials told us that they planned to change the oversight of the use of their purchase cards, shifting greater responsibilities from the medical centers to the VISNs.

VA is also developing a new inventory management system which officials expect will improve their ability to track information across facilities.

To summarize, VA has policies that its medical centers are required to follow with purchasing and tracking expendable medical supplies and reusable medical equipment. But based on preliminary observations from our ongoing work, there is inconsistent compliance with these requirements, creating potential risk to veterans' safety.

Mr. Chairman, this concludes my opening remarks. I am happy to answer any questions.

[The prepared statement of Dr. Draper appears on p. 73.]

Mr. MICHAUD. Thank you very much.

Ms. Finn.

STATEMENT OF BELINDA J. FINN

Ms. FINN. Thank you.

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to testify on the findings of the Office of the Inspector General regarding the Veterans Health Administration's contracting and procurement practices.

Maureen Regan, Counselor to the Inspector General, joins me at the table today. In addition to her legal duties, Ms. Regan manages the Office of Contract Review within the OIG.

In December 2009, the OIG testified on acquisition deficiencies in VA. At that time, numerous OIG audits, investigations, reviews, and inspections has identified systemic issues such as poor acquisition planning, problematic contract award processes, poorly written contracts, and inadequate contract monitoring that negatively affected VA's ability to attain quality goods and services in a timely manner at fair and reasonable prices.

These acquisition weaknesses significantly impact VHA, which purchased over $9 billion in health care related goods and services in fiscal year 2009.

Since December, we have continued to identify systemic acquisition weaknesses, low levels of compliance with Federal Acquisition Regulations (FARs) and VA acquisition regulations, and incomplete and unreliable data in VA and VHA acquisition systems.

For example, two national audits over contracts for patient transportation and Federal Supply Schedule health care staffing services found that strengthened procurement practices and contract monitoring could reduce improper payments and overpayments by $130 million over the next 5 years.

Additionally, our recent reviews of the VHA's nonrecurring maintenance contracts funded by the American Recovery and Reinvestment Act of 2009 (ARRA) have found that although VA and VHA oversight has improved compliance with FAR competition requirements, the contracting officers were not performing adequate contractor responsibility determinations.

These determinations are critical to mitigate possible risks to ARRA funds and ensure the expeditious completion of VHA projects. In fact, 60 of the 65 contracts we reviewed valued at $83 million lacked adequate contractor responsibility determinations.

In May 2010, we reported that the VA medical center in Philadelphia had inappropriately purchased brachytherapy services from the University of Pennsylvania without a contract between 1999 and 2005.

Additionally, OIG health care inspections at community-based outpatient clinics have found problems in the administration of contracts for clinic operations.

For example, the Contracting Officer's Technical Representatives (COTRs) are not notifying vendors about patients who should be disenrolled. Because VHA pays the contractor a capitated rate for

the enrollees, the community-based outpatient clinic (CBOC) vendors may be overpaid. The COTRs were also not consistently holding contractors accountable for meeting performance standards set forth in the contracts.

In fiscal year 2010, the Office of Contract Review has completed 65 pre-award and 26 post-award reviews. Thirty-two of the pre-award reviews were of proposals from VA affiliated institutions for sole source health care resource contracts. These reviews identified $39 million in potential savings that could be achieved during contract negotiations.

The Office of Contract Review continues to identify issues with a lack of communication between procurement and program officials and inadequate planning for these health care resources contracts.

The lack of communication and poor planning results in unnecessary contract cost because requirements have not been properly identified. The statements of work are inadequate and the estimated quantities are overstated.

We also routinely find that VHA's health care resources contracts lack adequate oversight to ensure VA receives the services it pays for.

Mr. Chairman, this concludes our oral statement. Myself and Ms. Regan would be pleased to answer any questions that you or other Members of the Subcommittee may have.

[The prepared statement of Ms. Finn appears on p. 78.]

Mr. MICHAUD. Thank you very much for your testimony and thank you Ms. Draper, as well.

Ms. Draper, why are the VA medical centers not entering the information about expendable medical supplies in their system? Do you have any idea why they are not doing that?

Ms. DRAPER. Yes. VA policy requires that all expendable medical supplies that are purchased on a recurring basis are to be entered into the inventory system. However, policies differ. The policies are ambiguous as to what recurring refers to. One refers to at least four times per year and others are just basically silent.

So what we found is that some facilities are entering all medical supplies and others are not. So there is confusion at the local level.

Mr. MICHAUD. Do you feel the VA Central Office provides sufficient guidance to the VA medical centers on implementing its policies on purchasing and tracking? If not, do you have any recommendations of what we can do to make them comply?

Ms. DRAPER. Yes. Our work is ongoing, so we are continuing to look at that area. And we are also going to be planning to talk to the VISNs about their role in oversight and compliance.

As part of our preliminary work, we have found that some policies are ambiguous and some policies appear to be contradictory. I can give you an example.

The purchase of medical equipment with purchase cards. One VA policy says that it is not allowed, another says that it is. So that is one area that is problematic.

Another issue is that there is conflicting guidance as to what reusable medical equipment should be inventoried. According to one policy, it is defined as equipment that costs more than $5,000 with a useful life of 2 years or more. However, reusable medical equip-

ment is any equipment that is designed by the manufacturer to be reused for multiple patients and arguably should be tracked.

Mr. MICHAUD. Ms. Finn, we have heard some concerns that OIG has decision-making authority over awarding contracts and that has caused some delays in the contracts and procurement process. Further, there has been concern that prospective contractors are unable to communicate with OIG to better understand why their bid has been rejected.

Could you comment on those two concerns? And what role does the OIG have in the contracting and procurement process?

Ms. REGAN. If it is a Federal Supply Schedule contract or health care resource contract that is awarded on a sole source basis, we have an agreement with the Department that we do the pre-award reviews to look for price reasonableness. We do the review and we give a report to the contracting officer with recommendations for negotiations. But that is the only role that we have in the contracting process.

If a vendor believes that there is some part of the process that was not done right; as the witness testified before, they were exceeding the scope of the GSA contract for the services, there is a protest process either to the contracting officer or the procurement executive or to the Government Accountability Office. But we do not get involved in that process at all.

Mr. MICHAUD. Okay. We heard Mr. Wise on the first panel say that he feels the VA is broken and that the VA said that.

Would both of you want to comment on that? If broken, how do we fix the problem?

Ms. FINN. Broken is a very definitive term that has a wide range of possibilities. I think there definitely are large areas for improvement in the VHA acquisition processes. As we have testified, we see problems again and again with planning for contracting, the awarding of contracts, and then the administration of contracts.

Fixing those issues is going to take a concerted effort; to improve the planning through communication between the program officials and the contracting officials. A number of the discussions we heard from the first panel seem to indicate problems with that type of communication.

Once we have an acquisition strategy, then we need oversight of the contracting process to ensure that the contracts are awarded properly and competed.

And, finally, the administration of the contract at the field level is always going to require expert and trained Contracting Officer's Technical Representatives to really ensure the contract provisions are met.

Ms. DRAPER. Our work, as I mentioned, we have identified issues with some VA purchasing and tracking policies with regard to medical supplies and equipment. And some of the policies are often ambiguous or contradictory.

And we have also tentatively identified gaps particularly related to the inventory management systems that may increase the risk or even contribute to patient safety incidents.

Our work indicates that VA could make improvements by ensuring that their policies are clear and comprehensive and that there are clear lines of accountability. Effective oversight and enforce-

ment to ensure compliance are also critical aspects of making those improvements.

Mr. MICHAUD. Thank you.

Mr. Brown.

Mr. BROWN OF SOUTH CAROLINA. I thank the panel for being here and giving us their insights.

As I mentioned in my opening statement, I am particularly concerned with your assertion that data in the VA and VHA acquisition support and information system is incomplete and unreliable.

And how does that compare to other Federal departments?

Ms. FINN. I do not have total experience with other Federal departments. I can tell you a little bit about the situation in VA.

We did an audit about 2 years ago of the Electronic Contract Management System (ECMS), which is a relatively new vehicle within VA to track contract actions. It was established to track contract actions over $25,000.

At the time we did our first audit, we found a wide range of contracts that were not being placed into the system for many reasons. It was difficult to work with and users were not necessarily aware of all the requirements.

With the ARRA requirements, VA and VHA required all of the ARRA contracts to be recorded in ECMS. So from our experience, we did find a lot more information on those contracts in ECMS, although we still have found issues with the completeness of the data in that contracting system.

Because VA and VHA are so decentralized, it is hard to get all of this information together in a system. Ms. Regan might have more insight.

Ms. REGAN. I would say there is also a difference between a contract action and a purchasing action. A lot of purchases are below $3,000 for items that are purchased off the Federal Supply Schedule contract or even open market and you are not required to do competition. So it is very hard to track individual purchases of an item even if the contracting action is in the system.

One example would be your Federal Supply Schedule contracts. The contracting action is in there. It has the pricing structure, but it is very difficult to follow who purchases what items off those contracts, especially when it is below the $25,000 threshold. So there is no visibility of those types of items out there.

I know when we do our work, we have to go to the vendors to find out exactly what VA purchased. But I will qualify that they do have a pretty good system in VA to track purchasing of pharmaceuticals because purchasing is done through a prime vendor. And they also have a good system to track prescriptions. We use that data consistently and we do get reliable data from the Department in that area.

Mr. BROWN OF SOUTH CAROLINA. How many average vendors do you have before you issue a contract?

Ms. REGAN. It depends on the value of your contract. If you are purchasing off a Federal Supply Schedule and it is under $3,000, you can issue it without any competition. Up to $25,000, I believe, or $100,000, you call up and get some offers from vendors. If it requires a statement of work, you are required to post an RFQ, re-

quest for quotation, on GSA Advantage to get quotes, give it to at least three vendors.

Again, it is the dollar amount, the $3,000, the $100,000 and over that makes a difference on how you will do your procurement.

Mr. BROWN OF SOUTH CAROLINA. I know that one of the members of the last panel said that there were too many vendors in the particular field that he was talking about. Some of you were in the room when he said that.

What is too many?

Ms. REGAN. I am not sure what is too many, but I do know that on the VA schedules, the Federal Supply Schedules, he was talking about the GSA Schedules. On the VA Federal Supply Schedules, anybody purchasing can go to the National Acquisition Center's Web site and actually put in the type of item that they want and it will come up with all the vendors. When they buy through the prime vendor for pharmaceuticals, the prime vendor has a list of every company that sells that drug, particularly generics where you have a lot of competition. So it is easier because you have visibility.

I know in my personal use of the GSA schedules, it is a little more difficult because they go by special item number. There may be a lot of businesses that fit into the general category, and it is very difficult to find those that have specifically what you are looking for.

So there are a lot of vendors. You could have 70 vendors listed for that special item number, but maybe only five of them have exactly what you are looking for. So it is very difficult to find the right vendors using GSA Advantage.

Mr. BROWN OF SOUTH CAROLINA. I know that we ask that we give special consideration to disabled veterans, for instance.

Are they flagged in a way that they would get preferential treatment if they were competitive or how does that work?

Ms. FINN. In many cases, VHA actually does a set aside for those type of procurements and then only vendors who qualify as a service-disabled veteran-owned small business or a veteran-owned small business can bid on those contracts.

Mr. BROWN OF SOUTH CAROLINA. Thank you. I see my time is expired.

Mr. MICHAUD. Thank you.

Mr. Carnahan.

Mr. CARNAHAN. Thank you, Mr. Chairman and Ranking Member.

I wanted to ask you to comment, if you would, about the specific findings with regard to the Cochran VA Medical Center in St. Louis.

Ms. DRAPER. We are actually going there next month. We have not conducted that work yet. Our work is ongoing.

Mr. CARNAHAN. So you have begun that work, but you have not made a specific site visit?

Ms. DRAPER. Yes. The site visit, I think it is going to happen in about 2 weeks. It is the first part of October.

Mr. CARNAHAN. Okay. Well, I would request that you notify us when that is going to happen specifically.

And you mentioned in your report inconsistent policies, noncompliance with oversight, and in particular the situation at the

Cochran VA Medical Center where dental instruments were not properly sterilized for at least a year.

What kind of oversight was supposed to be there that was not that did not catch that for at least a year's time?

Ms. DRAPER. One of the areas that we have found a particular concern in our work is that it appears that clinical department staff are allowed to purchase specialty items, surgical and dental instruments. And often those do not go through the required committee review and approval.

So the consequence of that is that staff responsible for cleaning and reprocessing that equipment is not always aware that it exists in the facility. And, actually, we have seen that on other site visits.

Mr. CARNAHAN. And the steps that are being taken to address the inconsistent policies, but also to address the oversight and enforcement of those policies, can you describe what is being done now to address that?

Ms. DRAPER. Yes. As I said, as I mentioned earlier, we are continuing to look at the oversight and compliance responsibilities and we are continuing to talk with VA. And we also plan to do additional work with the VISNs to see what their role is.

Ultimately responsibility for compliance at the facility level lies with the facility director and then it is also the responsibility of the VISN and VHA to ensure that there is compliance with the policies.

And as I mentioned, some of the issues arise because there is some ambiguity and contradiction in the policies. And, you know, our work has identified ambiguity and contradiction within the three requirements that we reviewed, and also where there are gaps related to the inventory management systems.

Mr. CARNAHAN. And when will those ambiguities be addressed so there is a clear standard throughout the VA?

Ms. DRAPER. Well, we hope that our report will be issued after we finish our next site visit and finish doing our analytical work. We are anticipating that the report will be issued in the spring.

Mr. CARNAHAN. And then, finally, one of the issues that has come to light in the conversations back in St. Louis is with regard to employees that have come forward, attempted to come forward. One employee talked about some problems early on was actually fired some believe in a retaliatory way. Others have been intimidated in terms of coming forward with information.

What is the VA doing in terms of protecting employees that want to come forward with information about improvements but also being sure that those responsible are being held accountable?

Ms. DRAPER. Yes. That is not really part of how we have looked at our work and that is probably a question that VA might be better able to answer. We are aware of the situation. And as I said, we are visiting St. Louis next month, so we will learn more about the particular situation there.

Mr. CARNAHAN. And let me ask the other witness from the OIG what steps can or should be taken with regard to those employees that may have helpful information in terms of how some of these things happen but also how to prevent them going forward so they are not being retaliated against when they may have important information to come forward?

Ms. FINN. Mr. Carnahan, I cannot address all the ways, but one option they have is to call the OIG hotline. We receive numerous complaints and questions, concerns from employees and entities over the course of a year. And we investigate many of them and work to protect the rights of that employee or the complainant.

Mr. CARNAHAN. All right. I see my time is up, Mr. Chairman. Thank you for having me sit in today on this hearing.

Mr. MICHAUD. Thank you very much, Mr. Carnahan.

Mr. Boozman, do you have any questions?

I would like to thank our second panel for coming forward. And I am sure there will be more questions that we will submit in writing. So, once again, thank you all for coming. I appreciate it.

The last panel includes Frederick Downs who is the Chief Procurement and Logistics Officer for VHA. He is accompanied by Dr. Andrea Buck who is the National Director of Medicine for VHA.

I want to thank you very much, Mr. Downs, for coming forward and I look forward to your testimony.

STATEMENT OF FREDERICK DOWNS, JR., CHIEF PROCUREMENT AND LOGISTICS OFFICER, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY ANDREA BUCK, M.D., J.D., NATIONAL DIRECTOR OF MEDICINE, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS

Mr. DOWNS. Thank you, Congressman.

And let me just get a second here to get my papers all straightened out. I was taking a lot of notes during the panels. I would like to be able to address those to you.

Good morning, Chairman and Ranking Member and Members of the Subcommittee. Thank you for inviting me to discuss the Veterans Health Administration contracting and procurement practices.

I have testimony here. I want to make one thing clear on my paragraph and then I would like to go right into answering some of these questions if that is okay with you. We will get right to it.

Mr. MICHAUD. Is there any objection? Hearing none, your full written testimony will be submitted for the record.

Mr. DOWNS. First, I want to state that acquisition reform is a central piece of the Secretary's charge to fundamentally change the Department of Veterans Affairs in ways that will transform it into a 21st Century organization that is people-centric, results driven, and forward looking.

And it is important to know that the integrated operating model is the Department's acquisition and transformation initiative. And VHA fully embraces the Secretary's transformation vision and the implementation of this integrated operating model.

And to go forward with that, you know, listen to the testimony first of the folks, the vendors and their concerns, and we want to make sure that people understand that we are very open to listening to what is going wrong, but we want to make sure that we are open to all the vendors and address their concerns.

But in the area of the concerns that were addressed by the different individuals, what we attempt to do in VHA and VA is we need a level playing field. We have a lot of competition that we

need to adhere to as far as making sure that everyone has a fair chance to apply for the contracts that we let out.

Contracting officers are one part of it. The needs of the clinical service or the service at hand is another part of it. In the area of construction, we have construction in facilities and they have their needs and requirements. And what they do is work together as a team in putting all of this together.

Contracting is difficult in the government, complex, but we are regulated by the FAR and by both the Federal Acquisition Regulations and the Veterans Administration Acquisition Regulations. And so when adhering to those, we follow a certain process and procedure to make sure that we are doing the right thing, that we are making the processes the way they should be.

And the competition out there will come to us and they will make presentations. We then take that information. We share it with the clinical programs or the other programs and they are able then to decide whether this is something they need or they do not need.

And I think in trying to address the concerns of the vendors, we are always open for that. And one of the areas that we are very conscious of is our small business and what we have done to improve our outreach to the small businesses.

Within VHA, we have appointed a small business administrator or point of contact in my office. At each one of the VISNs, we have a small business coordinator. And then they work with the facilities to ensure that when the inquiries come in from the small businesses or the large businesses, there is a point of contact to send that person to.

In my office, we do about 150 meetings a year with vendors. At the VISN level, I know that the VISN coordinators for small business say they get four or five inquiries a week from the different facilities. We have a brochure that we give to these individuals to help them do business with the government. Our job in VHA is to help that individual do business with us because we are successful if they are successful.

Now, one of the things that we have as a mantra or a philosophy is that we buy American, buy small business. And with that in mind, that is how we approach all of this.

And, in fact, our small business for this year for the service-disabled veteran-owned small businesses, we are at 17 percent. And so we address that aggressively.

In the ARRA funding this year, which VHA had $1 billion, we had 98 percent competition and 76 percent of that business went to small businesses and 75 percent of that was to service-disabled veteran-owned small businesses and veteran-owned businesses. That is an indication of the direction that we are going in the future.

We want to address these problems, but some of these things that are perceived as problems are not really problems but are part of the process. And we want to make that process as clear and as understanding as we can. That is the reason we have this openness and allow people to come in and talk to us, to meet with us.

And I have met with some of these individuals who were on the first panel and so we try to work as we should in making sure they have the information and learning how to do business with us.

[The prepared statement of Mr. Downs appears on p. 82.]

Mr. MICHAUD. Thank you very much.

How do you respond to the concerns that GAO and OIG have raised in their testimony? When you look at contracts associated with the ARRA funds, they found that 60 out of 65 were not in compliance with established rules.

I guess I do have a concern, especially when you are dealing with veterans' health. So how do you address the concerns that GAO and OIG raised today and what steps is VA taking to address these concerns? How quickly will you be able to address those concerns?

Mr. DOWNS. Well, sir, we are in the middle of addressing those concerns now. Been very active in developing action plans.

In VHA, what we have done is reorganized into a centralized integrated model and so that all the procurement people throughout VHA have been taken out of the chain of command of the local facilities and network directors. They now answer through their chain of command straight through to my office.

The other thing we have done, we have formed what we call three service area offices. And in those service area offices, we are setting up quality and compliance teams in addition to audit and review teams.

We also have in my office set up a quality officer and her job is to develop the policies and procedures, the standardization and to do the audits and direct the audits at the local level.

These problems that were mentioned by the OIG and the GAO have us very much concerned, but we have been working hard to address those. Certainly we are dealing with, in our area when it comes to inventory, for instance, we are dealing with seven antiquated stovepipe systems within each facility for inventory.

And we have that at 153 or 154 facilities. They were always designed as facility level, never national-level inventory systems. So for us to get data to control it from a national level, VISN level, even at the facility level is extremely difficult.

We understand what the problems are and that is the reason we have what we call strategic asset management. This was part of FLITE, which is the Financial Logistics Integrated Technology Enterprise system, and it was recently canceled. But the SAM, the Strategic Asset Management, piece of it is something that was handed to us in VHA. And I am not the SAM program management for that.

We have a pilot program in Milwaukee right now. We have gone through our first user's test, been very successful. And we intend to go live in Milwaukee in March 2011 and then we are going to have a post alpha time to make little tweaks to it if we need to because of the cancellation of Financial Accounting System and FLITE. In the data warehouse, some of the IT things that were going to be a part of that are now changed and so we are going to go through the process of making that alpha product our basic inventory model.

We will then go to the beta stations, approve a concept, and then we go nationwide. And we intend to do that, our goal, we think 2013, 2014, we will be nationwide.

Now, what that system allows us to do is to keep track of every piece of equipment from the time it comes into the medical center to the time it is accessed.

Then the reporting system is going to be the answer to many of the issues and problems brought out here in the OIG and GAO when it concerns equipment and supplies. We will be able to keep track of that at the facility level, at the VISN level, and at the regional level. In a way, it will be part of the 21st century.

And these antiquated systems, which are what is hindering us now because we are dependent upon manual reports, what we are trying to do right now is to hold these people accountable for making sure they are filling out their reports, they are putting information into the Automated Engineering Management System/Medical Equipment Reporting System of the Generic Inventory Package.

So we have a current process in which we are intensifying our ability to try and get compliance for them to do that. But until then, until we get our national product, we will continue our efforts on a facility-by-facility basis.

We are going through also a logistics transformation in addition to our acquisition transformation. We are making tremendous strides in logistics. But, again, this was the first time this office has existed in VHA and it has been in place for 5 years. And so there was no office before. There was no one in VHA to oversee or monitor the carrying out of the policies nationwide for almost 25 years.

And so what we are doing is making a lot of effort, a lot of effort into correcting that by reorganizing, going through a transformation. We are looking at all these policies you have heard where it is haphazard. We are standardizing our policy. We are setting up teams to go out and do the audits, the quality review teams.

There is a whole genre of good management kinds of actions we are taking to address all of these issues. This is extremely important to us, the patient safety issues.

I as a patient, I have to tell you in the VHA system, I am driven to correct these issues because there are almost six million of us using this VHA system. It is imperative that we do a good job with it.

So, yes, we are concerned. We are passionate. We are making the changes. We are locked into the processes, so that we are changing those processes also and writing new standard operating procedures.

And all this is being done very rapidly. The acquisition part started a year and a half ago. The end of this month, we will finish the acquisition part. And the final individuals at the local level who are doing purchases will be now a part of our chain of command which will address—I have gone too far.

Mr. MICHAUD. No. You mentioned you are taking the responsibility from the local level down to your office. And that was done what, a year and a half ago?

Mr. DOWNS. January of 2009 or January, February of 2009 was when we started the process.

Mr. MICHAUD. When you started. How do you look at, for instance, whether the VA actually does do a good job in purchasing prescription drugs, which cost $4.8 billion in 2011?

I do not know if it is the best question for you, Mr. Downs, or Dr. Buck. My concern is, even though you might be in compliance with whatever procedures the VA has set up, what about the utilization rate of those drugs?

As you heard from the first panel, distributing a 15-day supply, instead of a 30-day supply or a 2-month supply, could actually save dollars in the pharmacy area. Are you focused on that as well?

Mr. DOWNS. No, sir. Dr. Buck or myself would not be involved with that. That is a clinical decision by the pharmacists and clinicians. And we can take that for the record, but certainly not one I can answer.

[The VA provided the response in subsequent information, which appears on p. 34.]

Mr. MICHAUD. Okay. Thank you.

And my last question is, we heard Mr. Wise on the first panel quote a VA employee who admitted the VA is broken.

Mr. DOWNS. Well, we have about 300,000 employees and there are certainly some who are unhappy with it. But the individual in mind, and I know the individual, it is not broken. I have tried to compare this many times.

We are doing, in VHA at least, we do about 320,000 purchases a month. We are taking care of six million patients a year. We have the largest health care system in the United States. We are able to provide the service that the veterans need. And we are getting the job done day to day and it is proven by the fact that we are considered one of the top health caregivers in the United States.

And so we are getting the job done. So it is not that we are broken. What it is is that we have a system. The clinical change started in the 1990s when Dr. Kaiser turned this upside down and made quality patient care number one. But the infrastructure to support that, the supply, service, and the others, they were sort of disbanded and left to the field to do what they wanted to do. Those roles and responsibilities of the logistics people, the function still remained, they just got spread out. And that is one of the reasons that you hear about we have different policies and such.

Okay. One of the things that we are doing is bringing this back together because we need to have the infrastructure to support that top-quality health care. And that is the reason that logistics and acquisition are so important.

I am in charge of VHA's complete supply chain. And we have been working to correct all of those kinds of issues about how we bring it back together at the facility level, to the VISN level, how we then make that into a strategic plan to go into the future to meet the Secretary and Under Secretary for Health's objectives of keeping that health care where it needs to be.

So that is the reason we are so desperate, not desperate, we are so intense to try and make sure that we are speeding up this process of making these corrections. But we are still limited. We need to go through the testing process, for instance, on the SAM project.

On the logistics side, we are going through a lot of changes at the local level. And like I said, we just within the last year and a half have been able to put this organization into place, my Systematic Analysis of Operations (SAOs), my logistics transformation.

My Deputy in Procurement has only been on board for 6 weeks. My Deputy in Logistics has only been on board since December. And my Deputy in Prosthetics has been on board for 2 years. So we have a complete infrastructure that we have put together within VHA and that is the reason we are moving smartly forward to correct these issues.

We have the people in place. We have a lot more folks that we need to put into place both at our level and at the field level to ensure that the work starts getting done the way it should be and that we are doing audits and follow-ups, compliance and reviews, and have reports and metrics to back up what we are doing, all part of a very large plan, sir.

Mr. MICHAUD. Thank you.

Mr. Brown.

Mr. BROWN OF SOUTH CAROLINA. Thank you, Mr. Downs. I appreciate you being here today.

And I think those numbers put things back in perspective. It is a big process. It is a big operation and sometimes they try to micromanage one or two issues. I know we have been talking about it for a long time and I'm not sure this is a proper question for you.

But seamless transition from the DoD to VA, do you know how the progress of that is proceeding?

Mr. DOWNS. No, sir. I am not able to answer that question.

Mr. BROWN OF SOUTH CAROLINA. Okay. In the previous panel, they mentioned that there would be some relative savings if you did not go to the automatic prescription refill.

What do you think?

Mr. DOWNS. Well, that, sir, I have not studied that. I do not know. Again, the pharmacy people would be the best ones to answer that. I have not done an analysis on that.

Mr. BROWN OF SOUTH CAROLINA. I was just trying to evaluate it in my own mind. It seemed to me that it is a really convenient item not to worry about if you have blood pressure medicine coming, whether you have to make a call. It seemed to me the logistics of doing that would be certainly something that we would expense.

And if you are going to save money by not getting the medicine to the veteran, then I think that it would cost more to get the person back on blood pressure medicine regularly than it would be to send that prescription in the first place.

So I am not sure exactly what kind of savings would be attributed to that, or whether there would be any. There may be a downside to the administrative costs.

Mr. DOWNS. I was not sure of that either, sir. And like I said, I cannot address it professionally. I just know that as a patient, when I need to renew my blood pressure medicine, I just call and record and the next thing I know, it shows up on my doorstep.

Mr. BROWN OF SOUTH CAROLINA. Right.

Mr. DOWNS. So that is a pretty effective process.

Mr. BROWN OF SOUTH CAROLINA. You are not on automatic refill?

Mr. DOWNS. It is an automatic refill. I mean, I call them and they send it.

Mr. BROWN OF SOUTH CAROLINA. But you still have to make the call?

Mr. DOWNS. I make the call, yes. But that is a patient safety factor, I would think.

Mr. BROWN OF SOUTH CAROLINA. I see. Okay.

Mr. DOWNS. Because I am only allowed six refills and then I have to go back in to the doctor.

Mr. BROWN OF SOUTH CAROLINA. To get another prescription?

Mr. DOWNS. That kind of a thing.

Mr. BROWN OF SOUTH CAROLINA. Okay. Very good. Thanks for being here today. I have no further questions.

Mr. DOWNS. Okay.

Mr. MICHAUD. I have a question for Dr. Buck. You are the National Director of Medicine, so what do you do over in VHA? Is it establish policy or——

Dr. BUCK. Presently I am located in the Office of Patient Care Services and that is actually the area that I am in of subspecialty care. And it is primarily a policymaking function.

Mr. MICHAUD. Okay. I will ask you the question I asked Mr. Downs since you are in the policy area. When you look at the $4.8 billion that VA spends on drugs, what is the policy of the VA on utilization? This gets back to Mr. Brown's question. When a prescription runs out, do you automatically send the prescriptions to the veteran or do you give them a 15-day supply? Can you address the utilization issue?

Dr. BUCK. Sir, the way that our policymaking functions are organized, there is actually a separate pharmacy division, which has the expertise of doctorates in pharmacy who actually are responsible for the policymaking functions for pharmacy.

So, unfortunately, those folks are not represented here today, so I cannot answer your question.

Mr. MICHAUD. But as a doctor——

Dr. BUCK. Yes, sir.

Mr. MICHAUD [continuing]. Utilization, is there a problem with utilization or could you see that there is a problem with utilization?

Dr. BUCK. Sir, honestly I speak generally. The one thing that I do is I always try to answer the questions as honestly as possible. And the one thing that I strenuously avoid doing is answering one incorrectly. And that is what I would do in this case because I do not have that information.

Mr. MICHAUD. Now, I guess my concern is, and I have heard it actually in the private sector, where you have these drug manufacturers——

Dr. BUCK. Uh-huh.

Mr. MICHAUD [continuing]. With a very cozy relationship with doctors, such as pharmacists within VA. And my concern is that we are probably spending billions of dollars more than we have to on drugs for our veterans.

I want to make sure they get, you know, the prescriptions that they need. But I am also concerned about the waste in the system. And even though the procurement might not address that issue, it is part of the VA system.

And that is why as a doctor, I was just curious about whether or not you see utilization as a problem, not necessarily what the VA might be doing, but as a doctor, whether that could be a problem and whether we might be able to address it to actually save some money in the pharmacy area.

But we will forward that question to someone within the VA that actually can address it.

[The VA subsequently provided the following information:]

Question: When I look at the $4.8 billion that VA spends on drugs, what is the policy of the VA as far as utilization issues? Is there a problem with utilization?

Response: The Department of Veterans Affairs (VA) does not have a problem with drug utilization. Minor adjustments and corrections need to be continually made in any health care system, including VA, to assure drug utilization is consistent with emerging medical evidence and meets the needs of patients. In VA, medication utilization is guided by an extremely well-managed formulary process whose origin dates to the 1950s. VA has been a pioneer in the area of formulary management for nearly 60 years and is regarded by many experts as an industry benchmark in the United States for cost-effective, safe, evidenced based formulary management.

Formulary Management Infrastructure

The organizational responsibility for facilitating VA's formulary management process rests with the Pharmacy Benefits Management (PBM) office which is organizationally aligned under the Office of Patient Care Services (PCS), which in turn is aligned under the office of the Under Secretary for Health (U.S.H). In 1996, VA established a National Formulary process to augment and eventually replace independent local formulary practices which had been in use across the system. The purpose of implementing a national formulary process was to assist practitioners in clinical decision-making, to standardize and improve quality of patient care, to promote seamless portability of mediation access from one facility to another, to promote cost-effective evidence-based prescribing practices and to develop and disseminate clinically relevant pharmacoepidemiologic data. Within PCS, the PBM coordinates formulary management activities using a variety of subject matter experts organized into two primary decision-making bodies, the Medical Advisory Panel (MAP) and the Veterans Integrated Service Networks (VISN) Pharmacist Executives (VPEs).

The MAP provides physician oversight of the formulary process and is comprised of 12 practicing VA physicians including general internists, as well as specialists practicing in the areas of cardiology, critical care, endocrinology, geriatrics, infectious disease, and psychiatry; VA PBM clinical pharmacist specialists; a VPE and one physician from the Department of Defense. The MAP provides clinical oversight of the formulary management process. The VPE committee includes pharmacist representatives from each of VA's 21 VISNs, a representative from VA's National Center for Patient Safety (NCPS), a physician representative from the MAP and representatives from the DoD. This group provides operational and clinical oversight of the formulary management process.

Formulary Management Process

VA policy (VHA Handbook 1108.08; http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1834) requires that drugs newly approved by the Food and Drug Administration (FDA) and which have utility in VA, be automatically reviewed for potential addition to the VA National Formulary (VANF); this review occurs as soon as sufficient safety and efficacy information becomes available. The VA policy for updating the VANF specifies additional triggers for updating the VANF. Requests for change in VANF status may be submitted to the PBM by a VISN Formulary Committee, the VPE Committee, the MAP Committee, a VHA Chief Medical Consultant, or a VHA Chief Medical Officer. An individual or group of physicians may submit a request for VANF addition through their VISN Formulary Committee(s). In addition, the VA uses its evidence-based drug class reviews to pursue contracting opportunities within or across drug classes, allowing for

lower acquisition prices for pharmaceuticals, while maintaining or improving the quality of drug therapy. A review may also be initiated if new safety data becomes available that may require discussion of removal of a medication from the VANF, or implementation of restrictions to ensure safe and appropriate use of the medication.

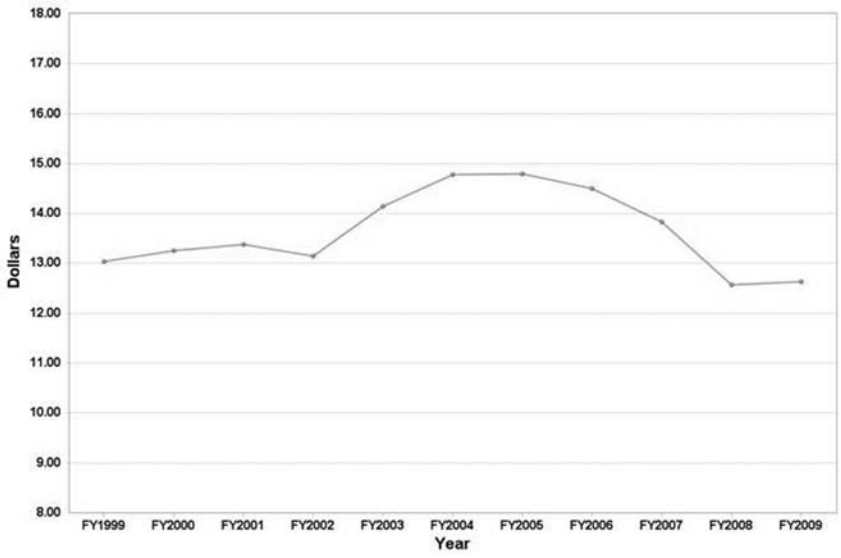
The review process for a medication consists of an extensive and in-depth evaluation of the published literature in order to determine the efficacy of the medication, with an emphasis on results reported for a patient population similar to the Veteran community; the potential for adverse events and long-term safety; and the cost-effectiveness compared to other available treatments. This review process begins with the PBM clinical pharmacist specialist, in consultation with MAP members and/or VA's physician subject matter experts, representing a variety of subspecialty disciplines. Input is also sought from VA clinicians and experts in the field.

The philosophy for VA's formulary management process is an unwavering reliance on well-researched, well-documented clinical evidence demonstrating that a specific drug can provide an expected cost-effective benefit for the Veteran population. According to an analysis of the VANF in 2001, the Institute of Medicine (IOM) stated:

> *"The VA National Formulary and formulary system that enable the VHA to make quality choices among drugs and negotiate favorable prices should be maintained . . . The VHA should continue to make careful choices among drugs, based first on quality considerations but with an understanding of cost implications, and should negotiate the best prices possible using the leverage of committed use and the ability to drive market share."*

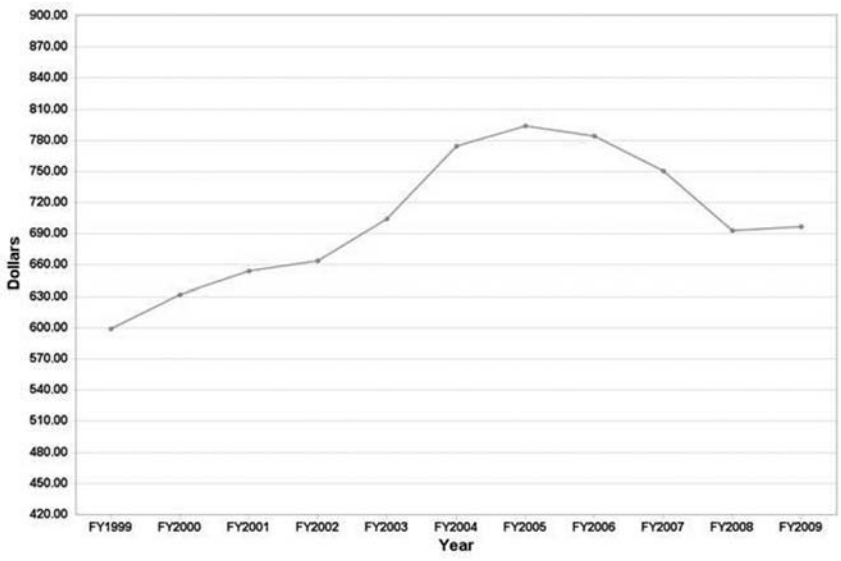
The cost of a medication is only one factor when considering the overall cost and quality of therapy; however, VA has been able maintain or improve the quality of medication therapy, while also keeping the price of medications low as shown in Chart 1 and Chart 2 below.

Chart 1: VA Average Cost of a 30-day Equivalent Outpatient Prescription



Note: The VA average cost of a 30-day equivalent outpatient prescription changed from $13.03 in FY 1999 to $12.64 in FY 2009, a 3.0 percent decrease over a 10-year period.

Chart 2: VA Average Outpatient Prescription Drug Cost Per Unique Patient



Note: The VA average outpatient prescription drug cost per unique patient changed from $599 in FY 1999 to $697 in FY 2009, a 16 percent increase over a 10-year period.

VA prescription drug costs per patient include all patients receiving drugs. In contrast, other prescription benefit plans report per member per month or per member per year, which underestimates costs because members that do not use the benefit are counted in the calculation. Patients served by other prescription benefit plans are typically younger with fewer chronic diseases than patients served by VA; therefore their prescription costs would be expected to be lower than VA's costs. Indeed, a recent study using data from the Medical Expenditure Panel Survey from the Agency for Health care Research and Quality (AHRQ) showed that Veterans who use the VA have substantially more medical and psychiatric issues than those that do not use the VA. Despite these differences, VA's costs are significantly lower than other health plans. These comparisons are illustrated below in Chart 3.

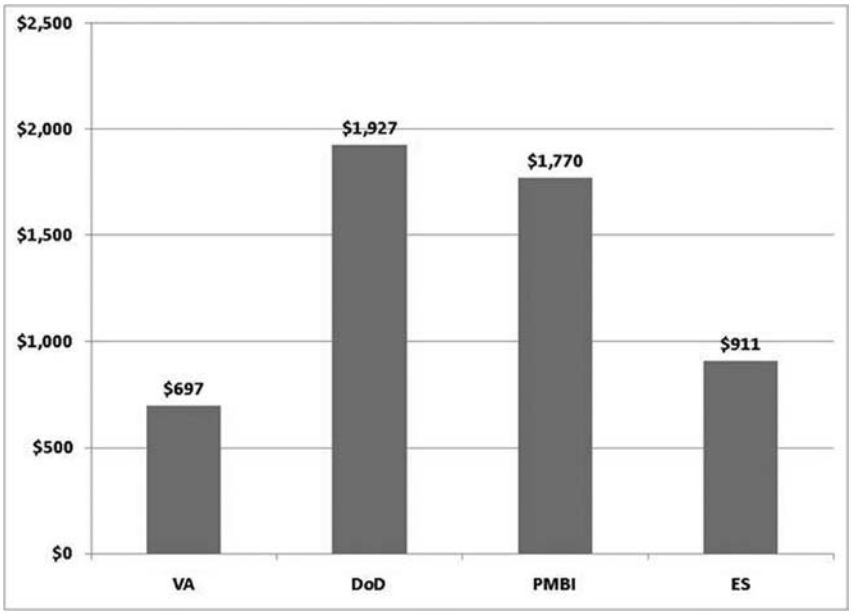
According to a presentation entitled, "*Overview and Update on DoD Pharmacy*" presented at the 2010 Military Health System Conference, the pharmaceutical cost per Department of Defense eligible beneficiaries aged 65 and older was $1,927 in FY 2009, compared to $686 in the same age group in VA during the same time period. The report is available at http://www.health.mil/Libraries/2010__MHS__Conference__Presentations/M36__T__McGinnis.pdf.

According to the Pharmacy Benefit Management Institute (PBMI) 2009 Prescription Drug Benefit Cost and Plan Design Survey, completed by 417 employers representing 7,041,676 members, the average net prescription drug cost per retiree per month extrapolates to $1,770 per member per year. In comparison, the VA average prescription drug cost per unique patient in FY 2009 was $697 and VA's cost is a gross cost; it does not subtract first party co-payments. The report is available at http://www .benefit design report.com/ Drug Cost Highlights / Per Member Per Month Metrics/tabid/88/Default.aspx.

According to Express Scripts, the overall per member per year drug cost was $911 based on the 36 million lives in the commercial client groups. In comparison, the VA average prescription drug cost per unique patient in FY

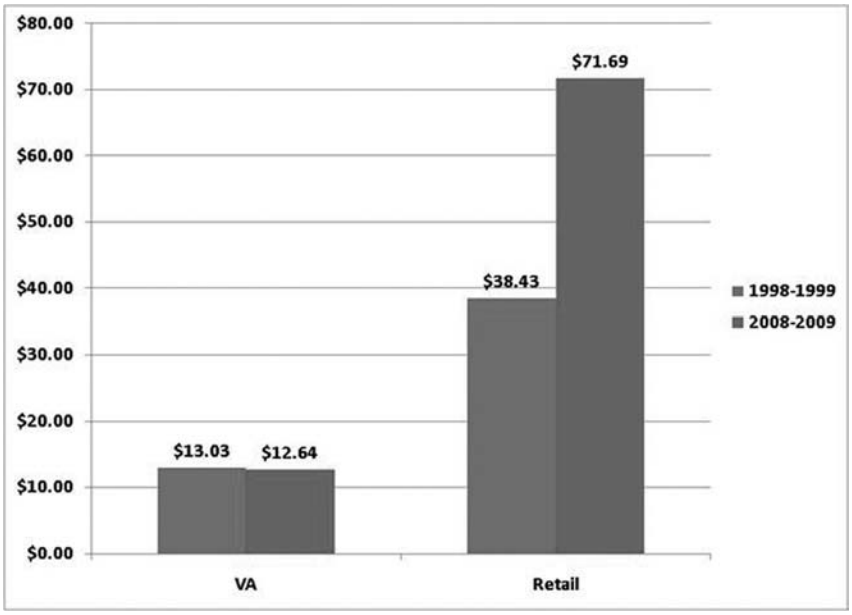
2009 was $697; again, other plans have younger, healthier patients than VA's patients and include all members, and unlike VA, patients are included regardless of whether or not they use the prescription benefit. The report is available at http://www.express-scripts.com/research/studies/drugtrendreport/2009/dtrFinal.pdf.

Chart 3: VA Average Outpatient Prescription Drug Cost per Unique Patient Compared to Other Prescription Benefit Plans



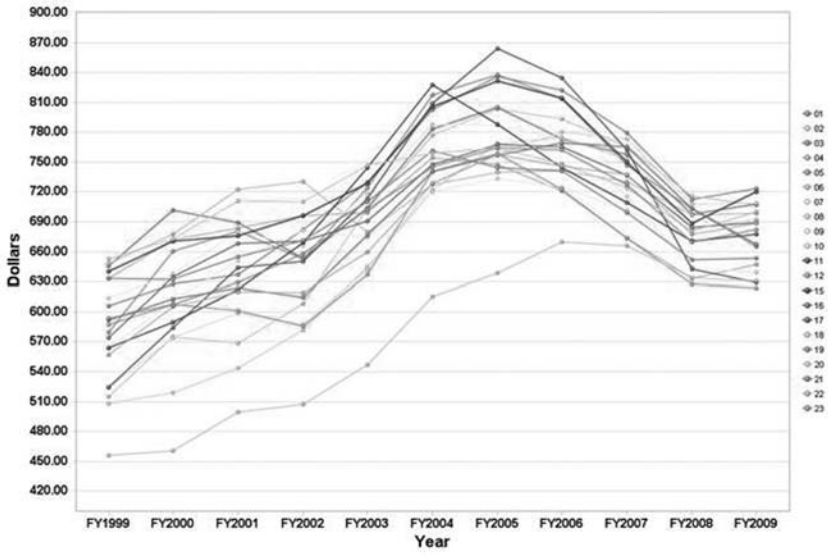
According to the Kaiser Family Foundation's (KFF) May 2010 Prescription Drug Trends report, industry data show that retail prescription prices (which reflect both manufacturer price changes for existing drugs and changes in use to newer, higher-priced drugs) rose from an average price of $38.43 in 1998 to $71.69 in 2008. The increase over the 10-year period is 87 percent. The change in prescription prices for VA over nearly the same 10-year period (FY 1999 to FY 2009) was a DECREASE of 3 percent. The report is available at http://www.kff.org/rxdrugs/upload/3057–08.pdf. The comparison is illustrated in Chart 4.

Chart 4: VA Average Cost of a 30-day Equivalent Outpatient Prescription Compared to Retail Prices



In response to recommendations from a 2001 U.S. Government Accountability Office (GAO) report and the 2001 IOM report on the VA formulary, VA monitors utilization and conducts safety and efficacy reviews using a central drug utilization analysis database. The results of these analyses are then used to assess future needs. One of the ways the database is utilized is to identify potential areas for managing drug costs through cost-avoidance initiatives. These are developed nationally, and may be implemented at the VISN or local medical care facility level. The intent of the program is to actively pursue pharmacy efficiencies and appropriateness of use for selected pharmaceuticals and reduce the variance in drug cost per patient across the system, while ensuring there is no negative impact on the quality of care. The program was formally initiated in Fiscal Year 2007 and has resulted in substantial cost avoidance and a subsequent reduction in the variance in drug cost per patient. The program documented cost avoidance of $264 Million in FY 2007, $354 Million in FY 2008, $191 Million in FY 2009 and $112 Million projected for FY 2010. As a result of these efforts, the variance in cost per patient has decreased substantially as show in the chart below.

Chart 5: VA Average Outpatient Prescription Cost per Unique Patient by VISN



Note: The variance in VA average outpatient prescription cost per unique patient decreased significantly from FY 1999 to FY 2009.

VA's primary motivation in formulary management has always been and always will be to improve the quality of care for Veterans. Economic considerations though important, are secondary compared to safety and efficacy. VA has often been criticized for not adding recently approved medications to the VANF, or for unduly restricting medications, and has been the subject of inquiries and investigations prompted by these criticisms by the Institute of Medicine, the Government Accountability Office and the Office of the Inspector General. Although some of the external reviews conducted to date made suggestions for minor process improvements, in general, VA's processes were determined to be safe and cost-effective and formulary decisions were determined to be based on sound reviews of the medical evidence.

During 2008 and 2009, VA PBM–MAP and VPEs reviewed 61 medications for potential VANF inclusion; 11 were added to the VANF, and 50 were approved for use via the non-formulary process. Criteria for use or additional restrictions were developed for 25 medications to ensure their safe and appropriate use. As described previously, extensive evidence-based reviews are conducted (refer to documents posted to http://www.pbm.va.gov) for VANF consideration or for developing guidance on a medication's place in therapy.

Consideration for VANF listing includes whether the medication is applicable to the VA population (e.g., medications for pediatric use will typically not be added, or for rare conditions not expected to be seen in the Veteran population), whether a medication will provide benefit over an existing VANF agent, and whether adequate safety data are available. Often, amedication may not be added to VANF at the time of initial review due to unanswered questions about long-term safety or lack of comparison data to less expensive or generic medications that are readily available on the VANF for the management of the majority of Veteran patients. An example of a medication that was not added to the VANF due to lack of long-term safety and efficacy outcome data compared to other available agents on the VANF was cerivastatin (Baycol®), a medication used to treat hyperlipidemia (high cholesterol), which is a common condition in the Veteran patient

population. The VA formulary included medications within this class with proven benefit in reducing cardiovascular morbidity and mortality that had been shown to be safe in treating patients with hyperlipidemia). Cerivastatin was marketed as a more potent agent; however, it did not have the long-term outcome data as with the other available agents. Subsequently, cerivastatin was removed from the market after deaths due to kidney failure. Rofecoxib (Vioxx®) was another example of a drug never placed on the VANF and withdrawn from the market due to cardiovascular toxicity associated with death.

Via a formal Memorandum of Understanding, the VA PBM works closely with the FDA through VAMedSAFE, a group within the PBM tasked with identifying and responding to medication safety signals via communication and guidance on improving the safe use of pharmaceuticals in VA. A recent example of the efforts of VAMedSAFE is the identification of a safety signal for the drug varenicline (Chantix®) which is used for smoking cessation, and the risk for serious adverse events including the potential for suicidal thoughts and actions. This resulted in safety communications disseminated to VA health care professionals, letters to Veteran patients, and modification to the VA criteria for use of this medication. Another safety initiative was to restrict the use of rosiglitazone (Avandia®) a drug used for diabetes that was found to be associated with an increased risk for heart attack and death. Prior to the safety signal, this medication was already restricted in VA patients, well before its use was being curtailed in other health care systems. In response to VA's action in restricting the medication from use in new patients and to provide guidance for alternate therapies, on October 18, 2007 it was stated in the New York Times (http://www.nytimes.com/2007/10/18/business/18drug.html?_r=2&adxnnl=1&oref=slogin&adxnnlx=1192713524-bGMLReuAbDJNXwuo9QSfEw) that:

> *"The Department of Veterans Affairs has decided to severely limit the use of Avandia, the once-popular drug for Type 2 diabetes, delivering another blow to the products maker . . ." The VA was also criticized by the manufacturer, quoted to be ". . . surprised and disappointed by the V.A. Central Office decision . . . We do not believe it is in the best interest of patients."*

More recently, the FDA has made similar recommendations restricting the use of rosiglitazone due to the safety concerns and after considering the risk vs. benefit of treatment with this drug.

We are extremely proud of VA's formulary management program. We have carefully developed and refined the VA formulary process over the past 15 years and are fortunate to have a process that meets the needs of Veterans in an evidence-based, comprehensive, safe, and efficient manner. VA's prescription benefit is a national plan that is managed by practicing VA physicians and pharmacists. While we value the products the pharmaceutical industry offers for use, the industry itself has no role in determining VA's need for their products, nor how those products are managed. VA has effectively neutralized the inappropriate impact the pharmaceutical industry can potentially have on health care delivery by a strict reliance on published evidence and by curtailing the marketing and advertising strength of the industry. Using a structured and evidence-based formulary management process benefits Veterans by assuring the VA prescription benefit is first and foremost safe, and then that it is cost-effective and sustainable well into the future. The clinical guidance and formulary recommendations of the VA PBM–MAP and VPEs are routinely accessed by State Medicaid programs, other health care organizations and providers, and the international pharmacy community and are a valuable public resource for those entities as they develop their own formulary policies and initiatives.

Question: When you look at when someone runs out, do you automatically send the prescriptions to the veteran or do you give them a 15-day supply?

Response: VA does not automatically send prescription refills to patients who run out of medication. Patients whose providers have authorized refills for a prescription may request a refill up to 10 days before their supply is exhausted. Patients have several ways to requests refills including via automated telephone request lines, via the internet, via mail and in person at the pharmacy window. The latter method is encouraged only for patients who have failed to reorder their medications 10 days before their supplies

ran out and who are in danger of interrupting their therapy if they do not get an emergency supply. In these cases, up to a 10-day partial supply of medication is commonly provided, with the full refill being sent in the mail.

Question: Now, I guess my concern is, and I have heard it actually in the private sector, where you have these drug manufacturers having a cozy relationship with doctors, whether it is a doctor or within the pharmacy system within the VA. And my concern is that we are probably spending billions of dollars more than we have to in drugs, you know, for our Veterans.

Response: VA is cognizant of potential for conflicts of interest, especially in regard to formulary management. In order to become a member of the voting bodies of the MAP and VPEs, an individual is unable to have financial ties to a drug manufacturer within the previous 12 months. In addition, each PBM clinical pharmacist specialist, MAP physician, and VPE completes an annual Confidential Financial Disclosure or in some cases, Public Financial Disclosure Report and is subject to the requirements of the Ethical Standards of Conduct for Employees of the Executive Branch. Each MAP and VPE meeting or conference call agenda where VA formulary issues are discussed includes a listing of the drug manufacturers at the end of the discussion item. Per VHA HANDBOOK 1004.07 *Financial Relationships between VHA Health Care Professionals and Industry,* verbal disclosures are solicited by the chairperson at the beginning of each of these meetings (and at appropriate times during that meeting for any late-arriving members). Any reported financial disclosures or perceived conflicts of interest are recorded in the minutes for that meeting and the individual is asked to recuse themselves from the discussion and are not allowed to participate in the voting for that issue. Requests for VA National Formulary addition initiated by a VA provider require accompanying disclosure of any potential conflicts of interest.

In order for the VA formulary process to succeed, the MAP and VPEs understand the value of input from VA providers in the field treating the Veteran; however, it is important that comments are free from potential bias. Therefore, a request for financial disclosure accompanies all new molecular entity drug monographs, criteria for use, and drug class reviews when soliciting input from field clinicians. In an effort to improve the process of requesting disclosure of financial relationships and interpreting comments received that may have a perceived conflict of interest, the MAP and VPEs recently invited a Medical Ethicist with the VA National Center for Ethics in Health care to discuss implementation of VHA Handbook 1004.07 *Financial Relationships between VHA Health Care Professionals and Industry,* which is consistent with current MAP and VPE requirements (http://www1.va.gov/vhapublications/ViewPublication.asp?pub__ID=2102; excerpt below):

"Responsibilities:

1. Health Care Professionals are responsible for:

- *Avoiding or managing conflicts of interest*
- *Certifying in VetPro as part of the VHA credentialing process: I understand that my professional obligations can be compromised by financial conflicts of interest; therefore, I will avoid conflicts or seek guidance in their management.*

2. Service Chiefs are responsible for:

- *Ensuring that VHA health care professional staff members are oriented to the types of financial relationships with industry that pose a potential for conflicts of interest.*
- *Reinforcing expectations regarding professional norms and conflicts of interest by, for example:*
  - *Reviewing individual prescribing data received from local P&T Committees.*
  - *Scrutinizing staff requests to use leave to participate in industry-sponsored events.*
  - *Assessing potential conflicts of interest in staff topic selection for presentations at VA facilities.*

3. Members of VHA decision-making and advisory groups are responsible for:

- *Making real-time verbal disclosures of potentially conflict-creating financial relationships with industry.*

4. Chairpersons of decision-making and advisory groups are responsible for:

- *Soliciting and managing follow-up on verbal disclosure of members' financial relationships.*

The handbook applies to any full-time, part-time, or without compensation employee or trainee (i.e., physicians, advanced practice nurses, psychologists, physician assistants, pharmacists, other associated health practitioners with prescriptive authority, and certain administrators) in VHA who makes treatment recommendations that pertain to commercial products or are involved in making formulary decisions, in developing clinical practice guidelines or institutional policies on care, or in other activities within the health care system that can have a significant effect on the range of treatment options available to patients.

Financial relationships that either constitute a conflict of interest or give the appearance of a conflict, including:

1. *Compensation for participation as a member, presenter, moderator, etc., on an industry-funded speaker's bureau.*
2. *Compensation for participation as an advisor, consultant, member, presenter, moderator, etc., on an industry-funded advisory board.*
3. *Compensation for participation as an author on an industry-funded publication.*
4. *Paid expert witness testimony provided on behalf of industry.*
5. *Industry-funded education or research grants, honoraria, or low interest loans.*
6. *Compensation for a paid role (Medical Director, Board Member, Resident or Trainee Representative, etc.) on a pharmaceutical, biotechnology, medical device, product, equipment, or technology company or their proxies.*
7. *Compensation for participation as developer, speaker, moderator, attendee, etc., of industry-funded Continuing Medical Education (CME) or other industry-sponsored programs, such as lectures, dinner meetings, or teleconferences."*

In addition, VHA Handbook 2003.060*Business Relationships between VHA Staff and Pharmaceutical Industry Representatives* (which is currently undergoing revision via the regulatory process) includes policy to control access of pharmaceutical representatives to VA providers in an effort to minimize disruption of patient care activities and to ensure that only VA approved guidance are promoted by the pharmaceutical industry representative. Only medications that are available on the VANF may be discussed, any speaker at an educational program sponsored by industry must disclose their financial relationship to the audience and meals may not be provided at such meetings. Also per the policy, medication samples (often used in an effort for providers in the private sector to begin to prescribe the medication) are not allowed to be distributed directly from the provider to the patient in VA.

Disclosure of any potential conflict of interest or financial relationship in the formulary decision-making process is also addressed in the *Principles of a Sound Formulary System,* which are endorsed by the VA PBM, which was a core participant in the Coalition that developed the recommendations. The Principles recognize that:

> *"The formulary system, when properly designed and implemented, can promote rational, clinically appropriate, safe, and cost-effective drug therapy. The Coalition has enumerated these principles, however, because it recognizes that patient care may be compromised if a formulary system is not optimally developed, organized and administered. This document contains "Guiding Principles" that the Coalition believes must be present for a drug formulary system to appropriately serve the patients it covers."*

By all measures, it is very unlikely that VA is spending more that it has to for drugs. VA has a long history of being a national leader in drug safety and evidence-based, cost-effective prescribing habits which underscore its independence from influence by the pharmaceutical industry.
Attachments:

[The attachments referenced below will be retained in the Committee files. Some attachments are accessible online at the Internet links listed.]

VHA HANDBOOK 1108.08*VHA Formulary Management Process,* February 26, 2009. Available at http://www1.va.gov/vhapublications/View Publication.asp?pub__ID=1834

VHA HANDBOOK 1004.07*Financial Relationships between VHA Health Care Professionals and Industry,* October 21, 2009. Available at http://www1.va.gov/vhapublications/ViewPublication.asp?pub__ID=2102

VHA DIRECTIVE 2003.060*Business Relationships between VHA Staff and Pharmaceutical Industry Representatives,* October 21, 2003.

Description and Analysis of the VA National Formulary. Institute of Medicine. January 1, 2000.

VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs. U.S. Government Accountability Office. January 29, 2001. Available at http://www.gao.gov/new.items/d01183.pdf

VA Drug Formulary: Drug Review Process Is Standardized at the National Level, but Actions Are Needed to Ensure Timely Adjudication of Nonformulary Drug Requests. U.S. Government Accountability Office. August 31, 2010. Available at http://www.gao.gov/new.items/d10776.pdf

Aspinall SL, Banthin, JS, Good, CB, Miller, GE, Cunningham FE. VA Pharmacy Users: How They Differ from Other Veterans. Am J Manag Care. 2009; 15(10) 701–708.

Sales MM, Cunningham FE, Glassman PA, Valentino MA, Good CB. Pharmacy Benefits Management in the Veterans Health Administration: 1995–2003. Am J Manag Care 2005;11:104–12.

Principles of a Sound Formulary Drug System. U.S. Pharmacopeia. October 2000. Available at http://www.usp.org/hqi/patientSafety/resources/sound FormularyPrinciples.html

V.A. is Limiting Use of Diabetes Drug, New York Times, October 18, 2007 available at http://www.nytimes.com/2007/10/18/business/18drug.html?__r=2&adxnnl=1&oref=slogin&adxnnlx=1192713524-bGMLReuAbDJNXwuo9QSfEw

FDA significantly restricts access to the diabetes drug Avandia, FDA News Release, September 23, 2010 available at http://www.fda.gov/newsevents/newsroom/pressannouncements/UCM226975.htm

Mr. MICHAUD. My last question involves concerns I have heard from veteran service organizations at the local level, on the time it takes to get an answer from the Central Office when trying to get VA to move quickly in a certain area.

Since we are centralizing everything, Mr. Downs, in your operation, how can you assure the Subcommittee that VA is going to do everything both accurately and in a timely manner as well? Are there any assurance you can give us that you will be moving forward quickly, but also ensuring accuracy?

Mr. DOWNS. Yes, sir. The key to the way we have centralized within VHA and the integrated model is that we have centralized direction but decentralized execution. So the acquisition people are in place at the medical center to do that day-to-day buying. The contracting officers are located within the VISN. They work there with teams with the facilities to purchase and to develop the contracts that are necessary for the purchases that are required to keep the medical center going.

The feedback mechanism, also we have what we call network contract managers at the VISN level, and they coordinate their activities with the nurse care managers (NCMs). They are respon-

sible for them. And one of the things that we have is the need to always make sure that we have a customer service relationship with the facility, the clinical folks and all the people that we deal with.

That has been an ongoing issue with the National Leadership Board. This week, I met with them and we went through that process. Two of the network directors are part of what we have called an Acquisition Committee. And so they give me feedback from the network director's point of view. I have three facility directors on there. They give me feedback.

I have also acquisition, my network contract manager, SAOs on that Committee along with the CLOs or chief logistics officers. So I have my field input coming in at all three levels. We have discussed with them policy because if we are going to have policy, they need to be able to carry it out. They need to be a part of it. And that ability to do that day-to-day purchasing is what is key.

Now, some of the veterans I know and reference, they worry about, you know, are we going to be able to provide service to them. Yes, indeed.

And the issue of rural health which has come in the conversations and the testimony has to do with can the veteran out in the rural area get the same kind of service. And, again, that is a balance because we want to serve that veteran there if it is a veteran who needs a prosthetic device. And the reason we want them to come down to the medical center for a review when they want a new one is to see if their health has changed or there has been some condition that needs to be addressed.

The VA has reached out and we try to also provide service in the area. We do that through fee basis or whatever necessary means that it takes to make sure that veterans are being served where they are. We do not want them to make those unnecessary trips down, but sometimes from a clinical aspect they need to be looked at by the medical team.

Other times we have the medical team that we will contract with in the local area. So it is a judgment call, sir, about how that is done. And we are trying to stay on top of all of those kind of issues because the veteran is the key person. And, again, it is judgment calls. It takes logic and common sense and certainly good communication between the patient and the VA as we try to work out a solution for them.

Mr. MICHAUD. Well, thank you very much.

I am awfully glad to hear that because, as I discussed with you the other day, that is a concern I have heard from veterans in really rural areas; having to drive 4 or 5 hours to go to the medical facility. And if they miss their appointment because of a snowstorm, then it is another month or so before they can get back for another appointment. That is a huge concern that I have heard from veterans who live in rural areas.

Mr. DOWNS. And I brought that up to the network directors at the National Leadership Board and they all agree with what I told you is that that was a mistake. When those things happen, that is a mistake because when a vet comes down like that and for some reason the doctor cannot be there or whatever happens and what

they try to do is we put the patient up for a day or a night in the hotel and arrange to get it redone the next day.

So we have a policy in place at the facility to make sure that the vet is taken care of. But there are times when things like that do happen. But all the network directors assured me that, oh, no, they have policies in place out there at the facility level to make sure that those long kinds of trips do not happen. And they do happen, but we try to make sure it does not happen very many times anyway.

Mr. MICHAUD. Well, thank you very much, Mr. Downs. I appreciate your testimony this morning and Dr. Buck's as well.

I know there will be some more questions that we will be submitting to you in writing and hopefully we can get responses as quickly as possible.

Mr. Boozman.

If there are no other questions, I want to thank all three panels for your testimony this morning. It has been very helpful and I look forward to working with you as we try to sort out some of the issues dealing with contracting and procurement.

So if there are no other questions, I declare the hearing adjourned.

[Whereupon, at 11:58 a.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Hon. Michael H. Michaud, Chairman, Subcommittee on Health

The Subcommittee on Health will now come to order. I would like to thank everyone for attending this hearing.

The purpose of today's hearing is to investigate potential weaknesses in VHA's contracting and procurement practices and explore ways that we can strengthen how VHA contracts and procures medical equipments and health care products for our veterans.

In recent years, we have seen many reports and studies on VA's contracting and procurement activities. These reports have identified the need for increased transparency and fiscal responsibility, as well as highlighted problems of inadequate competition and lack of accountability and oversight.

As a result of these deficiencies in VHA's contracting and procurement practices, veterans may not be getting the latest innovations in health care products. This was made evident at our June Health Subcommittee hearing on wireless health technologies and the difficulties that many private companies faced in informing VA about their products and getting their products in the hands of our veterans.

Furthermore, we are all aware of the problem of dirty reusable medical equipments at certain VA medical centers. Today, we will hear from GAO about a study that they are conducting on the purchasing and tracking of supplies and medical equipment. Their preliminary observations include the potential risks to veterans' safety when there is noncompliance with VA purchasing and tracking requirements.

Finally, internal control weaknesses with VHA's use of billions in miscellaneous obligations continues to be problem. Because VA contracting officials don't have sufficient controls over the authorization and use of miscellaneous obligations, it is unclear whether these obligations were for legitimate needs.

As we can see, the implications of contracting and procurement deficiencies go beyond the fiscal component to have a potentially negative impact on the health care that our veterans receive.

I look forward to hearing from today's witnesses, as we aim to better understand the challenges facing VHA contracting and procurement practices and work together to find potential solutions to these challenges.

Prepared Statement of Hon. Henry E. Brown, Jr., Ranking Republican Member, Subcommittee on Health

Thank you, Mr. Chairman, and good morning.

I'm pleased to be here today to discuss contracting and procurement issues within the Veterans Health Administration (VHA).

VA's troubled contracting and procurement processes have long been an issue of great concern to this Committee and the subject of various Government Accountability Office (GAO) and VA Office of Inspector General (OIG) reports that continue to cite major deficiencies and material weaknesses.

Given the wide scope of VHA's reach and budget, it is particularly important that we ensure that they have the proper procedures and oversight mechanisms in place to ensure that VHA procurement and contracting is done responsibly, appropriately, and with proper oversight.

In that vein, I am particularly concerned about testimony we will hear by the Office of Inspector General that ". . . data in VA and VHA acquisition support information systems is incomplete and unreliable."

Without accurate data, we have no idea what we're doing right, what we're doing wrong, where we are, where we're going, and where we need help.

This is unacceptable within a system that is responsible for the care of our Nation's veterans and spent a little over nine billion dollars on health care goods and services last fiscal year alone.

Streamlining contracting and procurement processes to eliminate the potential for waste, fraud, and abuse while at the same time improving the cost and comfort of doing business with VA to ensure our veteran heroes have access to the highest quality medical care is and should be at the top of our priority list.

I look forward to hearing from the witnesses on our first panel about the obstacles to doing business with VHA and from the government witnesses on our second and third panels about the functioning of VHA's acquisition system.

Although we are nearing the end of this legislative session, I am hopeful that we will be able to move legislation, H.R. 4221, the Department of Veterans Affairs Acquisition Improvement Act of 2009, introduced by our Ranking Member, Steve Buyer. This bill that I am an original cosponsor of would correct the long-term procurement issues within VA and provide greater oversight of VA's contracting and asset management processes.

I thank you all for being here for this discussion and I yield back the balance of my time.

Prepared Statement of Hon. Russ Carnahan, a Representative in Congress from the State of Missouri

Mr. Chairman, thank you for holding this important hearing on VA Health Administration Contracting and Procurement Practices. I appreciate the attention that is being given to this topic and hope that today's hearing provides insight into contracting and procurement practices that are working and suggestions on how to improve those that are ineffective.

In July, the House Committee on Veterans Affairs held a much needed field hearing in St. Louis, to address safety lapses at the John Cochran VA Medical Center, after 1812 veterans throughout the St. Louis and Illinois area received notification that they could have been exposed to blood borne pathogens such as Hepatitis B, Hepatitis C, and HIV while receiving dental care at the medical center. Since the hearing, I have been encouraged to hear that the Veterans Health Administration has implemented some new and more stringent oversight measures for reusable medical equipment and expendable medical supplies (like those used in dental clinics and endoscopy clinics).

However, it is painfully clear that much more work is needed.

It is critical that the VA identify and rectify any existing problems in regards to the purchasing and tracking of reusable medical equipment and expendable medical supplies. Yes, contracting and procurement are just small pieces of a much larger issue. But the VA must make considerable improvements to **all** policies and procedures at **every step of the process**, to make sure that incidents like the one at John Cochran Medical Center never happen again, and take whatever steps needed to ensure that our veterans are receiving the best health care.

To all the witnesses today—thank you for taking time out of your busy schedules to appear before us. I look forward to hearing your testimony.

Prepared Statement of Mark T. Munroe, Senior Vice President, Sales and Marketing, Mobile Medical International Corporation, St. Johnsbury, VT

On behalf of Mobile Medical International Corporation, of St. Johnsbury, Vermont, I want to thank Chairman Filner, Chairman Michaud and the rest of the Members of the Subcommittee for allowing me to testify here today. My name is Mark Munroe, Senior Vice President of Sales and Marketing for Mobile Medical. Mobile Medical is an international company that develops and manufactures commercial and military mobile surgical hospitals which meet all U.S. health care standards. These mobile health care solutions are rapidly deployable, fully integrated, self-contained and present innovative solutions for today's health care delivery needs. My purpose here today is to explain how Mobile Medical has worked with VA medical centers throughout the country, while describing some of the challenges associated with those experiences and pointing out some of our exciting success stories.

Let's begin with the New Orleans VA medical center. As you are aware, Hurricane Katrina struck New Orleans 5 years ago. Since Katrina, the New Orleans VA

Medical Center has not provided surgical or endoscopic services to the veterans of New Orleans. Veterans in the New Orleans region must seek out care at other facilities within the system. This often causes veterans to wait for needed procedures, or travel greater distances to receive the care they need. In January 2009, Mobile Medical moved to mitigate this disruption of services by responding to a request from the New Orleans VA Medical Center leadership for a proposal involving mobile surgery units. These units were to be used to meet a variety of needs and to serve as a temporary surgical facility during the hospital re-building process.

The New Orleans VA issued a solicitation on FedBizOps in May 2009 for mobile surgery units. This solicitation was subsequently cancelled and re-directed to the GSA schedule. It should be noted that while Mobile Medical was in the process of contracting with GSA, code compliant mobile surgery units did not exist on the GSA schedule. As a result of this action, companies with GSA contracts responded, but none of them, including the one to whom the GSA solicitation was ultimately awarded, met the VA criteria for a history of producing and deploying regulatory compliant Mobile Surgery Units. In addition, Mobile Medical learned that its proprietary company confidential information, provided as part of its January proposal, had been released to over 70 GSA schedule holders. Quoting from the attached summary of Mobile Medical's Federal legal action, "Judge Horn clearly found that the VA's actions were improper and the attempted modification was beyond the scope of the GSA schedule program. An agency placing an order under the GSA schedule program may not simply send out an RFQ as a "solicitation feeler," evaluate quotes for items that do not exist on anyone's GSA schedule contract, and then hope a selected contractor can convince the GSA a modification is within scope of their existing contract by the time the agency places an order. Such an end-run, which occurred in the case, violates even the most basic requirements of fair and open competition for Federal contracts."

As a small business working in a hub zone during difficult economic times, the last thing our company ever expected would be the need to sue the U.S. Government for actions taken during a procurement process. It should be noted that the legal costs alone with this process have run in excess of $300,000 dollars. Clearly oversight is necessary to ensure that other small businesses like Mobile Medical do not encounter this type of situation.

Standing in stark contrast to Mobile Medical's experience in New Orleans is our very positive experience serving the needs of veterans at the VA Medical Center in Muskogee, Oklahoma. At the Muskogee VA, Mobile Medical is providing two mobile surgery units in support of a full operating suite renovation project. The leadership at the Muskogee VA Medical Center, from the Director to the contracting officer, facilities engineering and surgical team, should be commended for their work on this model project. In this forum I am pleased to do that today. During a recent customer visit, a member of Mobile Medical's Board of Directors, retired Air Force Surgeon General, Paul K. Carlton, learned from VA officials that this facility is saving over $9 million dollars in construction costs by closing all of their operating rooms for the duration of the renovation period rather than phasing in the renovation. Quoting Dr. Carlton in his report to Mobile Medical, "the renovation project began in 2008 with strong leadership. After researching alternative options, the Medical Center closed five operating rooms and the project began using two Mobile Surgery Units. By doing this they are shaving $9.3 million dollars off the original construction quote for the project, even after spending $3.6 million to lease the mobile surgical units." The medical center is also avoiding another $14 million dollars that would have gone to local hospitals to carry the center's surgical caseload during the renovation for a total savings of $23.3 million dollars." Included in your packet is a copy of Dr. Carlton's full report to Mobile Medical. General Carlton's findings at the VA medical center in Muskogee support Mobile Medical's previous testimony to this Committee that a project utilizing 5 mobile units to support OR renovations projects around the country over a 3-year period would save the VA $90 million dollars. Those savings are in the attached executive summary and we urge Members to note that the Senate Military Construction/Veterans Affairs Subcommittee has included language in its report to the Senate (Report Number 111–226) urging the VA to utilize qualified mobile surgical units in OR renovation projects where such utilization clearly offers savings. I have attached the report language to my testimony. Mobile Medical has continually pointed out the significant cost avoidance that the VA can achieve nationally by applying the methods described above in many VA OR renovation projects. The Senate Mil/Con Appropriations Committee has responded with its recommendation to the VA. We restate again today our belief that 20 mobile surgical units could save over $1.5 billion dollars in 5 years of OR renovation scenarios.

A final example of a successful project is the VA medical center in Miami, Florida. Miami is currently utilizing six Mobile Units during a full operating room renovation project. While the Miami project was also challenged through the contracting process, again strong leadership was the key. Dr. Seth Spector, Chief of Surgery, has kept the project moving forward and in August of this year Miami was able to turn their operating rooms over to the Army Corp of Engineers for renovation, while continuing to provide full surgical services to the veteran's of the Miami service area.

While 5 minutes is a short time to share with you all of the successes and weaknesses in the VA contracting process, I am sure you will find our supporting documentation compelling. I look forward to any questions you may have and thank you for your time this morning.

Summary Federal Claims Court File No. 10–148C

On August 31, 2010, the Court of Federal Claims issued an Order acknowledging the Department of Veterans Affairs ("VA") misused the General Services Administration's ("GSA") Federal Supply Schedule ("FSS" or "GSA Schedule")[1] by attempting to purchase sophisticated mobile surgery units off of the GSA Schedule through an improper, out-of-scope modification to an existing GSA Schedule Contract that does not offer mobile surgery units. While the Court dismissed the case on other, unrelated grounds, the Court acknowledged Mobile Medical International Corporation ("MMIC") was correct in asserting the modifications were beyond the scope of the GSA Schedule Contractor's existing products. Therefore, the VA clearly acted improperly for attempting to use the GSA Schedule program to buy a sophisticated product (mobile surgery units) that were not otherwise on the GSA schedule.

The case, *Mobile Medical International Corporation* v. *United States,*[2] arose of out sole source negotiations between MMIC and the New Orleans Veterans Affairs Medical Clinic in New Orleans, Louisiana. Hurricane Katrina devastated the New Orleans Clinic, seriously impacting the VA's ability to offer crucial surgical procedures to New Orleans area veterans. As an industry leader and prior sole source provider to the VA, the VA naturally reached out to MMIC to help develop and meet the VA's needs regarding temporary surgical solutions.

However, these fair and open negotiations were derailed when personnel within the VA decided that MMIC's product—sophisticated, fully integrated mobile surgical suites that meet all JCAHO and Medicare standards of care for performing invasive surgery—could be purchased not from MMIC and not through an open competition of contractors who purport to compete with MMIC, but instead through the GSA Schedule program.

As discussed in Footnote 1, generally a "GSA buy" is only appropriate for "commercial" items or services, like a flatbed truck or a box of pencils. Mobile surgical trailers, on the other hand, are niche items and are not currently offered through the GSA Schedule program. To purchase a sophisticated, niche product like mobile surgery units, the VA should have engaged in open competition to obtain a fair and realistic price and to ensure fair access to the award.

But instead of fair, open competition for these mobile surgical trailers (pursuant to FAR 15), the VA attempted to avoid FAR 15's competition requirements and instead sought to modify existing products already offered by a GSA Schedule Contractor. Ultimately, the VA sought to convert a basic expandable truck, commonly used for sports broadcasting, into the same code compliant operating room offered by MMIC. The Contracting Officer contended, in response to MMIC's protest, "that the new trailers merely 'modified the already available [expanding trailer] with in scope customizations the [VA] required.'"

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[1] FSS schedules are most commonly referred to as "GSA Schedules" or Multiple Award Schedules ("MAS"). To avoid confusion, the memorandum will refer to the FSS program as the "GSA Schedule Program." Under the GSA Schedule program, Government customers have access to over 11 million commercial supplies and services at volume pricing. The items must be "commercially available" to qualify. Because these items are pre-qualified, commercial items, the GSA has pre-determined these items satisfy all FAR competition and price requirements.

Items may be reviewed through the GSA Schedule List, which contain a list of all GSA Schedules. Government contractors in turn enter into "schedule contracts" with the GSA in order to offer products through the GSA Schedule Program. This memorandum will refer to these contract holders as "GSA Schedule Contractors."

For more information, please visit: http://www.gsa.gov/portal/content/104447.

[2] No. 10–148C, Court of Federal Claims, August 31, 2010.

But the Court determined, even "[t]aking a liberal view of the trailers offered by [the GSA Schedule Contractor] on its modified GSA schedule contract, it would appear that the modified trailers differ significantly from the original expanding trailer and lab trailer on [their] original GSA schedule contract." "In sum," the Court concluded, "[the GSA Schedule Contractor] was offering non-FSS items in response to the FSS RFQ, although its FSS modifications were later approved. The modifications to [its] GSA schedule contract departed so far from the original schedule as to render the modified [expandable trailers], certainly with respect to the surgical and endoscopy trailers, outside the scope of its FSS contract as reasonably interpreted."

Although Judge Horn dismissed the action on other, technical grounds related to Federal jurisdiction and standing, Judge Horn clearly found that the VA's actions were improper and the attempted modification was beyond the scope of the GSA schedule program. An agency placing an order under the GSA schedule program may not simply send out an RFQ as a "solicitation feeler," evaluate quotes for items that do not exist on anyone's GSA schedule contract, and then hope a selected contractor can convince the GSA a modification is within scope of their existing contract by the time the agency places an order. Such an end-run, which occurred in the instant case, violates even the most basic requirements of fair and open competition for Federal contracts.

Texas A&M
Health Science Center
Office of Homeland Security
College Station, TX.
September 15, 2010

Mr. Rick Cochran
President and Chief Executive Officer
Mobile Medical International Corporation
2176 Portland Street, Suite 4
St. Johnsbury, VT 05819

Subject: Muskogee VA Medical Center Findings

Mr. Cochran:

Thank you for the opportunity to represent MMIC as a member of the Board of Directors at my recent site visit to the Muskogee VA Medical Center. My findings, which clearly offer a substantial savings to the Medical Center and importantly, no loss of **services for our Veterans, are as follows:**

1. The renovation project began in 2008 with strong leadership and after researching alternative options, the Medical Center closed five operating rooms and the project began using two Mobile Surgery Units™ away from the old operating suites, but still attached to the facility.
2. The overall project timeline for completion of the renovation is 1 year, and is on track.
3. By using two Mobile Surgery Units™ the Muskogee VA Medical Center stated they are saving four times the amount of a more costly phased in renovation. The phased method would have included splitting the project to keep one half of the operating rooms open at a time; therefore, significantly increasing, by four times the current amount, what the total project cost would have been.
4. By keeping surgical procedures in house, this is allowing utilization of the OR staff members; rather than potential for loss of the staff during the renovation.
5. Hard cost savings:
   a. OR renovation would have cost $17.2M using a split method. It cost $4.3M to do all at once=a hard cost savings of $12.9M. Then subtract the $3.6M to rent the units from the savings of $12.9M=$9.3M total cost savings, not **avoidance, savings**!
   b. Lower infection rates by at least a factor of two or three. Documented during actual split operation renovation projects. Each wound infection is estimated to cost $20,000, so the expected 1.5 percent wound infection rate would have yielded 1200 cases x 1.5 percent=18 cases during normal operations. If the infection rate doubled, we would have seen 36 wound infections, plus a tremendous amount of misery for the patient. This method avoided that extra 18 wound infections, saving 18 x $20,000=$360K.

c. Total cost savings then total $9.3M plus $360K=$9.66M.

6. In addition there are other positives to consider: IF the OR's were closed and cases sent downtown, THEN:
   a. At 600 cases per room per year, each case costing $12,000 to send downtown, that means each room was worth at least $7.2M. The total cost of renting the units was $3.6M. So the cost avoidance would be 2 × $7.2=$14.4, minus the cost of leasing the units at $3.6 meant a cost avoidance of at least $10.8M! The VA, when they saw these numbers, said the real cost would be some multiple of $12,000—probably at least 3 times as much. That meant a cost avoidance of at least 3 × $14.4 = $43.2M minus the cost of the units at $3.6M = $39.6M by using the two Mobile Surgery Units™!
   b. The medical centers would have had to close without the ability to do emergency surgical cases.
   c. The OR staff could have been lost entirely, no work. The VA could have had trouble finding staff again.
   d. The VA could not have fulfilled its readiness mission.

In conclusion, hard cost savings of $9.66M plus additional cost avoidance of up to $39.6M, plus the other positives make this a very wise decision for the VA system! This method should be evaluated for use throughout the entire VA system.

Sincerely,

Paul K. Carlton, Jr., MD, FACS
LtGen, USAF, MC, retired
Director, Office of Innovations and Preparedness

CALENDAR NO. 469
111TH CONGRESS 2D SESSION
SENATE REPORT 111–226

MILITARY CONSTRUCTION AND VETERANS AFFAIRS, AND RELATED AGENCIES APPROPRIATION BILL, 2011

JULY 19, 2010.—Ordered to be printed

MR. JOHNSON, from the Committee on Appropriations, submitted the following

REPORT

[TO ACCOMPANY S. 3615]

The Committee on Appropriations reports the bill (S. 3615) making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2011, and for other purposes, reports favorably thereon and recommends that the bill do pass.

Amounts in new budget authority

Total of fiscal year 2011 bill as reported to the Senate	$143,530,131,000
Total of fiscal year 2012 advance appropriations included in this bill	50,610,985,000
Amount of 2010 appropriations	182,750,300,000
Amount of 2011 budget estimate	143,531,666,000
Bill as recommended to Senate compared to—	
Amount of 2010 appropriations	−39,220,169,000
Amount of 2011 budget estimate	−1,535,000

57-470PDF

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Cost Saving Initiative.—Over the past decade, the Department has undertaken an effort to modernize its medical facilities through new construction and renovation. This recapitalization effort is imperative to the delivery of high quality medical care. Often when a new surgical ward or other treatment facility undergoes construction, the VA has to find alternative areas for treatment or contract care to non-VA medical providers. The Committee believes that the VA could achieve cost savings during renovation or construction by either leasing or purchasing mobile units. The Committee encourages the Department to launch a pilot project in at least two VISNs that have renovation or construction projects underway, to lease or purchase mobile surgical units through a full and open competition while construction is underway. Additionally, the VA should develop metrics for a cost benefit analysis to determine whether this approach has achieved savings versus contracting care through local medical providers.

MMIC / Mobile Medical INTERNATIONAL CORPORATION

MOBILE SURGERY UNIT™
OR
MOBILE ENDOSCOPY UNIT™

MMIC PROPOSAL TO VA CENTRAL OFFICE
(reflecting the use of 20 Units within the VA System)

Cost of sending patients to another hospital

Cost to VA per procedure =	$ 12,000
Number of procedures per OR per year = 583	
Number of ORs = 20	
Total Cost Avoidance per year =	$139,920,000/yr
Project Period = 5 Years	
Total Cost Avoidance =	***$699,600,000***

Costs

Lease 20 Units @ $75,000/mo for 5 Years	$90,000,000
Sale of 20 Units @ $2,500,000 Each	$50,000,000

Potential VA Savings Through Leasing =	***$609,600,000***
Potential VA Savings Through Sale =	***$649,600,000***

MMIC EXPERIENCE

- **University of Virginia Medical Center**
- **San Ramon Regional Medical Center** *(Tenet Healthcare System)*
- **Santa Rosa Regional Medical Center** *(Kaiser Permanente)*
- **Washington Hospital**
- **Muskogee, OK VA Medical Center**
- **Shriners Hospitals for Children**
- **Mount Edgecumbe Medical Center**
- **White River Jct., VT VAMC**
- **John Muir Medical Center**
- **Miami, FL VAMC**
- **Martinsburg, WV VAMC**
- **Muskogee, OK VAMC**

Mobile Surgery Unit™ (MSU)
Model MSU-01

The Mobile Surgery Unit™ is a fully integrated, U.S. healthcare compliant (CMS certifiable / Joint Commission accreditable) mobile ambulatory surgery center providing a large medical suite that provides 1000ft² (92.90 m²) of usable space including an entry, pre- and post-operative area, nurses' station, scrub station, operating room, soiled utility room, and clean utility room.

The MSU contains the following:

- Dual hydraulically expanding sides with leveling system
- Integrated Heating, Ventilating and Air Conditioning (HVAC) System with 99.99% HEPA filtration providing up to 25 air exchanges per hour in the operating room
- Integrated power system with redundant emergency back-up systems, i.e. Generator, Uninterruptible Power Source, 12-Volt Battery Back-up
- Integrated surgery center infrastructure, i.e. medical gas, vacuum, telecommunications, nurse call, scrub sink, system monitoring, synchronized time, operating room light, X-ray illuminator, instrument sterilization, plumbing, and modular cabinetry

DESIGN FEATURES

Integrated Expandable 53' Trailer
The expandable trailer is designed in accordance with American Institute of Architects (AIA) guidelines for healthcare facilities, National Electrical Codes (NEC), International Plumbing Codes (IPC), National Fire Protection Association (NFPA) standards for Life Safety.

Heating, Ventilating and Air Conditioning (HVAC)
Heating and cooling and heating with air distribution plenums and High Efficiency Particulate Air (HEPA) filtration.

Emergency Power System
Integrated emergency back up power system with Uninterruptible Power Source for critical medical equipment and lighting operation.

Medical Suite Configuration
Fully integrated medical suite meeting U.S. healthcare codes for air quality and exchanges and medical gas delivery. Five (5) Patient Care Stations for delivery of medical gas and vacuum with emergency power outlets.

Modular Storage Cabinetry
Rail-mounted modular cabinetry and roll around carts for medical supplies storage.

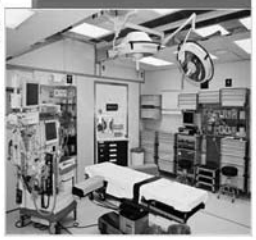
20100208PC01Rev0
Approved for General Release

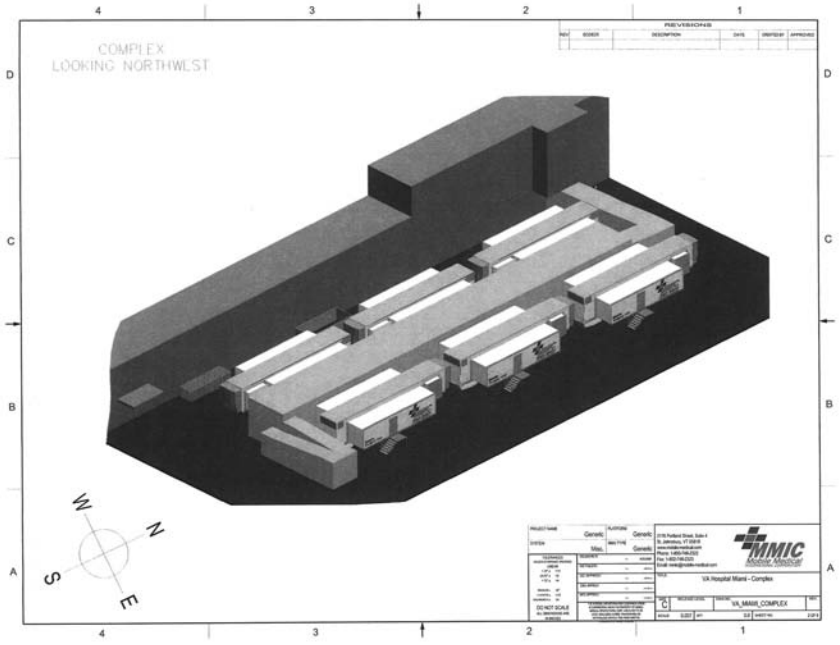
MMIC Mobile Medical International Corporation

Configured in a 53 Ft. (16.15m) hydraulically expandable trailer, the MSU provides State Licensable, CMS / Medicare Certifiable, Joint Commission (JCAHO) Accreditable ambulatory surgical services where you need them.

Ideal for :

- Hospital Renovation
- OR Over-Capacity
- Rural Outreach
- Physician Groups

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Mobile Medical International Corporation

World-class mobile medical facilities for commercial, military, international and emergency response applications

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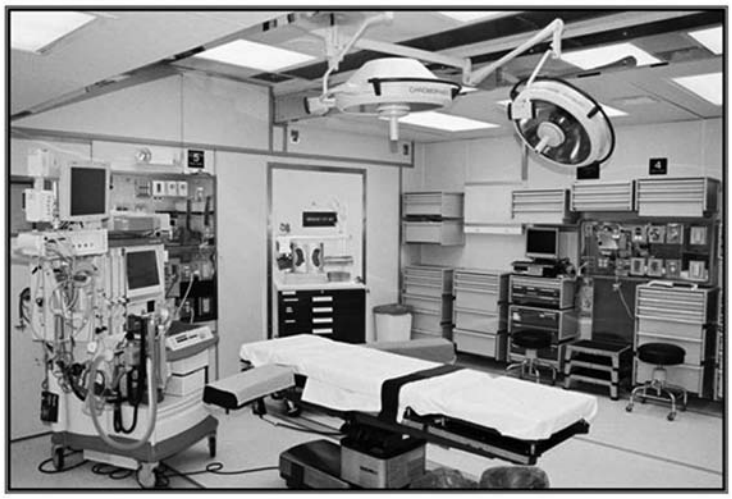
Mobile Surgery Unit™

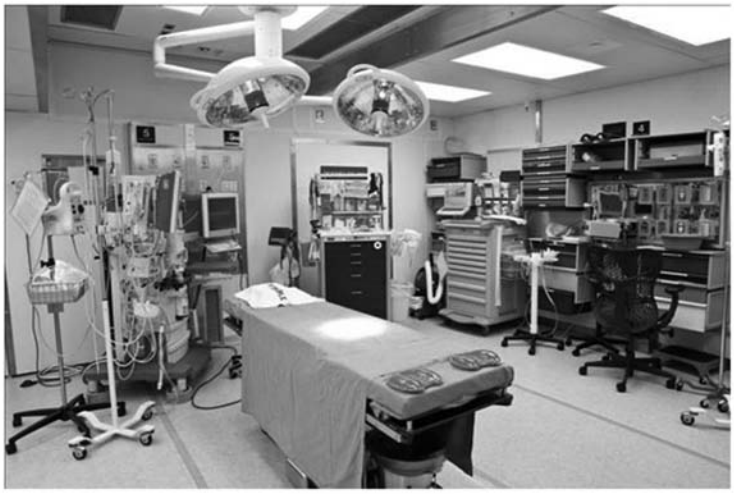
MSU Surgical Suite



Miami, FL VAMC

Muskogee, OK VAMC

Muskogee, OK VAMC



Prepared Statement of Derek Newell, MPA., MPH, President, Robert Borsch Healthcare, Palo Alto, CA

Mr. Chairman and other Members of the Committee: Thank you for giving me the opportunity to provide testimony to the Committee. My name is Derek Newell and I am President of Robert Bosch Health care. Bosch, which makes the Health Buddy and T–400 remote monitoring devices, has been providing remote patient monitoring in the Veterans Health Administration (VA) since 2003 and is the largest provider of in-home monitoring services to the VA. Bosch serves over 30,000 veteran patients and accounts for approximately 70 percent of the remote monitoring devices used by the veteran population.

The population we serve suffers from chronic illnesses like congestive heart failure, diabetes and lung disease, and most have more than one condition. The Health Buddy and the T–400 Systems collect patient symptoms and vital signs, such as blood pressure or blood sugar levels, and provide education and self-support tools through a series of questions answered by patients. The responses are prioritized by risk and transmitted to care managers within the VA. This risk stratified output then enables care managers to quickly determine what kind of intervention is necessary for each patient, preventing escalation of symptoms.

These technologies have demonstrated positive results in improving the health care of our Nation's veterans' population and in reducing costs, for example, 25 percent reduction in inpatient days and 19 percent reduction in hospital admissions. The VA has been visionary in building upon the successes of this rapidly emerging segment of the health care delivery system.

Regarding improvements in the procurement process, first, we applaud the transition of procurement and purchasing of home monitoring devices to the Denver Acquisitions Center, which will integrate and mainstream procurement practices for home monitoring technologies, including the Health Buddy, and T–400. The purchasing was previously done through the prosthetics department, which is excellent at purchasing physical objects, but is not accustomed to purchasing devices that also have content, applications and services integrated with them. Our devices are required to be connected to our data centers and to be available to upload data from the veteran and download content and programs for the veteran. Moving the procurement to the Denver Acquisitions Center allows separate payment for materials,

applications, content and services, which will be increasingly important as these elements become increasingly intertwined with physical devices.

While we compliment the VA's innovation to date, we believe there are a number of ways that Congress could assist the agency in improving the contract and procurement process to expedite greater use of home-based remote health care and other innovative technologies.

Based on our experience, I suggest the following enhancements that would improve contract and procurement processes in the VA.

- **Preferred Partners:** The cost of some of the systems and technologies, as well as the cost of continual innovation, require vendors to have some reasonable sense that they will have a successful relationship with the VA. Currently, remote monitoring vendors need to commit to installing hardware in a data center within the VA as well as within a backup data center within the VA. After this they are free to sell their technologies to the related VISN's, but there is no guarantee on how many units the VA will buy or how many units any vendor would sell. Rather than have a broad spectrum of vendors (the current proposal is 6), we recommend a more limited number of vendors with a larger commitment to and from each vendor (maximum 3 vendors). This would meet the VA goals of ensuring adequate competition within the VA and avoiding major supply disruptions if one vendor has financial or production problems, but it would also ensure a viable market for each vendor within the VA.

Targeted Innovation: Recently the VA has started communicating to partners about its vision of veterans' health needs and priorities, however this could still be improved. Better communication and funding targeted innovation with preferred partners would enable us to respond in a more timely manner to the needs of the VA and to be partners in finding solutions. At present, a majority of our information comes only when a solicitation is released. Only then do we have a concrete knowledge of the VA's national perspective and the goals and priorities. The short turnaround cycles for proposal submissions do not allow for the innovation that would be possible with longer planning cycles. The recent Innovation grants proposed and funded by the VA are a step in the right direction.

- **Introduce continuity into the FSS contracting process** by appointing a single point of contact for partners. Currently we interact with a variety of FSS contract staff, which creates a constant learning curve for them. We encourage a move back to FSS's former process of a consistent point of contact, which would streamline information flow and trim down bottlenecks.
- **Greater sharing of information** between VHA and other Federal health care agencies could expedite telehealth adoption rates by the VA and those agencies. We believe poor information-sharing hampers agencies' ability to make mid-course program corrections and, by keeping information "under wraps," effectively limits adoption of emerging and known best practices.

Mr. Chairman and Members of the Committee, we believe these few but concrete and specific actions would go a great distance to support the VA's efforts to expand the use of telehealth technologies. In this regard, we admire the VA's efforts to date and hope that our years of experience in interacting with the agency as a private vendor will be of use to the Committee.

I appreciate this opportunity to testify and would be happy to answer any questions you might have.

Prepared Statement of Lincoln Moss, Senior Vice President and Chief Operating Officer, Ramtech Building Systems, Inc., Mansfield, TX, on behalf of Modular Building Institute

Chairman Michaud, Ranking Member Stearns and Members of the Committee, I am Linc Moss, Senior Vice President and Chief Operating Officer of Ramtech Building Systems, Inc. a vertically integrated design-build commercial modular construction firm based in Mansfield, Texas. I am testifying today on behalf of MBI—the Modular Building Institute—a not-for-profit trade association established in 1983 that serves to represent companies involved in the manufacturing and distribution of commercial factory-built structures.

MBI appreciates the opportunity to speak to the Committee on ways to improve contracting with the Department of Veterans' Affairs (VA). Throughout the construction industry there has been concern with the VA as to the solicitation of construction projects that call for a delivery system referred to as "Design-Bid-Build."

This traditional project delivery method is often more costly and less efficient than other delivery methods and its restrictive nature prohibits alternate forms of construction such as permanent modular, tilt-wall and pre-engineered steel construction from being able to participate in the bidding process. Within the last few months there have been two separate RFP's issued by the VA that Ramtech was interested in bidding on. However, because the RFP was issued using a Design-Bid-Build approach, Ramtech and other alternative forms of construction firms were unable to participate.

As is explained in greater detail throughout this testimony, the Department of Veterans' Affairs could greatly improve the way it solicits construction projects if it utilized an alternate project delivery system known as "Design-Build." Over the past decade, the use of Design-Build has greatly increased in the United States, making it one of the most significant changes in the construction industry. The Design-Build method, which has been embraced by several government agencies, including the United States Army Corps of Engineers (USACE), streamlines project delivery through a single contract between the government agency and the contractor. This simple but fundamental difference not only saves money and time, improves communication between stakeholders, and delivers a project more consistent with the agency's needs, it also allows for all sectors of the construction industry to participate.

The Increased Use of a Design-Build Delivery System—How would it benefit the Department of Veterans' Affairs?

The Design-Build project delivery system offers the VA a variety of advantages that other construction delivery systems cannot. Typically, under the Design-Build approach, an agency will contract with one entity to both design and construct the project. This is in contrast with Design-Bid-Build, where an agency has to contract with multiple entities for various design and construction scopes during the construction project.

By greater utilization of the Design-Build delivery system, the Department of Veterans Affairs can achieve these goals:

- **Faster Delivery**—collaborative project management means work is completed faster with fewer problems;
- **Cost Savings**—an integrated team is geared toward efficiency and innovation. Furthermore, with Design Build, construction costs are often known far earlier than in other delivery methods. Because one entity is typically responsible for the entire project, they are able to predict costs more accurately than when a Design-Bid-Build system is utilized. The contracting for Design-Build services allows the agency several decision points during design. The decision to proceed with the project is made before substantial design expenditure and with knowledge of final project costs;
- **Quality**—Design-Builders meet performance needs, not minimum design requirements, often developing innovations to deliver a better project than initially foreseen;
- **Single Entity Responsibility**—one entity is held accountable for cost, schedule and performance. With both design and construction in the hands of a single entity, there is a single point of responsibility for quality, cost, and schedule adherence. The firm is motivated to deliver a successful project by fulfilling multiple objectives, such as with the budget and schedule for completion. With Design-Build, the owner is able to focus on timely decision-making, rather than on coordination between designer and builder;
- **Reduction in Administrative Burden**—owners can focus on the project rather than managing separate contracts;
- **Reduced Risk**—the Design-Build team assumes additional risk. Performance aspects of cost, schedule and quality are clearly defined and responsibilities balanced. Change orders due to errors are virtually eliminated, because the design-builder had responsibility for developing drawings and specifications as well as constructing a fully-functioning facility.

Just to underscore the benefits of a Design-Build project delivery system, the Construction Industry Institute, in collaboration with Pennsylvania State University performed a study examining the various construction methods and found that:

- ***Unit Cost:*** Design-Build was typically 6 percent less costly than a Design-Bid-Build system;
- ***Delivery Speed:*** Design-Build was 33 percent faster than Design-Bid-Build;
- ***Quality:*** Design-Build met and exceeded quality expectations at all levels

Unfortunately, the Department of Veterans' Affairs has been unwilling to embrace the Design-Build construction method as much as other Federal Agencies. According

to VA personnel, only 30 percent of VA solicitations call for a Design-Build delivery system, while the rest rely on a Design-Bid-Build delivery method.

As our Nation prepares for an influx of returning warriors, it is imperative that we are able to provide them with the services that will help them assimilate into civilian life. Medical clinics, dental facilities, physical rehabilitation facilities, mental health treatment facilities as well as interim veteran housing will need to be provided in an efficient and cost effective manner. By adopting the Design-Build approach, the VA could provide these facilities in a compressed time frame while ensuring that the product delivered is top quality.

A Design-Build System Opens Opportunities for Alternative Design Offerings

By utilizing a Design-Build philosophy, the Department of Veterans Affairs could allow for sectors of the construction industry, such as modular construction, tilt-wall and pre-engineered steel to offer products as well as project means and methods that are currently not exercised due to the restrictive nature of Design-Bid-Build project delivery methods.

Numerous permanent modular contractors such as Ramtech have performed services for the VA facilities but because of the limited amount of Design-Build solicitations, the opportunities are severely limited.

Recently, the National Institute of Standards and Technology (NIST) released a report identifying modular construction as an underutilized resource and a breakthrough for the U.S. construction industry to advance its competitiveness and efficiency. One of the findings in the NIST report was ***"Greater use of prefabrication, preassembly, modularization, and off-site fabrication techniques and processes."***

For those of us who specialize in alternative construction such as permanent modular, this report simply validated what has been known for a long time: Construction methods such as permanent modular leads to improved efficiency and productivity.

By greater utilizing the Design-Build delivery system into the Department of Veterans' Affairs construction policies, the VA could greatly increase the amount of projects that contractors utilizing alternative forms of construction could participate in and therefore experience the benefits as outlined in the NIST report.

Let me emphasize that alternative construction methods such as permanent modular are not always the solution. There is no one perfect building system for every application. However, by expanding opportunities for them to be part of the process the Federal Government can be assured that it gets the 'best value' by seeing all the options before awarding a contract.

The Design-Build Delivery System Enhances Service-Disabled, Veteran-Owned Small Business Participation

Because the Design-Build method typically relies on a single source for both the design and construction of the project, Design-Build contractors often partner with architectural/engineering firms to assist in the design of the project. This fact facilitates partnering between Service Disabled, Veteran-Owned Small Business with construction firms such as Ramtech that perform the work.

Because of this direct working relationship between the SDVOB and the Design-Build contractor, the project is consolidated eliminating unnecessary levels within the project structure. Because the Design-Build method encourages these relationships, businesses such as those that comprise the membership of MBI have forged excellent partnerships with SDVOB's to perform on projects for various government agencies.

In the permanent modular construction field, a relationship with a contractor such as Ramtech means that a SDVOB partner will get approximately 60–70 percent of the building delivered and installed by Ramtech while a SDVOB partner performs the site work, utility connections, foundation and roof. SDVOB's often do not have the logistical capability to site- build an entire building, but they have the ability to perform other critical functions that comprise 30–40 percent of the project.

Undoubtedly, one of the top goals of the VA is to ensure that there are increased contracting opportunities for SDVOB's with the VA. To that end, MBI feels that simple changes could greatly increase SDVOB participation in construction projects.

One way to expand the involvement of Service Disabled, Veteran Owned Businesses is by encouraging and expanding the use of the Design-Build approach.

Conclusion

Contractors that rely on a Design-Build delivery system have, and continue to overcome obstacles when it comes to working with the Department of Veterans Af-

fairs. While businesses such as Ramtech are anxious to compete, the current trend of Design-Bid-Build projects issued by the VA inevitably prohibits that participation.

The construction industry has seen great advances over the past 10 years, and one of those is the Design-Build delivery system. More and more contractors are beginning to utilize Design-Build because of the advantages that are offered. However, until agencies such as the VA decide to solicit more projects using a Design-Build method, these companies will be unable to participate. The members of MBI ask that the Veterans' Affairs Committee look into the issues discussed today in the hopes of improving the way the VA procures construction projects. Our recommendations would ensure that the Federal Government gets the 'best value' and also maximizes opportunities among SDVOB's and alternative construction methods.

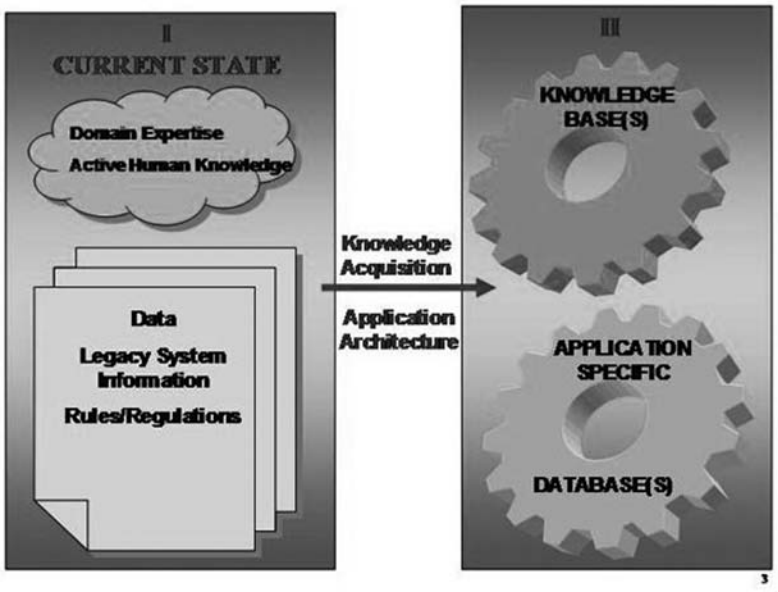
On behalf of MBI, as well as on behalf of Ramtech Building Systems, Inc, I thank you for your time and attention to these matters. It is our hope the Committee can continue to rely on MBI as a valuable resource when it comes to issues relating to the construction industry.

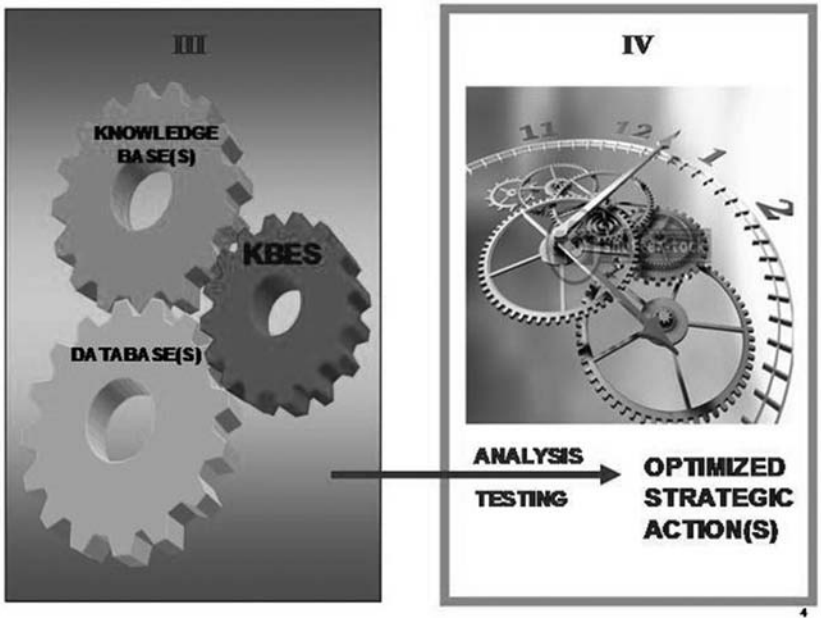
Respectfully Submitted.

Prepared Statement of Jay Wise, Ph.D., Chief Executive Officer, Wise Knowledge Systems, Inc., Piper Creek, TX

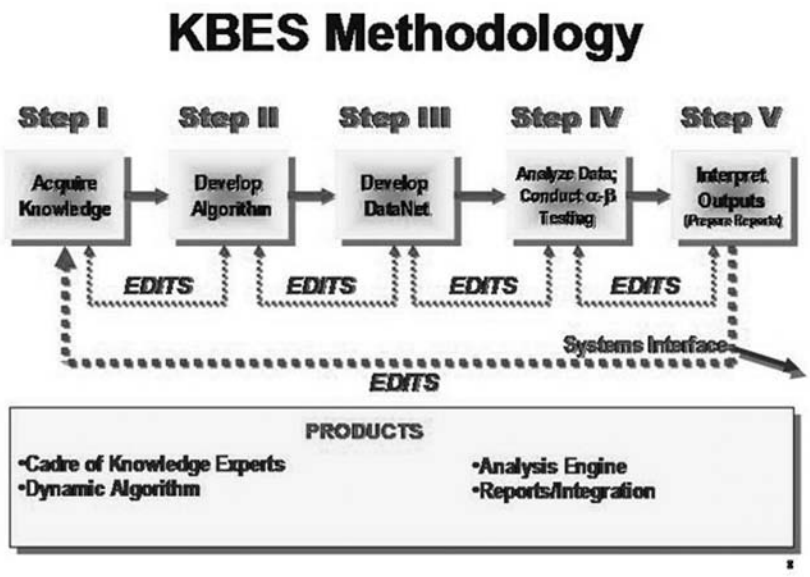
Introduction

Wise Knowledge Systems, Inc. (WKS) has produced the Knowledge-based Expert Systems (KBES) application as an advanced modeling and simulation/decision discovery and support tool. KBES keys on continual input from *whole communities of domain experts* to evaluate situations and decisions and produce information on optimized strategic actions. This cumulative knowledge continually refines the KBES output resulting in a very current and very accurate contribution to actionable knowledge.



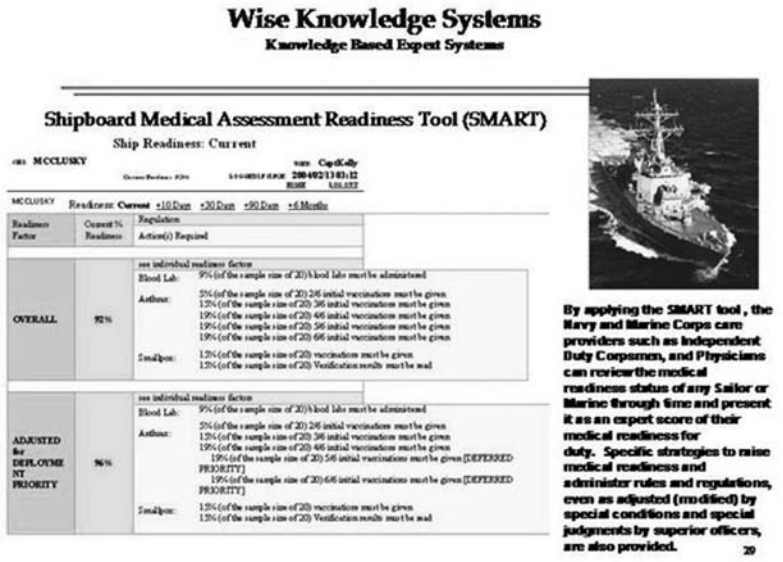


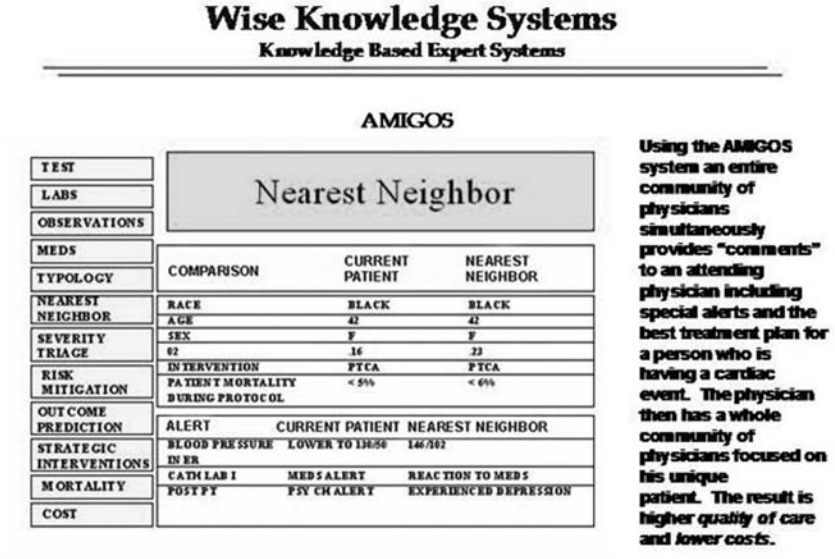
KBES is a learning tool that continually evolves via the use of the experts.



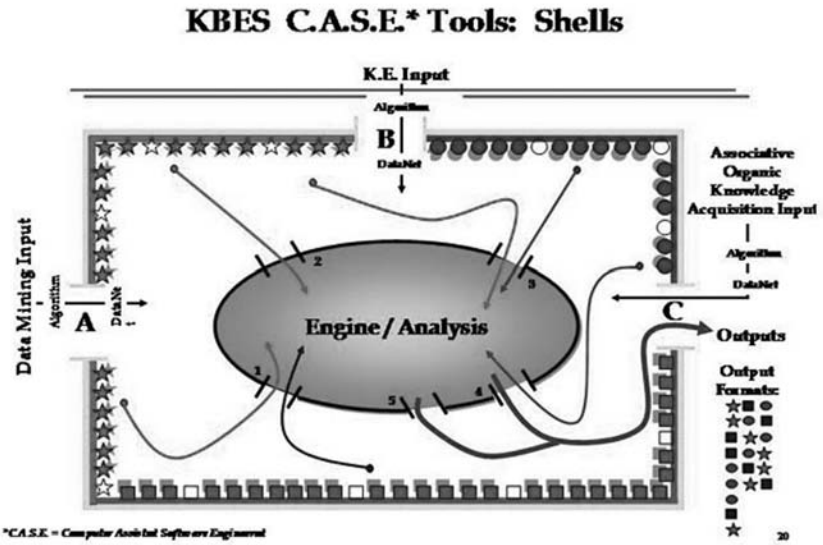
KBES is accurate at a minimum of 95 percent, and has received important validation and praise from mathematicians at major universities, the Office of the Chief of Naval Operations, juried scientific journals, the Smithsonian Institute where it is part of their collection, and, in the private sector. KBES has been successfully deployed in both private sector operations, and in active military operations.

The production of the dynamic assessment of medical readiness for the Navy produced highly accurate and user friendly information on current and future state of medical readiness with modeling and simulation to produce optimized strategies for medical readiness.

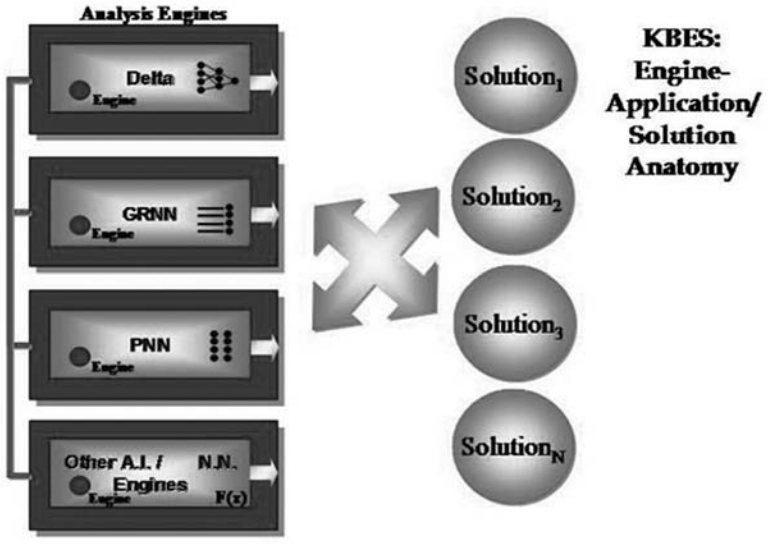




The architecture of all KBES models and applications supports the interchange of values for "triggers" that can open new pathways and establish a different or new decision and optimized strategic interventions. All of the KBES analytical engines are modular and can be used individually or in tandem.



The four KBES analysis engines work both individually and in combination. The output of these analyses is actionable action based on the sum of the knowledge of the domain experts using the application. In certain cases, the analyses can produce a decision or suggest an action that is not part of the typical responses and thereby improve the final outcome.



Excerpts, reviews and deployment details for all WKS KBES models, technology, and applications are available both on request and at the WKS Web site: wiseknowledgesystems.com.

Precise dates and times and full transcripts of meetings and conversations are available on request.

The following is a very small sample of the documents, and communications for WKS and the VA since 2004.

Overview

10/15/2007

Dr. Wise met in Washington with Dr. Paul Tibbits. Dr Tibbits says he is aware of WKS' KBES as successfully applied to the Navy Shipboard Medical Administrative Readiness Tool (SMART). Dr. Tibbits says he wishes to identify the best application of the KBES technology for the VA.

Wise Knowledge Systems, Inc. has received positive praise following analysis of KBES technology by:

Paul Tibbits, M.D.–Veterans Administration
Roy Pratt–HP
Joe Goodin–Office of the Chief of Naval Operations
The Smithsonian Institute
Dr. John Sharp–UMKC School of Medicine
Frank Sisti–Software Engineering Institute
Dr. Dale Alverson–Telemedicine Director, University of New Mexico
Ciro Rodriquez–U.S. Congress, House of Representatives
W.C. Vanderwagen, M.D.–Indian Health Service
Wendell Porth–St. Lukes Lutheran Hospital
Richard A. Cooper–Trinity University, Department of Mathematics
Bill Silva–Dyncorp
Wise Knowledge Systems, Inc. clients, since 1985

Although WKS continued to provide the full information/material to Dr. Tibbits since our initial meeting with him, the following individuals have, in meeting with WKS, said initially that they have either **not received any information from Dr. Tibbits, and/or, they have not reviewed the material.** *Following their review with Dr. Wise* **each said that the KBES application would support the VA/VHA health mission with veterans.** Other than Ms. Lloyd, VHA, and Ms. McCutcheon, VA OAL, **each said that they would recommend a pilot KBS project for VA to Dr. Tibbits.** Importantly, ***Dr. Tibbits wrote the most positive evaluation of KBES for the VA, yet he failed to put KBES on the "list" for prioritization for acquisition.*** Other than Ms. McCutcheon, **each of these individuals said they would not acquire KBES because: *"the VA is broken, nobody here wants to work/it is hard to find anybody at the VA who wants to work, and the VA is not mature to use this technology".***

This response may be seen as rather extraordinary when one reviews the assessment given by Dr. Tibbits himself, and by Joe Goodin of the Office of The Chief of Naval Operations.

Chief of Naval Operations
Medical Resources, Plans, and Policy (N931)
2000 Navy Pentagon
Washington, DC 20350-2000
June 26, 2006

Dr. Jay Wise
Wise Knowledge Systems, Inc.
292 Post Ave.
San Antonio, Texas 78215

Dear Dr. Wise,

As you know, the Navy continues to develop tools that track and forecast medical readiness as part of our comprehensive medical common operational picture. These tools must provide optimized strategic courses of actions and accurate expert scores for all levels of operations, from individuals thru the entire fleet. Your Shipboard Medical Administrative Readiness Tool (SMART) has accomplished this task for the Navy. SMART is now successfully integrated with our MedCop application. This integration is significant as it provides medical commanders with a more complete picture of actionable information. Users report that the integrated application is fast and easy to use; I am convinced this is due in large part to the WKS knowledge engines. Scalability is a concern and the WKS engines have proven their ability to handle large data sets.

Currently SMART has been deployed to the hub of the Pacific Fleet in Pearl Harbor, Hawaii and to the newly formed Naval Expeditionary Combat Command (NECC) in Little Creek, Virginia. The NECC deployment is particularly exciting because we are part of establishing the concept of operations of a new combat command that includes amphibious ships, Marine expeditionary forces, Sea Bees, and special operations.

To repeat what I said in an earlier letter to you: "Your system has demonstrated the ability to assimilate, analyze, and then learn the business processes we use to maintain and improve the medical health status of our active duty Sailors and Marines." I believe that your accomplishments in this "digital health" area would be useful to any organization requiring actionable health status information and an optimization of scarce health care resources. We look forward to investigating the further application of your KBES tools in our on-going efforts to optimize Navy and Marine Corps medical readiness.

Sincerely,

Joseph E. Goodin III
Program Manager for Information Technology

The following is the SPAWAR evaluation as edited by Dr. Paul Tibbits.

POINT PAPER

10 Sept 2009

Subj: Use of modeling and expert system to strengthen system development lifecycle (SDLC), as related to IT systems capacity planning.

BACKGROUND

On an enterprise level, the SDLC processes present at the VA are still too fragmented, with multiple opportunities for improvement in process documentation, modeling, and standardization, as well as accuracy of capacity forecasting and adherence to software efficiency constraints.

If applied properly, the use of the modeling and exper systems approach has the potential to provide significant value to the SDLC processes by:

- Facilitating process and data discussions with stakeholders;
- Modeling transaction volumes based on actual vs paper based processes and "what if" variations in between;
- Aligning SDLC processes and organizations;
- Identifying potential root cause issues based on similar process data;
- Supporting change and communications.
- Deploying in a modular, flexible, and secure manner with lowest possible risk of poor systems performance.

The implementation of modeling and expert systems methodology could yield early benefits in facilitation and communications while benefits surrounding toolsets and data modeling would be limited until process alignment has been achieved and initial data is available for use in the models.

ANALYSIS

MODELING AND EXPERT SYSTEMS METHODOLOGY

There are a variety of commercial approaches to use of modeling and expert systems which approach process modeling, knowledge management, and data analysis in a proprietary manner.

Value in process modeling, knowledge management, and data analysis are typically seen in 3 discrete areas: Communications facilitated by the knowledge, data gathering, modeling process; the extensibility of the models themselves; and the potential for root cause analysis and process improvement based on data and structural analysis.

- Communications facilitation value is typically measured as "soft" returns. Benefits can be seen in training/mentoring, team building, and other areas of organizational and individual development.
- Model extensibility value can be measured by perceived benefits to functionally related processes which allow for value to be replicated with less cost and/or as ongoing management tools such as dashboards and training toolsets.
- Root cause analysis can be an outcome of both modeling and data analysis.
  - Value in data analysis is dependent on the amount and type of data available. Detailed data modeling implies sufficient data to make it useful for achieving buy in on outcomes
  - Benefits of data analysis are limited typically by confidence in models and quality of data. The confidence in the model is based on the transparency of the modeling process and the facilitation approach. The quality of data is often in question when processes are not standardized or if stakeholders are not involved in developing underlying assumptions.

MODELING AND EXPERT SYSTEMS

- Are flexible and modular.
- Have been deployed on a number of databases and operating environments.
- Can receive either "stand alone," "batch," or "real-time" data inputs based on standard data base sharing techniques.
- Have been accredited and deployed in DoD environments.
- Can be a reasonable methodology for leveraging benefits in a secure and flexible manner.

Ms. McCutcheon simply said *"I see no value in it. You (WKS) can start over with the VA!"*

These individuals are:

Navy Captain Christine Boltz
Greg Donham—VA
Navy Commander Margret Beaubein
Dr. Julius Chou
Ms. Susan Lloyd—VHA
Dr. Michael
Valivullah—VA
Dr. Pat Pearcy—SPAWAR
Ms. Wendy McCutcheon—VA OAL

Dr. Tibbits says his efforts and funds are spent to *"support the status quo"* at the VA. Dr. Tibbits says *"I will just go down the hall and get the money from my boss"*. Dr. Tibbits said that Ms. McCutcheon was now the sole authority for acquisition for the VA for health and medical applications and that the first people funded by her office were "raving" about her performance.

Dr. Tibbits and Ms. McCutcheon say that, though they know WKS is a Veteran owned small business, *they will not consider Wise Knowledge Systems, Inc. using the GSA, because the "GSA is not helping us (VA)".*

Cathy Wiblemo of Chairman Filner's office reports she has heard/seen nothing in response to Chairman Filner's request to the Secretary of the VA for the Secretary's office to "provide the Committee with evaluation and feedback of SMART. Please re-

spond by November 16, 2007", Ms. Wiblemo has said there remains no response by the Office of the Secretary of the VA to this request by Chairman Filner.

Following a conversation with Chairman Filner's staff, Chairman Filner and I spoke and he invited me to testify at this hearing.

Summary

Since 2004, WKS has been in communication with leadership at the VA to develop an understanding of a potentially important, potentially life saving, resource allocation technology to the VA. This is WKS Knowledge-Based Expert System (KBES) technology. KBES has received very positive technical reviews as an advanced modeling and simulation decision, support technology from every point of assessment to which it has been assigned by both the Navy and the VA, and in the private sector. The critical health area of CRTBI and the fundamental nature of SDLC development for the VA make positive movement on these topics significant to the mission of the VA. There is clearly ***an important ethical issue of the VA being enabled to keep its promise and deliver its mission to American veterans.***

Once a technology has been tested, evaluated, praised, and successfully focused on an emergent health issues or in support of technology that supports health; nonresponse is an unacceptable option. The leadership at the VA, their staff and colleagues all seem to agree that the KBES technology could be very good for the VA, but some persons of authority have decided that they will not attempt to acquire or apply KBES because the VA is" not mature, is broken, and that the people at the VA do not want to work". These individuals at VA seem to be defaulting the responsibility for a decision. Failing that they simply do not respond.

It is an unfortunate part of our American history that treaties (contracts) were made with the American Indian tribes to remove them as an obstacle to what was called progress. These treaties or agreements were made by our government *knowing they would not be kept.* The explanation for this fraudulent manipulation was often that "Indians are not people/they are not human beings". One wonders if the individuals mentioned above at the VA, in maintaining the "status Quo", failing to provide state-of-the-art medical and health care to our young people enlisting in the service, while referring to the VA as "immature, broken and not willing to work", also considers these young Americans as "not human beings".

This arrogant and non-productive behavior is not appropriate when the health and lives of American Veterans, and their families are at risk.

While it is clear that the vast majority of individuals at the VA are sincerely dedicated to American veterans and do want to work for the mission of the VA, there remains a few in leadership positions who frustrate the evolution of the medical responses and capabilities now available to the VA. WKS recommends installing and supporting qualified individuals in these important positions who have the experience and expertise to follow up on positive evaluations, and acquire state-of-the-art advanced medical and health care technology, like KBES. Saying that "the VA is broken and nobody here wants to work" as the rationale for non-acquisition of proven technologies does not support the critical mission of the VA, nor does it compliment those at the VA who work hard and are not broken and give much more than for hollow lip service for American veterans. We all look forward to a more positive approach to acquisition for the future of the VA and American veterans. Do the right thing. Honor the contract with American veterans.

I want to thank the Committee and in particular Chairman Dr. Bob Filner for giving our experience a voice. I will try to answer any questions you may have now.

Respectfully presented.

Jay Wise

Wise Knowledge Systems

Prepared Statement of James A. Clair, M.P.A., M.S., Chief Executive Officer, Goold Health Systems, Augusta, ME

Chairman Michaud, Ranking Member Brown, and Members of the Subcommittee: thank you for your kind invitation to discuss Department of Veterans' Affairs (VA) procurement practices and, specifically, how the VA might benefit by incorporating certain cost containment strategies within their pharmacy benefit management (PBM) and Nursing Home Care programs. I am accompanied today by Lorraine Lachapelle, RN, Goold Health Systems' Director of Community Assessments.

Goold Health Systems is a national health care management company that specializes in meeting our clients' specific health care objectives with a special emphasis on cost containment. At all times we are driven by evidence-based medicine and

achieving clinically effective outcomes. We manage certain health benefits as directed by our clients in a very detailed, granular level so that health care costs are contained and, in many cases, reduced on a per user per year (PUPY) basis.

Our work is accomplished in "clinical-analyst teams" that are lead by Goold doctors, pharmacists and nurses who team with our data analysts, software developers, database administrators and project managers to achieve effective cost-containment strategies for our clients. Our primary clients are the State Medicaid Agencies. We have offices in Augusta, Maine; Atlanta, Georgia; Cheyenne, Wyoming; and Des Moines, Iowa.

GHS provides four major business offerings to our clients: (1) pharmacy benefits services administration; (2) community assessment services; (3) medical prior authorizations; and (4) business outsourcing services. My testimony today will be focused on items 1 and 2 above.

I would like to preface my remarks by stating that the VA does a very good job at providing pharmacy services. They purchase in a very cost-effective manner, have a modern and effective dispensing network and have deployed many effective technical and clinical solutions so that our Nation's veterans receive the services they require.

My testimony focuses on three ways in which the VA can enhance the monitoring and evaluation of certain health benefits so that veterans receive their services:

- Medication Management
- Pharmacy Program Integrity
- Long-Term Care Assessments

1. Medication Management

The U.S. Department of Health and Human Services' (U.S. DHHS) Centers for Medicare and Medicaid Services (CMS) recommends Medication Therapy Management (MTM)—a program that sets out to ensure optimum therapeutic outcomes, reduce the risks of side-effects when using medications and must be coordinated as part of a care management plan. GHS then expands upon MTM by using predictive modeling to analyze pharmacy and medical claims data to measure the probability of exceeding set cost parameters for *high cost users* and *complex medical conditions.* Problematic patients are ultimately placed in an Intensive Benefits Management (IBM) or Chronic Pain Management (CPM) program. We utilize regression analyses that correlate chronic conditions with total drug cost; we then identify individuals who would benefit from our targeted interventions. Once in IBM or CPM the patient is linked to one physician/prescriber and one pharmacy/dispenser for management of complex medical conditions and chronic pain issues, ensuring that those patients receive appropriate drug therapies. We provide educational materials and monitoring services to those individuals to help them better understand their medical conditions, as well as work with them on medication adherence and potential drug interactions. We also work with their providers to help ensure that optimal clinical outcomes are achieved. Savings accrue to our clients because of the intensive involvement of the provider, patient and GHS clinical team. Examples of health conditions we focus on for IBM have been narcotics use, asthma & Chronic Obstructive Pulmonary Disease (COPD).

Other examples of Medication Management strategies involve formulary management, which uses our clinical and analytical expertise to most effectively manage the drug benefit, including:

Formulary Management: 15 Days Supply Limit

GHS performs extensive analyses to identify drugs that have high discontinuation rates shortly after the onset of therapy. It was reasoned that limiting the number of days supply of these first scripts would result in savings from reducing waste. About 30 drugs were identified that met our criteria. These drugs tend to have high discontinuation rates due to either significant side effects or relative lack of efficacy. Targeted areas for this effort include long-acting narcotics, stimulants, psychiatric medicines, urinary and continence products, and smoking cessation drugs (e.g, Chantix).

Formulary Management: Dose Consolidation

Many existing drugs now only need to be taken once per day. There is a considerable amount of savings available if these drugs are not allowed to be used more frequently without good clinical cause. Examples of targeted dose consolidation are Zyprexa and Risperdal, two anti-psychotic drugs that have allowed our State clients to save over 1 percent of their pre-rebate expenditures annually by aggressively pursuing dose consolidation.

2. Pharmacy Program Integrity

Program Integrity by definition should ensure that our tax dollars are not put at risk through fraudulent violations of the rules or abuses of the system. It should ensure that appropriate payments are paid only to legitimate providers for services only to eligible beneficiaries.

Like many other health care managers, we have significantly expanded our Program Integrity efforts over the last few years. Some health care expert's have found that as much as 10 percent of all payments in health care can be attributed to fraud, waste or abuse. The National Health Care Anti-Fraud Association estimated that 3 percent of the health care industry's expenditures in the United States are due to fraudulent activities. This calculates to an annual amount of approximately $51 billion.

In a recent analysis for one of our State clients we created a "Monthly Outlier Report" on pharmacy expenditures and trends. The analysis was performed for each drug filled in the previous month, a review of the average amount spent per drug and the average quantity per days supply based on quantity limits was undertaken. Those drug claims that fell outside established guidelines were flagged for audit. This resulted in claims being reviewed as a result of improper use of override codes and, subsequently, many of these outlier claims were reversed. For this one State client with a pharmacy budget of approximately $200 million per year, we expect the results of this specific audit to yield between $500,000 to $1 Million dollars in savings.

By way of example I have listed below two other areas of pharmacy practice that are prime candidates for Program Integrity review:

Automatic Early Refills

In pharmacy benefit programs like the VA, where there is a heavy reliance on mail order, it is important that the mail order provider be monitored to ensure that mail order pharmacies wait for the patient to ask for their medication to be refilled. This doesn't preclude a mail order pharmacy from making outgoing calls to ask a patient if they would like their next dose of medication sent, but it would not allow a mail order pharmacy from *automatically* sending the prescription to them in all cases.

Near Duplicates

Each medication intended for human use is assigned a number called an NDC (National Drug Code). It is a unique product identifier that, for example, distinguishes an Oxycodone 10 milligram (mg) tablet from an Oxycodone 20 mg tablet.

"Near duplicates" can occur with generics when a different NDC of the same drug/same strength is used a few days after that patient's first prescription was filled. In many cases, this is an appropriate fill due to the legitimate loss of medication. However, these can also be billing errors or inappropriate dispensing such that these claims should be reversed. Monitoring utilization at this level can yield additional savings to the VA if it is not being done now.

3. Long-Term Care Assessments

Through the early 1990's Nursing Facilities (NF) Medicaid costs were increasing at annual rates far exceeding the general inflation rate or even the higher rate at which health care costs were increasing. Eligibility determinations for Medicaid NF care were determined by the provider, leading to much higher utilization rates than otherwise supported by independent review. As a result Maine State Government instituted an independent, objective Maine Medicaid eligibility screening process with the following objectives: to create a single entry for medical/functional eligibility assessments for long-term care (LTC) programs; to increase consumer participation and control; to educate consumers about in-home long-term care programs and other alternatives to nursing and residential facility care; to identify and address caregiver needs; to reduce the long-term costs of services by requiring greater emphasis on rehabilitation and health promotion; and to reduce the number of unnecessary admissions to, increase the number of discharges from, and decrease the length of stay in, nursing facilities.

Within strict time parameters set by our client, the GHS Intake Screener's job is: to provide accurate prescreening to determine the need for a medical/functional assessment, maintain a waiting list for assessment as needed and refer consumers to appropriate resources.

When an evaluation is indicated, the GHS Registered Nurse (RN): conducts an accurate, objective medical/functional eligibility assessment using the automated Medical Eligibility Determination (MED) tool in a way that is always based on sound

clinical judgment and in compliance with appropriate policy; and provides timely information about all long-term care service options, including a thorough explanation of consumer-directed options, regardless of payment source.

GHS employs approximately 35 nurses who perform the LTC assessments on-site with the assistance of a laptop, portable printer and cell phone.

In State Fiscal Year 2010 (ending June 30, 2010), we performed over 15,000 assessments. The State's share of the Medicaid NF expenses in 2010 are more than 35 percent lower than their SFY 1994 peak in nominal (non-inflation adjusted) dollars. This is the result of some policy changes made by Maine State Government and the LTC Assessment process. Comparing where the unmanaged NF budget was headed to where it actually is today has yielded annual State savings that exceed $100 million.

It is important to point out that the State of Maine has invested some of the annual cost-savings toward a stronger network of Home-Based Care (HBC) services so that those clients determined to be eligible to remain in their home setting would have the supporting services available to them.

Conclusion

Mr. Chairman, the VA is a very effective provider of important pharmacy and medical benefits to our country's veterans. The strategies described above have been proven to be very effective in containing health care costs for our Medicaid clients. We believe that these clinical management approaches can assist the VA in further containing costs.

Thank you again for the opportunity to testify. My colleague and I would be pleased to answer any questions you may have.

Prepared Statement of Debra A. Draper, Ph.D., M.S.H.A., Director, Health Care, U.S. Government Accountability Office

VA Health Care: Preliminary Observations on the Purchasing and Tracking of Supplies and Medical Equipment and the Potential Impact on Veterans' Safety

GAO Highlights

Why GAO Did This Study

VA clinicians use expendable medical supplies—disposable items that are generally used one time—and reusable medical equipment (RME), which is designed to be reused for multiple patients. VA has policies that VA medical centers (VAMC) must follow when purchasing such supplies and equipment and tracking—that is, accounting for—these items at VAMCs.

GAO was asked to evaluate VA's purchasing and tracking of expendable medical supplies and RME and their potential impact on veterans' safety. This testimony is based on GAO's ongoing work and provides preliminary observations on (1) the extent of compliance with VA's requirements for purchasing and tracking of expendable medical supplies and RME and (2) steps VA plans to take to improve its oversight of VAMCs' purchasing and tracking of expendable medical supplies and RME. GAO reviewed VA policies and selected three requirements that GAO determined to be relevant to patient safety. At each of the five VAMCs GAO visited, GAO reviewed documents used to identify issues related to the three requirements and interviewed officials to gather further information on these issues. The VAMCs GAO visited represent different surgical complexity groups, sizes of veteran populations served, and geographic regions. GAO also interviewed VA headquarters officials and obtained and reviewed documents regarding VA headquarters' oversight. GAO shared the information in this statement with VA officials.

What GAO Found

During its preliminary work at the five selected VAMCs, GAO found inconsistent compliance with the three VA purchasing and tracking requirements selected for review. Noncompliance with these requirements created potential risks to veterans' safety.

- *Requirement for VAMC committee review and approval.* At two of the VAMCs, officials stated that the required designated committee review and approval occurred for all of the expendable medical supplies and RME that the VAMCs had not previously purchased. These reviews are designed to evaluate the cost of the purchase as well as its likely impact on veterans' care. However, at the remain-

ing three VAMCs, officials stated that the required committee review and approval of the expendable medical supplies, such as those used in conjunction with dialysis machines, did not always occur. As a result, these purchases were made without evaluating the likely impact on veterans' care.

- *Requirement for signatures of purchasing and approving officials.* At one of the VAMCs, VAMC officials discovered that a staff member in a dialysis department ordered an expendable medical supply item for use in dialysis machines, without obtaining the required signature of an approving official. That staff member ordered an incorrect item, the use of which presented a risk of exposing veterans to infectious diseases, such as Human Immunodeficiency Virus.
- *Requirement for entering information in VA's inventory management systems.* Officials from one of the five VAMCs told GAO that information about expendable medical supplies that were ordered on a recurring basis was entered into the appropriate inventory management system, as required. At the remaining four VAMCs, officials told GAO that information about certain expendable medical supplies—those used in a limited number of clinical departments such as dialysis departments—was not always entered into the system. This lack of information can pose a potential risk to veterans' safety; in the event of a recall of these items, these VAMCs may have difficulty determining whether they possess the targeted item.

VA reports that it plans to improve its oversight of VAMCs' purchasing and tracking of expendable medical supplies and RME. For example, VA headquarters officials stated that, effective October 1, 2010, VA plans to shift greater responsibility for reviews of purchase card transactions from the VAMCs to the Veterans Integrated Service Networks, which are responsible for overseeing VAMCs. VA headquarters officials also told GAO that VA is developing a new inventory management system, which it expects will help improve VA's ability to track information about expendable medical supplies and RME across VAMCs. VA expects this new system to be operational in March 2011.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss the Department of Veterans Affairs' (VA) contracting and procurement practices. VA operates one of the largest integrated health care delivery systems in the United States, providing care to over 5.5 million veterans annually. Organized into 21 Veterans Integrated Service Networks (VISN), VA's health care system includes 153 VA medical centers (VAMC) nationwide that offer a variety of outpatient, residential, and inpatient services.[1] These services range from primary care to complex specialty care, such as cardiac and spinal cord injury care. In providing these health care services to veterans, VA clinicians at VAMCs use supplies and equipment that must be purchased by VA. These include expendable medical supplies, such as needles and scalpel blades, which are generally used once, and reusable medical equipment (RME), which is designed to be reused for multiple patients and includes such equipment as endoscopes and some surgical instruments.

VA has established policies that VAMCs are required to follow when purchasing items such as expendable medical supplies or RME and tracking—that is, accounting for—these items at their facilities.[2] For example, VA requires that a designated VAMC committee review and approve purchases of any expendable medical supplies or RME that the VAMC has not previously purchased. VA also requires that VAMCs enter information about certain expendable medical supplies and certain RME at their facilities into the appropriate inventory management system. VA's purchasing and tracking policies help ensure that VAMCs make effective use of available resources and that they know which supplies and equipment are being used at their facilities.

VA's purchasing and tracking policies are also designed, in part, to help ensure the safety of veterans who receive care at VAMCs. For example, VAMCs need information on the RME in use at their facilities in order to ensure that they have procedures for properly reprocessing[3] these items. VAMCs also need information on the

[1] The management of VAMCs is decentralized to the 21 VISNs.

[2] See, for example, VA Handbook 7176, *Supply, Processing and Distribution (SPD) Operational Requirements* (Aug. 16, 2002) and Veterans Health Administration (VHA) Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009).

[3] Reprocessing refers to the steps by which RME is prepared for reuse, and includes cleaning and disinfecting or sterilizing the medical equipment.

supplies and equipment in use in their facilities in order to determine when they have expendable medical supplies or RME that are the subject of a manufacturer or U.S. Food and Drug Administration (FDA) recall or a patient safety alert.[4]

Congressional committees and certain Members of Congress have raised questions about VAMCs' purchasing and tracking of expendable medical supplies and RME and their potential impact on veterans' safety. My testimony today consists of preliminary observations as part of our ongoing work on VA's oversight of compliance with its policies for purchasing and tracking expendable medical supplies and RME. These observations, based on site visits to five selected VAMCs, raise concerns about the safety of veterans receiving care at these facilities. We cannot determine the extent to which the purchasing and tracking problems in the five selected VAMCs reflect the broader VA health care system.

In my remarks today I will provide preliminary observations on (1) the extent of compliance with VA's requirements for purchasing and tracking of expendable medical supplies and RME and (2) steps VA headquarters plans to take to improve its oversight of VAMCs' purchasing and tracking of expendable medical supplies and RME.

To identify the extent of VAMCs' compliance with VA's requirements for purchasing and tracking of expendable medical supplies and RME, we reviewed VA policies[5] and selected three purchasing and tracking requirements that we determined were relevant to veterans' safety issues. The requirements we selected are (1) having a designated VAMC committee review and approve purchases of any expendable medical supplies and RME that the VAMC has not previously purchased, (2) obtaining signatures of purchasing and approving officials, and (3) entering information about expendable medical supplies and RME at VAMCs into VA's inventory management systems. We selected these requirements to inform our discussions with VAMC officials about patient safety incidents related to the purchase and tracking of expendable medical supplies and RME that were identified at certain VAMCs in 2009.[6] We judgmentally selected five VAMCs to visit: the VAMCs in Albany, New York; Cheyenne, Wyoming; Detroit, Michigan; Miami, Florida; and Palo Alto, California. These VAMCs represent different surgical complexity groups,[7] sizes of veteran populations served, and geographic regions. At the five VAMCs, we reviewed applicable VAMC committee meeting minutes[8] and other documentation used to identify problems related to the three purchasing and tracking requirements we selected for our review. We also interviewed VAMC officials to gather additional information on these problems. To obtain information on steps VA headquarters plans to take to improve its oversight of VAMCs' purchasing and tracking of expendable medical supplies and RME, we interviewed VA headquarters officials responsible for overseeing VAMCs' purchasing of expendable medical supplies and RME. In addition, we obtained and reviewed relevant documents regarding VA headquarters' oversight, including internal reports and policy memorandums. We shared the information provided in this statement with VA headquarters officials.

We are conducting this performance audit in accordance with generally accepted government auditing standards. We conducted the work for this statement from March 2010 to September 2010. The audit 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

VA policy specifies how VAMCs can purchase expendable medical supplies and RME. VAMCs can purchase expendable medical supplies and RME through their ac-

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[4] A patient safety alert is a notification sent to VAMCs from VA's National Center for Patient Safety regarding veterans' safety.

[5] We reviewed applicable VA policies, including VA Handbook 7176, *Supply, Processing and Distribution (SPD) Operational Requirements* (Aug. 16, 2002); Department of Veterans Affairs, *VA Financial Policies and Procedures, Volume II, Chapter 6, Miscellaneous Obligations* (Jan. 2009); VHA Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009); and VA Directive 1725.1, *Accountability* (Apr. 5, 1996).

[6] We are continuing to review VA's policies to determine whether additional requirements relate to these patient safety incidents and should be included in our ongoing work.

[7] VA assigns each VAMC a complexity score between 1 and 3 (level 1 is broken down further into 1a, 1b, and 1c), with level 1 being the most complex, using a facility complexity model. That model uses multiple variables to measure facility complexity arrayed along 4 categories, namely patient population served, clinical services offered, education and research complexity, and administrative complexity.

[8] We reviewed minutes from the following committees: commodity standards, equipment, infection control, medical executive, and reusable medical equipment.

quisition departments or through purchase card holders, who have been granted the authority to make such purchases. Purchase cards are issued to certain VAMC staff, including staff from clinical departments, to acquire a range of goods and services, including those used to provide care to veterans. According to VA, as of the third quarter of 2010, there were about 27,000 purchase cards in use across VA's health care system.

VA has two inventory management systems, which VAMCs use to track the type and quantity of supplies and equipment in the facilities. Each VAMC is responsible for maintaining its own systems and for entering information about certain expendable medical supplies and certain RME in the facilities into the appropriate system. Specifically, the Generic Inventory Package (GIP) is used to track information about expendable medical supplies that are ordered on a recurring basis.[9] The Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) is used to track information about RME that is valued at $5,000 or more and has a useful life of 2 years or more.[10] VAMC officials told us they use information about the items in their facilities for a variety of purposes, for example, to readily determine whether they have expendable medical supplies or RME that are the subject of a manufacturer or FDA recall or a patient safety alert.

VA's purchasing and tracking policies include the following three requirements for VAMCs:

1. A designated VAMC committee must review and approve proposed purchases of any expendable medical supplies or RME that have not been previously purchased by the VAMC.[11] The Committee, which typically includes administrative staff and clinicians from various departments, reviews the proposed purchases to evaluate the cost of the purchase as well as its likely impact on veterans' care.[12] For example, the Committee that reviews and approves proposed RME purchases often includes a representative from the department responsible for reprocessing RME, in order to determine whether the VAMC has the capability to reprocess—clean and disinfect or sterilize—the item correctly and that staff are appropriately trained to do so. Proper reprocessing of RME is important to ensure that RME is safe to use and that veterans are not exposed to infectious diseases, such as Human Immunodeficiency Virus (HIV), during treatment.
2. All approvals for purchases of expendable medical supplies or RME must be signed by two officials, the official placing the order and the official responsible for approving the purchase.[13]
3. VAMCs must enter information on all expendable medical supplies that are ordered on a recurring basis and all RME that is valued at $5,000 or more and has a useful life of 2 years or more into the appropriate inventory management system, either GIP or AEMS/MERS.[14] VA does not require information about RME that is valued at less than $5,000 to be entered into AEMS/MERS.

GAO's Preliminary Work Identified Examples of Inconsistent Compliance with VA's Purchasing and Tracking Requirements at Five Selected VAMCs

At the five VAMCs we visited, our preliminary work identified examples of inconsistent compliance with the three purchasing and tracking requirements we selected for our review. In some cases, noncompliance with these requirements created potential risks to veterans' safety. We are continuing to conduct this work.

VAMC committee review and approval.

- Officials at two of the five VAMCs we visited stated that VAMC committees reviewed and approved all of the expendable medical supplies the VAMCs purchased for the first time. However, at the remaining three VAMCs, officials told

[9] GIP is used to track additional items besides expendable medical supplies, including nonmedical supplies.

[10] AEMS/MERS is used to track additional equipment besides RME, including information technology equipment.

[11] Generally, a VAMC's commodity standards committee reviews and approves purchases of expendable medical supplies and a VAMC's equipment committee reviews and approves purchases of RME.

[12] See VA Handbook 7176, *Supply, Processing and Distribution (SPD) Operational Requirements* (Aug. 16, 2002).

[13] Department of Veterans Affairs, *VA Financial Policies and Procedures, Volume II, Chapter 6, Miscellaneous Obligations* (Jan. 2009).

[14] See VHA Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009) and VA Directive 1725.1, *Accountability* (Apr. 5, 1996).

us that VAMC committees did not conduct these reviews in all cases. Officials from these three VAMCs told us that certain expendable medical supplies—for example, new specialty supplies—were purchased without VAMC committee review and approval. Specialty supplies, such as those used in conjunction with dialysis machines, are expendable medical supplies that are only used in a limited number of clinical departments. Without obtaining that review and approval, however, the VAMCs purchased these supplies without evaluating their cost effectiveness or likely impact on veterans' care.

- At one VAMC we visited, officials told us that clinical department staff were permitted to purchase certain RME—surgical and dental instruments—using purchase cards and that these purchases were not reviewed and approved by a committee. Therefore, the VAMC had no assurance that RME purchased by clinical department staff using purchase cards had been reviewed and approved by a committee before it was purchased for the first time. As a result, these purchases may have been made without assurance that they were cost effective and safe for use on veterans and that the VAMC had the capability and trained staff to reprocess these items correctly.

Signatures of purchasing and approving officials.

- At one of the five VAMCs we visited, VAMC officials discovered that one staff member working in a dialysis department purchased specialty supplies without obtaining the required signature of an appropriate approving official. That staff member was responsible for ordering an item for use in 17 dialysis machines that was impermeable to blood and would thus prevent blood from entering the dialysis machine. However, the staff member ordered an incorrect item, which was permeable to blood, allowing blood to pass into the machine. After the item was purchased, the incorrect item was used for 83 veterans, resulting in potential cross-contamination of these veterans' blood, which may have exposed them to infectious diseases, such as HIV, Hepatitis B, and Hepatitis C.[15]

Entry of information about items into VA's inventory management systems.

- At the time of our site visits, officials from one of the five VAMCs we visited told us that information about expendable medical supplies that were ordered on a recurring basis was entered into GIP, as required. In contrast, officials at the remaining four VAMCs told us that information about certain expendable supplies that were ordered on a recurring basis, such as specialty supplies, was not always entered into GIP. Since our visit, one of the four VAMCs has reported that it has begun to enter all expendable medical supplies that are ordered on a recurring basis, including specialty supplies, into GIP. By not following VA's policy governing GIP, VAMCs have an incomplete record of the expendable medical supplies in use at their facilities. This lack of information can pose a potential risk to veterans' safety. For example, VAMCs may have difficulty ensuring that expired supplies are removed from patient care areas. In addition, in the event of a manufacturer or FDA recall or patient safety alert related to a specialty supply, VAMCs may have difficulty determining whether they possess the targeted expendable medical supply.
- Officials at one VAMC we visited told us about an issue related to tracking RME in AEMS/MERS that contributed to a patient safety incident, even though the VAMC was not out of compliance with VA's requirement for entering information on RME into AEMS/MERS. Specifically, because VA policy does not require RME valued under $5,000 to be entered into AEMS/MERS, an auxiliary water tube, a type of RME valued under $5,000 that is used with a colonoscope, was not listed in AEMS/MERS.[16] According to VAMC officials and the VA Office of the Inspector General, in response to a patient safety alert that was issued on the auxiliary water tube in December 2008, officials from the VAMC checked their inventory management systems and concluded—incorrectly—that the tube

[15] As of June 2, 2010, the VAMC reported that all testing has been completed and that no veterans have acquired infectious diseases as a result of this incident. The VAMC found that one of the 83 veterans identified was dialyzed on an uncontaminated machine and therefore this veteran was not notified or tested for these infectious diseases.

[16] VAMC officials stated that they also checked GIP to determine whether the auxiliary water tube was listed and determined that it was not listed in that inventory management system. According to a VA headquarters official, the auxiliary water tube is not required to be entered in GIP because it is not ordered on a recurring basis.

was not used at the facility.[17] However, in March 2009, the VAMC discovered that the tube was in use and was not being reprocessed correctly, potentially exposing 2,526 veterans to infectious diseases, such as HIV, Hepatitis B, and Hepatitis C.[18]

In addition, officials from VA headquarters told us that when information about certain RME is entered into AEMS/MERS, it is sometimes done inconsistently. The officials explained that this is because AEMS/MERS allows users to enter different names for the same type of RME. As a result, in the case of a manufacturer or FDA recall or patient safety alert related to a specific type of RME, VAMCs may have difficulty determining whether they have that specific type of RME.

VA Reports It Plans to Change Its Oversight of Purchasing and Tracking

During our preliminary work, we discussed with VA headquarters officials examples of steps VA plans to take to improve its oversight of VAMCs' purchasing and tracking of expendable medical supplies and RME. For example, VA plans to change its oversight of the use of purchase cards. Specifically, VA headquarters officials told us that designated VAMC staff are currently responsible for reviewing purchase card transactions to ensure that purchases are appropriate. However, one VA headquarters official stated that these reviews are currently conducted inconsistently, with some being more rigorous than others. VA headquarters officials stated that VA plans to shift greater responsibility for these reviews from the VAMCs to the VISNs, effective October 1, 2010. In addition, VA plans to standardize the reviews by, for example, adding a checklist for reviewers. Because this change has not yet been implemented across VA, we can not evaluate the extent to which it will address the appropriateness of purchases using purchase cards.

Our preliminary work also shows that VA plans to create a new inventory management system. VA headquarters officials told us that they are developing a new inventory management system—Strategic Asset Management (SAM)—which will replace GIP and AEMS/MERS and will include standardized names for expendable medical supplies and RME.[19] According to these officials, SAM will help address inconsistencies in how information about these items is entered into the inventory management systems. VA headquarters officials stated that SAM will help improve VA's ability to monitor information about expendable medical supplies and RME across VAMCs. VA provided us with an implementation plan for SAM, which stated that this new system would be operational in March 2011. At this time, we have not done work to determine whether this date is realistic or what challenges VA will face in implementing it.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other Members of the Committee may have.

GAO Contacts and Staff Acknowledgments

For further information about this statement, please contact Debra A. Draper at (202) 512–7114 or draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Key contributors to this statement were Randall B. Williamson, Director; Mary Ann Curran, Assistant Director; David Barish; Alana Burke; Krister Friday; Melanie Krause; Lisa Motley; and Michael Zose.

Prepared Statement of Belinda J. Finn, Assistant Inspector General for Audits and Evaluations, Office of Inspector General, U.S. Department of Veterans Affairs

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to testify on the findings of the Office of Inspector General (OIG) on the Veterans Health Administration's (VHA) contracting and procurement practices and possible solutions to VHA procurement problems. I am accompanied today by Maureen Regan, Counselor to the Inspector General.

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[17] See VA Office of the Inspector General, Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities, 09–01784–146 (Washington, DC: June 2009).

[18] As of August 17, 2010, the VAMC reported that it has successfully notified 2,523 of the 2,526 veterans of possible exposure to infectious diseases and that there were 17 new positive test results. VA reports that these results are not necessarily linked to RME issues and it is continuing its evaluation.

[19] SAM will be used to track additional items besides expendable medical supplies and RME.

Background

In December 2009, the OIG testified on acquisition deficiencies in VA.[1] At that time, numerous OIG audits, investigations, reviews, and inspections had identified systemic issues such as poor acquisition planning, problematic contract award processes, poorly written contracts, and inadequate contract monitoring that impacted VA's efforts to effectively and economically deliver goods and services to VA facilities. Our testimony also addressed concerns that procurement problems led to inadequate competition for contracts, the misuse of funds, and a general lack of assurance that VA procurements achieved fair and reasonable prices or were in the best interest of the Government. We attributed many of these systemic procurement problems to VA's decentralized organizational structure for procurement activities, inadequate oversight and accountability, and inaccurate and incomplete procurement data.

Update

Our work since we testified in December continues to identify systemic weaknesses in procurement practices that negatively impact VA's ability to obtain quality goods and services in a timely manner at fair and reasonable prices. We also continue to identify compliance issues with Federal Acquisition Regulations (FAR) and VA Acquisition Regulations (VAAR) and find that data in the VA and VHA acquisition support information systems is incomplete and unreliable. The impact of these weaknesses is significant for VHA because of the high dollar cost of health care-related goods and services—$9.05 billion spent in fiscal year (FY) 2009—and because they negatively impact VHA's oversight and ability to make good decisions.

I will now discuss the results of recent work which continues to highlight weaknesses in VHA's acquisition processes.

Audit of Oversight of Patient Transportation Contracts

Our May report on patient transportation services contracts, *Audit of Oversight of Patient Transportation Contracts,* (Report Number 09–01958–155, May 17, 2010), found that VHA missed opportunities to provide full and open competition in their efforts to solicit offers from potential contractors and make contract awards. Contracting officers (COs) did not properly plan and prioritize for the time needed to open new solicitations needed for ambulance services, medical car patient transportation, and other patient transportation requirements.

We identified 9 of 36 patient transportation contracts, with an estimated value of about $12.3 million, that were inappropriately awarded as sole-source and then were extended for up to 6 months after the contract expired. According to COs that we interviewed, this was due to acquisition staff shortages that increased their workload and resulted in insufficient time to solicit new contracts. For seven of nine contracts, the required information, including the number of trips and the type of equipment needed, was not provided by the requesting service in order to develop an accurate solicitation proposal. In 14 of the 36 contracts (39 percent) we reviewed, basic contract documentation required by the FAR such as price negotiation memoranda, determinations of price reasonableness, best value analyses, notices of awards, insurance certificates, and Contracting Officer Technical Representatives (COTRs) designation letters were missing. We also found that COs did not adequately monitor the contractor performance which we estimated could result in VHA overpaying contractors as much as $91.8 million over the next 5 years if COTRs did not consistently review contractor invoices and verify the appropriateness of charged mileage rates and additional mileage charges.

This national audit highlights serious weaknesses in acquisition award and administration processes that fail to adequately protect VHA's contractual interests. VHA needs to provide more oversight to ensure it has adequate statements of work that can guide its staff to know what VHA is buying and measure contractor performance effectively.

VHA Recovery Act Audits

We have issued two audit reports dealing with VHA Recovery Act contract awards for non-recurring maintenance (NRM) projects, *American Recovery and Reinvestment Act Oversight Advisory Report—VHA Non-Recurring Maintenance Contract Award Oversight Needs Strengthening (*Report Number 09–01814–97, March 15, 2010) and *American Recovery and Reinvestment Act Oversight Advisory Report: Vet-*

[1] Statement of Maureen T. Regan, Counselor to the Inspector General, Office of Inspector General, Department of Veterans Affairs, Before the Subcommittee on Oversight and Investigations, Committee on Veterans Affairs, United States House of Representatives, December 16, 2009.

erans Health Administration's Efforts to Meet Competition Requirements and Monitor Recovery Awards (Report Number 09–00969–248, September 17, 2010).

Our March review found that COs failed to maximize competition because they did not consistently and properly publicize solicitations in FedBizOpps, as required. The more recent September review, which was conducted after the Office of Acquisition, Logistics, and Construction (OAL&C) issued policy guidance and VHA increased its oversight of these awards, found that VHA achieved a competition rate of over 98 percent. These contracts, where VHA oversight processes generally ensured COs used competition and properly assessed bids, demonstrate how strengthened national and field-level acquisition oversight and governance structures can improve competition and reduce unnecessary sole-source contracting.

Although oversight improved compliance with FAR competition requirements, we found that COs were not performing adequate contractor responsibility determinations to mitigate possible risks to Recovery Act funds and to ensure VHA received the best value. Sixty of the 65 contracts (92 percent) we reviewed, valued at $83.1 million, lacked adequate contractor responsibility determinations. This occurred because guidance from OAL&C failed to include all elements required to make contract award responsibility determinations. Additionally, some COs did not address all the elements because they relied heavily on their prior experiences with prospective contractors, instead of checking the General Service Administration's Excluded Parties List System or obtaining reports to assess the contractor's current financial resources as required.

Federal Supply Schedule Contracts for Professional and Allied Services

Our June report, *Audit of VISN Procurement Practices for FSS Professional and Allied Health care Staffing Services (*Report Number 08–00270–162, June 7, 2010) found that health care services orders were not being adequately reviewed and had ordering and competition issues. Task orders issued by VA entities against these schedules totaled $339 million in FY 2009.

Review of these health care services orders supported that:

- Contracting officers had not adequately assessed Federal Supply Schedule (FSS) health care staffing services vendors' price quotes to ensure the reasonableness of prices.
- Contracting officers did not ensure labor rates for FSS health care services orders remained at or below FSS not to exceed (NTE) rates.
- Contracting officers did not effectively evaluate all-inclusive FSS health care staffing services orders to prevent improper payments. We found that improper payments occurred when order prices exceeded FSS NTE rates and FSS vendors received unsupported travel reimbursements.

Weaknesses related to ordering and competition issues included:

- Contracting officers did not ensure adequate competition when they failed to issue requests for quotations to a minimum of three FSS health care staffing vendors.
- Contracting officers did not adequately plan when they used local contracts to order health care staffing services even though the same vendors offered the same services for less on the FSS.
- Controls were not adequate to prevent Medical staff from bypassing contracting officers and making unauthorized commitments when they inappropriately placed orders directly with FSS vendors.

As a result we concluded that Veterans Integrated Service Network (VISN) procurement practices and ordering procedures are not consistently ensuring the proper, cost effective use of FSS health care staffing services contracts, the integrity of the FSS procurement process, and compliance with the FAR. We reported that strengthened FSS health care staffing services procurement practices could reduce VHA expenses and improper payments by at least $7.7 million annually or $38.5 million over the next 5 years.

A companion report also found similar systemic weaknesses in acquisition processes, *Review of Federal Supply Schedule 621 I—Professional and Allied Health care Staffing Services* (Report Number 08–02969–165, June 7, 2010). This report details how VHA paid more than fair and reasonable prices due in part to a failure by contracting officers at VA's National Acquisition Center to comply with FSS contract requirements and award contracts with fair and reasonable pricing.

Other Reports

Our inspection of the Brachytherapy program at the VA Medical Center in Philadelphia, *Health care Inspection Review of Brachytherapy Treatment of Prostate Can-*

cer, Philadelphia, Pennsylvania and Other VA Medical Centers (Report Number 09–02815–143, May 3, 2010), revealed that between 1999 and April 2005, the Medical Center inappropriately purchased services from the University of Pennsylvania without a contract in place. Since April 2005, the Medical Center was purchasing services under an interim contract that was issued and extended in violation of VA policy. The interim contract was inappropriately extended despite the fact that VA had received a proposal from the University for a long-term contract. Further, a pre-award review provided to the contracting officer showed that the prices being paid under the interim contract were significantly higher than what was determined to be fair and reasonable. In addition, we found that the COTR was approving payments without verifying that the services were provided and approving payments for engineering services that were outside the scope of the interim contract.

Our continuing health care inspections of the administration of Community Based Outpatient Clinic (CBOC) contracts have identified deficiencies in contract administration that have resulted in overpayments that may be uncollectible. The reviews found that COTRs were not complying with their responsibilities under the contract to notify vendors of patients who were disenrolled because they had not been seen within a 12-month period, had changed to another clinic, or who had died. Because payment under these contracts is set at a capitated rate, VA overpaid for veterans who should have been taken off the rolls. The inspections also found that COTRs were not consistently holding contractors accountable for meeting performance standards set forth in CBOC contracts. For example, at one clinic a COTR was required to assess the contractor's compliance with access to care and entry of medical data benchmarks on a quarterly basis and assess penalties for noncompliance. However, the COTR had completed only one assessment during the calendar year reviewed.[2] In a similar case involving a different CBOC, OIG inspectors found that the former and current COTRs on a CBOC contract did not assess whether the contractor met performance criteria and whether financial penalties applied.[3] Good administration of CBOC contracts is critical because VHA had more than 200 contracted CBOCs nationwide as of July 2009.

OIG Contract Review Work

Our Office of Contract Review (OCR) conducts pre-award, post-award, drug pricing, and special reviews of vendor proposals and contracts through a reimbursable agreement with VA's OAL&C. The majority of reviews are related to FSS contracts awarded by the VA National Acquisition Center for pharmaceutical, medical and surgical supplies, and equipment; and contracts for health care resources awarded by VA medical facilities. In FY 2010 to date, OCR completed 65 pre-award and 26 post-award reviews. The pre-award reviews identified more than $370 million in cost savings that could be achieved during contract negotiations and post-award reviews recovered more than $20 million for VA's Supply Fund.

Pre-award reviews are required for both FSS and health care resources proposals where the estimated contract costs exceed predetermined dollar thresholds. The pre-award reviews provide valuable information to assist contracting officers in negotiating fair and reasonable contract prices. Of the 65 pre-award reviews, 32 were for health care resource proposals. The potential cost savings for these proposals was more than $39 million.

OCR continues to identify information submitted by vendors that is not accurate, complete, and current that would result in VA paying inflated contract prices. Also, OCR continues to identify the lack of communication between procurement and program officials and inadequate planning as a management challenge for health care resources contracts. The lack of communication and poor planning results in higher and unnecessary contract costs because requirements have not been properly identified, the statements of work are inadequate, and the estimated quantities are overstated. We also routinely find that VHA's health care resources contracts lack adequate oversight provisions to ensure VHA receives the services it pays for.

Post-award reviews are conducted to determine if a contractor submitted accurate, complete, and current pricing data to the contracting officer during negotiations as required by the terms of the contract. These reviews also determine whether the vendor adhered to other terms and conditions of the contract such as the Price Reductions Clause. Post-award reviews include OCR's efforts to ensure pharmaceutical

[2] *Community Based Outpatient Clinic Reviews-Smithville, MS and Memphis, TN; Knoxville, TN; and Norton, VA; Chattanooga and Nashville, TN* (Report Number 10–00627–174, June 16, 2010).

[3] *Community Based Outpatient Clinic Reviews-Macon and Albany, GA; Beaver Dam, WV and Rockford, IL; Sioux City, IA and Aberdeen, SD; and Waterlook, IA and Galesburg, IL* (Report Number 09–01446–37, December 2, 2009).

vendors are in compliance with statutory drug pricing provisions contained in Section 603 of P.L. 102–585, *The Veterans Health Care Act of 1992,* which sets statutory price limits of covered drugs for VA, the Department of Defense, the United States Public Health Service, and the Coast Guard. OCR's post-award program is a significant factor in the success of VA's voluntary disclosure program where a vendor can disclose non-compliance with contract terms and conditions that resulted in the Government overpaying for goods or services and reimbursement agreements are established. These voluntary disclosures are typically resolved administratively but are referred to the Department of Justice if warranted.

Recent VA Actions

VA has made progress in the development of its acquisition workforce. VA established its Acquisition Academy in September 2008 to address growing acquisition workforce challenges. VA's acquisition workforce, consisting of COs, COTRS, and program/project managers, has lost institutional knowledge through downsizing and retirements and is trying to keep pace with the increasingly numerous and complex contracts needed to support VA's mission.

VA's recent implementation of an automated acquisition information system, eCMS, to monitor contracts and orders demonstrates the potential eCMS has to increase transparency and VA acquisition oversight capabilities at the local and national levels. However, we are continuing to find VHA and VA need to ensure that staff properly and consistently use the system across the country for all procurements at or above $25,000. Before VA can consistently rely on this acquisition information system to leverage its significant buying power, it must have assurance that the system provides adequate visibility and transparency over complete and accurate information.

Conclusion

VHA needs to ensure that its program offices and acquisition personnel are engaging in disciplined acquisition practices that consistently protect the Government's interests. VHA cannot realize its full buying potential unless it better ensures compliance with regulations and establishes visibility and transparency over purchases.

We understand that VA recognizes deficiencies in its acquisition processes and infrastructure and has taken steps to strengthen contracting practices. However, many of VA's reforms are still in the early process of planning and implementation. Our oversight will continue to provide valuable information to VA and Congress as VA pursues its acquisition initiatives. Future OIG work will focus on the effectiveness of VA's efforts to improve the skills and competencies of its acquisition workforce, program managers, and program staff serving as COTRs because the performance of these key personnel is critical to the improvements VA needs to make in its acquisition processes.

Mr. Chairman, this concludes my statement and we would be pleased to answer any questions that you or other Members of the Subcommittee may have on these issues.

Prepared Statement of Frederick Downs, Jr., Chief Procurement and Logistics Officer, Veterans Health Administration, U.S. Department of Veterans Affairs

Good morning Chairman Michaud, Ranking Member Brown, and Members of the Subcommittee. Thank you for inviting me to discuss the Veterans Health Administration (VHA) Contracting and Procurement practices.

Acquisition reform is a central piece of the Secretary's charge to fundamentally change the Department of Veterans Affairs (VA) in ways that will transform it into a 21st Century organization that is people-centric, results-driven, and forward-looking.

VA is in the process of developing a strategic roadmap to guide this acquisition transformation, while ensuring that we always remain focused on satisfying Veterans' needs and customer service expectations, while controlling costs. A central part of this effort is establishing an Integrated Operating Model for the Department to provide a strong management infrastructure across functional work domains. This will ensure that service delivery requirements are fully satisfied, necessary innovation and improvements are achieved, and accountability is fixed for performance outcomes at all levels throughout the Department. A top initiative under the Integrated Operating Model is the Department's Acquisition Transformation initia-

tive. VHA fully embraces the Secretary's transformation vision and the implementation of this Integrated Operating Model.

VA is committed to providing the most advanced, creative, and innovative technologies to meet the needs of our Veterans. Within VHA, our health care experts are directly involved in patient care and provide input on current practices, while developing technical knowledge to drive the selection and purchase of new technologies. As new technologies become available, VHA staff members from clinical, logistics and acquisition disciplines form a team to carefully review potential applications before determining which advances to adopt. VHA leadership is committed to obtaining the most advanced and innovative technologies while improving the guidance, oversight, and business processes associated with contracting and procurement in the delivery of services to our Veterans.

My testimony today will cover VHA's recent reorganization of contracting and procurement processes, highlighting the strengths of our program. I will also touch on issues of particular interest to the Subcommittee, including the use of purchase cards at VHA medical centers. Finally, I will conclude with a brief discussion of how VA uses innovative technologies to better serve Veterans.

Reorganization of VHA Acquisitions

VHA continues to transform and improve its acquisition operations. This year we have implemented a new acquisition business model that promotes centralized decision-making and decentralized execution. VHA has realigned its acquisition staff under a centralized structure with three regional offices. These regional offices will concentrate on running an acquisition organization with a deliberate approach to training and oversight. The four major focus areas of our organization are:

1. Customer and stakeholder satisfaction;
2. Operational regional service area offices;
3. Performance monitors; and
4. Seamless transition.

VHA's primary goal in reorganizing its acquisition operations is to transform into a customer-focused organization through the effective and innovative use of acquisition policies, procedures and processes to provide the best possible care to our Veterans and reduce the risk of patient safety. Veterans Integrated Service Network (VISN) Directors and the Network Contract Managers will collaboratively prepare Customer Service Agreements. The agreements will focus on establishing customer service measures that meet the intent of regulations established in the Federal Acquisition Regulation (FAR) and Veterans Affairs Acquisition Regulation (VAAR) while simultaneously providing excellent customer service and patient care. VHA leadership has communicated clear expectations for each acquisition organization and provided appropriate training to staff to ensure they are competent and effective leaders within the organization.

All acquisition personnel previously reporting to the VISN or Medical Center Directors have now been realigned under the Procurement and Logistics Office (PL&O). This Office has created three Service Area Offices based on geographic location: Pittsburgh, PA, Minneapolis, MN, and Sacramento, CA. VHA has created several goals for these Service Area Offices:

- Achieve cost savings of 3.5 percent in fiscal years 2010 and 2011, as identified in the Office of Management and Budget's (OMB) Improving Government Acquisition Initiative;
- Enforce standardization of contract requirements; and
- Establish staff as business consultants and value-added team members for VHA.

To achieve the cost savings goal, VHA will leverage its buying power by combining procurements across the country to obtain more favorable pricing and discounts. VHA also intends to reduce the administrative costs associated with Interagency Acquisitions, for example the requirements sent to the Army Corps of Engineers, by bringing these services back into VHA. VHA has further stepped up efforts to decrease the use of sole source and other high-risk contracts, focusing instead on increasing competition and securing better prices. This reorganization will help ensure fiscal responsibility for the Department and for the American taxpayer. This structure allows the VHA PL&O to drive organizational standardization and individual performance, while promoting direct responsibility and accountability through a professional certified workforce.

VHA's reorganization also included developing quality assurance and compliance programs to promote standardization and greater compliance with Federal regulations and policies. The quality assurance program is designed to plan, implement,

monitor, identify and correct processes. It establishes checks and balances as required by the VA Office of Acquisition and Logistics Information Letter 001AL–09–02, Integrated Oversight Process, dated June 19, 2009. The overall goal is to implement an oversight process that is efficient in how time and resources are allocated and effective by holding acquisition professionals responsible for building quality into the acquisition process.

The VHA Operations Quality Assurance Office provides direct oversight to VHA acquisition activities and conducts yearly site visits to Service Area Offices. The Quality Compliance Office provides the Chief Procurement Office a comprehensive assessment of the entire acquisition program, not just individual procurement actions. The compliance program's key elements include: (1) organizational management; (2) human capital; (3) acquisition planning and information management; and (4) contracting. The goals of the quality compliance program are to ensure compliance with VA policies, procedures and regulations; determine if the processes are helping us achieve our stated objectives; validate our processes and discover "best practices" to improve our business model; and establish an ISO9001:2008 Quality Management Standards organization. ISO9001:2008 is a family of standards for quality management systems developed by the International Organization for Standardization. Combined, the Quality Assurance and Quality Compliance programs will provide oversight necessary for VHA to become a world-class professional acquisition organization. In sum, this reorganization improves oversight, performance, and customer service, and ensures VA policies and procedures are followed. All of this contributes directly to achieving the Department's mission and improving patient care.

Purchase Cards

As part of the overall VHA acquisition reorganization, VHA is establishing a centralized purchase card program under the Network Contract Managers. VHA's PL&O has implemented VISN Purchase Card Manager and Purchase Card Coordinators to monitor all credit card transactions within a VISN. These coordinators previously reported to their own facility. Reporting to centralized Network Contract Managers increases oversight of the facility level. Under the existing structure, most purchase card coordinators fulfill this responsibility as a collateral duty and do not report to an acquisition professional. Full-time, dedicated VISN Purchase Card Managers and Purchase Card Coordinators will conduct daily reviews of transactions, increase the number of audits and other reporting mechanisms for oversight, and will be dedicated to monitoring the purchase card program.

Based on an audit of VHA government purchase card practices issued in 2008 by VA's Office of the Inspector General, VHA implemented training to approving officials on using the revised approving official checklist to ensure cardholders maintain adequate documentation to support their purchases. On February 18, 2010, the Deputy Under Secretary for Health for Operations and Management mandated that all purchase card approving officials receive this training. Each VISN Purchase Card Manager submitted written certification when the training was complete. Moreover, to monitor the appropriate use of purchase cards, VHA Handbook 1730.1 requires the Facility Director to perform an annual review of the Purchase Card Program and provide certification of the program to their respective VISN Director by June 30 of each year. The Handbook also requires the VISN Purchase Card Program Managers chair an annual review team and conduct site reviews at each facility within their area of responsibility. Managers conduct reviews using several audit guides in addition to the requirements identified in the 1730.1 Handbook. VHA's P&LO is developing standard operating procedures that address cardholder audits and site reviews, and these tools will be the standard practice for all VISNs.

Health Care Resources

VHA provides care to Veterans directly in a VHA facility or indirectly through either fee-basis care or through contracts with local providers. This strategic mix of in-house and external care provides Veterans the full continuum of health care services covered under our benefits package. VHA health care resource contracting is accomplished under the provision of VA Directive 1663, "Health Care Resources Contracting." VA's Directive 1663 further implements provisions of Public Law 104–262, "The Veterans Health Care Eligibility Reform Act of 1996," which significantly expanded VA's health care resources sharing authority in title 38 United States Code (U.S.C.) sections 8151 through 8153.

VHA medical center directors and VISN directors determine when additional health care resources are required. It is VHA policy to provide Veterans care within the VA system whenever feasible. However, there are times when VHA is unable to provide care within the system. For example, VHA may have difficulty recruiting

a qualified clinician. In these cases, the medical center director must first consider sending patients to another VHA medical center. Contracting for necessary services will only be considered if other options within VHA are not appropriate or viable. If contracting for services is required, a competitive bid is the first option considered.

There are two principal avenues to contract for health care services: conventional commercial providers and academic affiliates. VHA's academic affiliates (schools of medicine, academic medical centers and their associated clinical practices) provide a large proportion of contracted clinical care both within and outside of VHA. All non-competitive VHA health care resource contracts $500,000 or more and competitive contracts over $1.5 million are reviewed through a thorough process that includes the Office of General Counsel (for legal sufficiency), VHA's Patient Care Services (for quality and safety), VHA's Office of Academic Affiliations (for affiliate relations assessment), and VHA's PL&O (for acquisition technical review for policy compliance).

VHA exercises its responsibility to provide quality contracted care to Veterans through several clinical and administrative oversight mechanisms. This includes credentialing and privileging, quality and patient safety monitoring, and specific quality of care provisions included in the contract itself. Facility directors are responsible for ensuring that these oversight mechanisms are consistently and effectively applied to all in-house contracted care. All applicable VHA quality and patient safety standards must be met for medical services provided under contract in a VHA facility. Ensuring quality standards for VHA contracted care outside of a facility is more difficult, but VHA includes language in contracts that allows for industry standard accreditation or certification requirements, clinical reporting, and oversight. The Office of Acquisition, Logistics, and Construction is in the process of developing policy to implement Federal Acquisition Certification (FAC) for Contracting Officers' Technical Representatives (COTR). The new guidance will requires training to maintain or be designated as a COTR. This will further help ensure health care staff are well-trained to manage important health care contracts.

VHA Logistics

VHA's P&LO also develops and fosters best practices in logistics for VHA. Through the VHA Acquisition Board, P&LO develops the annual VHA Acquisition plan that forms the basis for VHA's acquisition strategy. This strategy seeks to procure high quality health care products and services in the most cost effective manner. P&LO develops and implements a comprehensive plan for the standardization of health care supplies and equipment. This includes developing and administering clinical product user groups. P&LO is also responsible for improving supply chain management within VHA, which includes establishing and monitoring logistics benchmarking data. P&LO serves as the liaison for logistics staff in each of the 21 VISNs.

VHA's supply chain processes utilize the Integrated Funds distribution Control Point Activity, Accounting and Procurement (IFCAP) module that includes a Generic Inventory Package (GIP). The GIP system fully integrates and allows for a seamless relationship between purchasing and expendable supply inventory. Use of GIP allows logistical managers to automate inventory practices that track expendable items from purchase until use by the end user. VHA tracks over 1,300 inventories consisting of 928,816 line items. The inventories include medical, surgical, dental, imaging, and laboratory supplies, as well as engineering and environmental management supplies.

VHA classifies equipment as non-expendable or expendable and tracks this equipment in the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS). For AEMS/MERS, this includes tracking the location of equipment, maintaining ownership, and submitting a work order as needed. VHA currently tracks over 17,000 equipment lists, which make up 2.1 million pieces of equipment. Through the 3rd quarter of fiscal year 2010, VHA has inventoried 13,000 of these equipment lists, ensuring that equipment is found and being used properly. The remaining 4,000 lists are expected to be inventoried in the 4th quarter of 2010.

VHA continues to make improvements to the lifecycle management of equipment and expendable supplies. These improvements have included updating policies and procedures over the last 2 years, providing new training programs for logistical staff, improving oversight through management reports on equipment, and strengthening communication channels with stakeholders in engineering, bio-medical engineering, and information technology.

Medical Equipment in VHA

VHA has approximately $5 billion worth of medical equipment in service at more than 1,400 sites of care with over 750,000 discrete devices in hundreds of different categories. VHA centralized the responsibility for medical equipment maintenance, including all equipment in all clinical departments, within Biomedical Engineering (BME). BME provides corrective maintenance, periodic maintenance and training, and education to ensure safe, high quality care. BME works directly with clinicians, logisticians and acquisitions staff to facilitate the strategic purchasing of equipment. BME strategically identifies equipment due for replacement, conducts market research, defines functional requirements with clinicians, writes specifications and statements of work, leads in the technical evaluation of proposals and is the contracting officer's technical representative (COTR) on contracts. When combined with our logistics and centralized procurement functions, a VISN-focused BME program is allowing VHA to improve its maintenance and technology management, realize cost savings, and strategically lead VHA to provide the best health care possible to our Nation's Veterans.

Conducting Business with VHA

VHA's mission is to honor American's Veterans by providing exceptional health care that improves their health and well-being. VHA will continue to use and support new and innovative technologies to enhance the quality of life for Veterans. Providing service, supply and construction acquisitions are central to VHA's success in meeting its mission. We purchase these goods and services on national, regional, and local levels. Acquisitions are accomplished by sealed bidding, negotiation, or simplified acquisition procedures. Purchases are accomplished through the use of mandatory sources such as VA's Federal Supply Schedules Parts 65 and 66. A significant portion, however, is acquired from sources obtained through the publication of solicitations in the Federal Business Opportunities (FedBizOpps), commercial advertising, or any other accepted means that will provide the procuring activity with a sufficient number of responsible bidders and offerors to ensure full and open competition. The most suitable, efficient, and economical procedure will be used, taking into consideration the circumstances of each acquisition.

Conclusion

Mr. Chairman, this concludes my statement. Thank you again for the opportunity to speak about VHA's reorganized contracting and procurement functions. Our recent reorganization establishes more accountable business practices that allow VHA to continue to provide the highest quality of care for our Veterans at the best rate of return for the American taxpayer. I am prepared to respond to any questions you or the Members of the Subcommittee may have at this time.

The Coalition for Government Procurement
Washington, DC.
September 20, 2010

The Honorable Michael H. Michaud
Chairman, House Veterans' Affairs Subcommittee on Health
338 Cannon House Office Building
Washington, D.C. 20515

Re: Hearing on "VHA Contracting and Procurement Practices" before the Subcommittee on Health of the U.S. House of Representatives Committee on Veterans' Affairs

Dear Chairman Michaud:

On behalf of the Coalition for Government Procurement (Coalition), I am writing to thank you for your offer to submit for the record the Coalition's views on contracting with the Department of Veterans Affairs (VA). We submit our remarks for the hearing on "VHA Contracting and Procurement Practices" before the Subcommittee on Health of the U.S. House of Representatives Committee on Veterans' Affairs on September 23, 2010.

The Coalition for Government Procurement (CGP) is a multi-industry association representing over 330 member companies that sell commercial products and services to the Federal Government, including pharmaceutical and medical device manufacturers that sell commercial products to the Federal Government primarily through the Federal Supply Schedules administered by the VA under a delegation of authority from the General Services Administration (GSA).

We are writing today based on our members' experiences with the VA National Acquisition Center (NAC). Three years ago we reached out to the VA NAC with concerns about the timeliness of contract actions and the significant delays our members were experiencing. At that time, we were told by VA officials that they had just gone through personnel changes and to please give them time to adjust. We agreed to give NAC officials time to reorganize and bring new hires up to speed.

Our members have been patient and since then have experienced reorganization at the VA NAC designed to improve efficiency. Today, however, the VA NAC remains among the slowest contracting centers in government acquisition. The length of time needed to negotiate Federal Supply Schedule (FSS) contracts and contract modifications has worsened not improved, and is particularly slow when compared to FSS contract actions at the General Services Administration.

The Coalition has enjoyed strong relationships with VA officials at the VA NAC and here in Washington, DC, and has discussed with them our concerns. However, VA officials in Washington have been reluctant to meet with us, despite our members accounting for a significant amount of the business that runs through the VA NAC. By comparison, the Coalition regularly meets with officials from GSA concerning the Schedules program that GSA administers.

Last year, the VA NAC reorganized in an effort to resolve problems with the length of time it takes to process contract actions, including awards and modifications. In order to streamline the process and prevent backlogs, the VA changed the system of assigning contracting officers from one in which contracting officers were assigned to contractors for the life of the contract, commencing with pre-award negotiations. Under the reorganization, the contracting officer assigned to negotiate the contract has no responsibility for administering the contract. Post-award, the contracting officer processing a modification request or answering a question is the next available one, not the same one, much like a call-in center, and thus there is no familiarity with the contractor or continuity of service.

Survey Results

The Coalition surveyed all of our health care members doing business with the VA regarding their experience with the VA NAC since the reorganization. All ratings were made in comparison to members' contracting experience prior to the reorganization. Over 40 members responded. These companies account for well over half of the total sales made through NAC FSS contracts. As such, we believe that these results show that the NAC currently cannot keep pace with innovations and new products that could have a significant impact on the care provided to veterans. Based on the survey results, there is no question in our members' minds the VA NAC is broken.

A summary of the survey results are below:

- 85 percent said the VA NAC was more efficient before the reorganization
- Over 75 percent said the timeliness of VA NAC Contracting Officers in responding to their questions regarding the administration of their contract was below average or poor
- 74 percent said the timeliness of VA NAC Contracting Officers in responding to their needs was below average or poor
- 75 percent said their experience in adding products or services to their contract was below average or poor
- 66 percent said their experience with the VA NAC concerning contract modifications was below average or poor
- 46 percent said the original award process took over 1 year
- 48 percent said it took over 6 months for their last modification request to be processed
- Over 50 percent said the knowledge level of the Contracting Officers assisting them was below average or poor
- 59 percent said their experience in adjusting prices on their contract was below average or poor
- Over 78 percent ranked their overall experience with the VA NAC as below average or poor

Reform

Clearly, there are opportunities for procurement reforn1 at the VA NAC. First, we would encourage the Subcommittee to look at management of the NAC. Our members did not experience the contracting issues expressed in the survey results previously. It is worth noting that at least one prior NAC Executive Director was a pharmacist at the VHA, came up through the FSS program ranks, and understood how the program worked. After the prior Executive Director left, there was

a 2-year long search tor his replacement. The problems began in the past three to 4 years since his departure and have been exacerbated by the reorganization.

In fairness to the NAC, in our view, one of the primary reasons the procurement system at the NAC is broken is the inappropriate insertion of the VA Office of Inspector General (OIG) into the contracting process. We believe the OIG has an important and necessary role to play in preventing fraud and abuse and assisting the Contracting Officers' determination of fair and reasonable prices. That role does not include serving as a defacto program manager looking over the shoulders of Contracting Officers and second guessing their decisions to award contracts. Particularly with respect to pre-award audits, the OIG should be in a supportive role and not assume primary price negotiation and decision-making responsibility. In short, the OIG should not have operational responsibility, but that is what the case is here.

The Coalition is very familiar with the role of the GSA OIG and regularly interfaces with that office. In our experience, the GSA OIG acts within the customary role of an IG. As a result, contracting officers at GSA are more willing to work with contractors and are far more flexible regarding the supporting documentation necessary for them to establish fair and reasonable prices. We believe it is the VA's requirement for pre-award audits on most FSS contracts and contract modifications, and the usurpation by the VA OIG of the contracting officer's role as the determinator of fair and reasonable prices that is the cause of the sustained delays in contract actions at the NAC.

Our survey results are clear on this issue. When asked "In your negotiations with the VA, what did your CO rely on?", many members said the VA OIG Pre-Award Audit. We hear frequently from our members that after receiving and accepting an offer from a Contracting Officer, the OIG will step in and make the Contracting Officer withdraw the offer. There will never be true reform unless the VA OIG understands its role and operates appropriately.

A final issue of concern is the grade of VA Contracting Officers. Our understanding is that VA CO's are one grade below the level of their colleagues in other agencies. This makes it difficult for the VA to retain experienced, senior level contracting officials. The VA should give serious consideration to increasing the grade of its Contracting Officers in order to attract and retain high caliber personnel.

Recommendations

1. The VA should reconsider the reorganization of the NAC
2. The VA OIG Must Operate appropriately, and not as a defacto program manager
3. The VA should increase the grade of its Contracting Officers

The Coalition appreciates the opportunity to provide input on this important topic.

Sincerely,

Larry Allen
President

Statement of Hon. Bart Gordon, a Representative in Congress from the State of Tennessee

Thank you, Chairman Michaud and Ranking Member Brown, for holding this important hearing on the Contracting and Procurement Practices of the Veterans Health Administration. As I am not a member of this committee, I appreciate the opportunity to submit my statement and questions for the record.

The VA Consolidated Mail Outpatient Pharmacy (CMOP) program is an important resource for our veterans. The program provides mail order refills of prescriptions to veterans using advanced automated systems at seven facilities located throughout the country. This provides an efficient, effective and safe manner for our veterans to receive the medication they need without having to leave home.

I am submitting this statement today to seek clarification of the VA's decision to switch from blister pack to bottle delivery in the distribution of medication through the Mid-South CMOP. My primary concern is ensuring the VA conducts the most efficient and effective policy for all United States veterans and taxpayers.

Seven years ago, Murfreesboro Pharmaceutical Nursing Supply (MPNS) was awarded a contract with the Mid-South CMOP to supply veterans in the region with

the delivery of medication through the outpatient program. MPNS was specifically contracted to supply this medication in blister packs because, at that time, the VA determined them to be safer and more efficient for the veteran and the delivery process than the traditional method in a 120cc bottle.

The contract has been extended six times but expired January 31, 2010. In May of this year, the VA announced it would no longer provide this medication in blister packs, but instead would switch to bottles.

Seven years ago, MPNS advised the VA and was later contracted specifically to provide blister packs. Blister packs maintain the integrity of the medication during transport, and avoid theft by being less-easily detected during delivery. Over these years, MPNS has provided a cost efficient and effective service without issue.

Why now, in 2010, is the VA changing a process that has worked effectively? An individual analysis by the company estimates it can save the VA more than $300,000 per year by continuing to provide the medication under existing procedures.

Three weeks ago, I asked for documentation of the business case review that was cited by the VA as a reason for changing its existing policy to use blister packs. On September 22, I received a chart of final numbers showing differences between the CMOP automated fill procedure and the MPNS manual fill. I have yet to receive any documentation of the methodology used in determining these numbers, and I am requesting it again now.

This is one small instance in an incredibly complex system. If the VA feels a change in policy is prudent, I respect and applaud that decision. But before we change procedure, we must be sure that this change is necessary and warranted. My concern is that this change will not only cost jobs, but also cost the taxpayers and veterans.

Statement of Richard Reeves, Chief Executive Officer, Murfreesboro Pharmaceutical Nursing Supply, Murfreesboro, TN

Mr. Chairman and Members of the Subcommittee, on behalf of Murfreesboro Pharmaceutical Nursing Supply (MPNS) located in Murfreesboro, TN, and its 20 employees, I am pleased to submit the following statement for the record.

At the outset, I want to commend you and the Subcommittee for holding this important hearing. As a Veteran, I truly believe that our collective effort to provide the brave men and women who fight on behalf of our country with the best quality health care is one of our most fundamental responsibilities. Having been a proud participant in the contracting process that delivers medication to our Veteran's, I am pleased to see the Subcommittee take a comprehensive view of the Department of Veteran's Affairs (VA) contracting practices.

As a matter of background, MPNS was founded in 1982 to provide pharmacies a user-friendly solution to regulatory changes in the long-term care industry. The solution MPNS brought to the table was providing long term care pharmacies FDA compliant and cGMP adhering repackaged unit dose medications in a universal format from a centralized closed door pharmacy.

In 2003, the VA, and in particular the Consolidated Mail Outpatient Pharmacy (CMOP) approached MPNS to provide recommendations and advice on more effective formats for the delivery of medication than traditional 120cc bottles. The VA had grown concerned that this particular medication (for erectile dysfunction) was not being delivered in the most optimal nor cost effective manner. We concurred!

Seems that this particular medication was only to be delivered in doses of 2, 4 or 6 pills and in a 120cc bottle. In the course of delivery, it sounded as though there were 6 marbles in a bottle, making the medication a prime target for tampering or theft and re-sale.

MPNS recommended going with a solution of blister packs. This delivery method would meet the standards of the CMOP in correcting their concerns and also save significant revenue for the VA that we would hope would be directed to other programs for our Veteran's returning from combat. For the past 7 years, the Mid-South CMOP has been the only one utilizing this automated method and MPNS has been providing the service with no complaint.

Mr. Chairman, the use of blister packs with pharmacies is a crucial delivery method that should be considered for all medications and with each CMOP. I first recommended this method to the CMOP not for my own purposes, but because it is simply the safest and most economical format for the delivery of medication under any circumstance.

The following are just a few of the key issues comparing blister pack delivery to bottle delivery:

A 120cc vial (bottle) costs the CMOP 60–65 cents per prescription due to the added cost of the bottle. This is twice the amount of the blister pack. The blister pack is priced based on a per tablet charge of 8 cents. Delivery of the medication was based on packages of 2, 4 or 6 tablets per childproof vial. Most deliveries averaged 4 tablets for an average cost of 32 cents per delivery. At no time should a delivery in this scenario exceed 48 cents. From our experience with ED medication and based on 1 million deliveries, using blister packs can save the VA around $300,000 annually. There will be times when the delivery of medication will include medication that far exceeds our example, making the bottle delivery more cost effective. However, for smaller deliveries, the CMOP should not give up it's ability to provide medication on a per pill cost and utilize a more effective means of delivery of that medication.

In addition to the cost of the medication, you must consider the integrity of the medication. In some cases the dosage can be diminished in the delivery process if it is chipped as a result of the medication rattling in a bottle. This issue also addresses discretion related to the mailing of the product. One of the participating factors in the Mid-South CMOP using blister packs had been an issue of discretion and concern over theft.

Finally, every year, millions of prescription bottles find their way into our landfills. VA should be taking a responsible look at ways they can decrease their participation in this issue by finding more environmentally responsible formats of delivery such as blister packs.

Mr. Chairman, our goal today is to inform you of this issue. We respectfully request that the Subcommittee work with the VA to develop a plan for all upcoming procurements through the CMOP to utilize blister packs wherever possible. Further, we believe that the VA should use its upcoming CMOP procurements to test automated blister pack delivery against automated bottle delivery methods between two willing CMOP's to determine which method is more cost effective.

Thank you.

MATERIAL SUBMITTED FOR THE RECORD

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Mr. Mark Munroe
Senior Vice President, Sales and Marketing
Mobile Medical International Corporation
P.O. Box 672
2176 Portland Street
St. Johnsbury, VT 05819

Dear Mr. Munroe:

Thank you for your testimony at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?
2. To what do you attribute the notable differences in your contracting experiences with the Muskogee, Miami, and New Orleans VAMCs? You cited strong leadership at the Muskogee VAMCS. Have there also been specific policies that may have contributed to these very different experiences?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

U.S. House of Representatives—Committee on Veterans' Affairs
Subcommittee on Health
"VHA Contracting and Procurement Practices"
September 23, 2010
Mobile Medical International Corporation
Response to Questions

Question 1: Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?

Response: Yes. There are a number of standards which MMIC would recommend be implemented to help facilitate and improve the contract in process. They are:

1. Standards initially need to be developed that take into consideration the medical requirements at all VA medical centers.
2. Standards need to be religiously followed and not be deviated from without proper documentation.
3. Quality of care for our veterans needs to be placed at the top of those standards.
4. During any acquisition process an acquisition plan needs to be developed. That plan needs to be followed and plan should be the same across all Medical Centers.

Question 2: To what do you attribute the notable differences in your contracting experiences with the Muskogee, Miami, and New Orleans VAMCs? You cited strong leadership at the Muskogee VAMCS. Have there also been specific policies that may have contributed to these very different experiences?

Response: At the Muskogee VAMC strong leadership was the key. However, Muskogee's use of an acquisition plan that was not only developed across all divisions, but also followed by each division was forefront in their success. A policy

which requires each medical center to develop and follow such a plan should be implemented. Contents of a sample plan are attached to this response.

Additionally, health and safety of all Veterans serviced was placed at the forefront in Muskogee. During an open solicitation for a solution, Muskogee leadership did not waiver from the following requirements that the chosen solution:

1. Have a history of success at other VA and government owned Medical Centers
2. Demonstrate a history of:
   a. JCAHO accreditation
   b. Medicare Certification
   c. State Licensure

Acquisition Plan

Acquisition Background and Objectives

Statement of Need
Cost
Capability or Performance
Delivery or Performance-Period Requirements
Trade-Offs
Risks

Plan of Action

Sources
Competition
Source-Selection Procedures
Acquisition Considerations
Budgeting and Funding
Product or Service Descriptions
Contractor versus Government Performance
Inherently Governmental Functions
Management Information Requirements
Test and Evaluation
Logistics Considerations
Contractor Access to Federally-Controlled Facilities and/or Information
Contract Administration
Other Considerations
Milestones for the Acquisition Cycle
Acquisition Plan Preparation Participants

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Mr. Derek Newell
President
Robert Bosch Healthcare
2400 Geng Road, Suite 200
Palo Alto, CA 94303

Dear Mr. Newell:

Thank you for your testimony at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?
2. In your testimony, you noted that home health device companies contracting with VA may need to make an investment, such as installing hardware, without any certainty as to how many units of the device VA will purchase. How does VA currently address this concern of prospective contractors?
3. In your testimony you mentioned that companies such as Bosch often do not understand the innovations that VA is looking for until a solicitation is issued. Can you please expand on the benefits that the innovation grants can have for

remedying this gap between the VA and prospective contractors? What other measures might VA take?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Bosch Healthcare Responses to Veterans Health Subcommittee Questions
November 15, 2010

Question 1: Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?

Response: As the largest health care provider in the Nation, the VHA is a leader in the establishment and use of new and innovative care technologies, such as telehealth. As a result, the private health care system often follows the VHA's lead in the use and deployment of these technologies. Vendors routinely offer the VHA the newest and most cutting edge technologies, often developed prior to a private sector demand—making the VHA the first customer for new technologies and products. However, the VHA's Federal Supply Schedule contracts contain sales provisions that require prior sales of devices in the commercial sector. This is problematic because, as noted earlier, the commercial sector often follows—rather than leads—the VHA's vision for and procurement of new technologies. Therefore, Bosch Health care recommends that the VHA develop a contracting mechanism that would allow and encourage VHA adoption of new technologies without provisions requiring prior commercial sales.

Question 2: In your testimony, you noted that home health device companies contracting with VA may need to make an investment, such as installing hardware, without any certainty as to how many units of the device VA will purchase. How does VA currently address this concern of prospective contractors?

Response: Our experience has been that VA is attempting to address this concern through monthly contracting fees (per patient per month) where investment costs are incorporated into the "General Services" fees. In theory, this practice could work; however, the VHA generally is only willing to guarantee a minimal number of devices for purchase. Thus, the number of devices that VHA is willing to guarantee falls short of the number needed to minimize the investment risk of its partners. We recommend that when entering agreements, the VHA work with its vendors to jointly establish the number of devices that is sufficient to incentivize private sector investment without placing undue burden on the VA budget.

Question 3: In your testimony you mentioned that companies such as Bosch often do not understand the innovations that VA is looking for until a solicitation is issued. Can you please expand on the benefits that the innovation grants can have for remedying this gap between the VA and prospective contractors? What other measures might VA take?

Response: The Innovation Grants are a good start to a partnership with the private sector to spur development and testing of innovative products and methodologies. However, this type of endeavor is more suited for the innovations of industry rather than fulfillment of the VHA's vision. As a result, we believe another approach is also in order—one that would allow the VHA to share its vision of the tools, devices, methodologies, and processes that are needed for next generation health care.

Such an approach would include a complete technology roadmap consisting of VHA's vision, its short- and long-term goals, and its ideas about specific technology solutions that would meet those goals. In turn, this would create the clarity and transparency needed for vendors to address the VA's specific needs and plan for the future. This challenge can be achieved by VA communicating more frequently with its industry partners, and should include (1) a focus on the health specialty or VHA product line in question, (2) what VHA believes is currently working or not working in that area, and (3) its "wish list" for future product development.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Mr. Lincoln Moss
Senior Vice President and Chief Operating Officer
Ramtech Building Systems
1400 U.S. Highway 287 South
Mansfield, TX 76063

Dear Mr. Moss:

Thank you for your testimony at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?
2. In your contact with VA, what opportunities have you had to express your views on the merits of moving from a design-bid-build approach to a design-build approach, or other changes in the procurement process that you feel would represent an improvement?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Modular Building Institute
Committee on Veterans' Affairs, Subcommittee on Health
United States House of Representatives
Follow-Up Questions on VHA Contracting and Procurement Practices
Wednesday, November 3, 2010

Question 1: Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?

Response: The primary focus of our testimony on VHA Contracting and Procurement Practices was the advantage to the Department of Veterans Affairs that a Design-Build project delivery system offered over traditional Design-Bid-Build. We are firmly convinced that by adopting a culture that embraces Design-Build, the VHA will achieve greater efficiency and value in future construction projects.

Not only are there less "moving parts" to the process, this approach allows alternate forms of constructions to participate, potentially increasing value even further. As an industry, MBI understands it is vitally important that veterans play an active role in the Contracting process when it comes to working with the Department of Veterans Affairs and the VHA. It is our goal to ensure that when it comes to construction projects, veteran involvement increases. It is our belief that the VHA and the VA, in general should incorporate the changes discussed in our September 23rd Testimony to maximize veteran involvement.

If this simple but fundamental construction policy was changed it would reflect greater opportunities for design-build contractors, who, in turn, would be able to partner with veteran-owned businesses to complete projects.

Undoubtedly, one of the top goals of the VA is to ensure that there are increased contracting opportunities for SDVOBs with the VA. To that end, MBI feels this one change could greatly increase SDVOB participation in construction projects.

Question 2: In your contact with VA, what opportunities have you had to express your views on the merits of moving from a Design-Bid-Build approach to a Design-Build approach, or other changes in the procurement process that you feel would represent an improvement?

Response: While MBI has reached out to the Department of Veterans Affairs, Office of Construction on this matter, to date, we have not received a response to our request for a meeting to discuss the current construction policies within the VA. MBI remains committed to working on this issue through all appropriate channels and is continuing to pursue the VA to discuss this matter in greater detail.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Jay Wise, Ph.D.
Chief Executive Officer
Wise Knowledge Systems, Inc.
6210 Bear Creek Road
Pipe Creek, TX 78063

Dear Dr. Wise:

Thank you for your testimony at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?
2. In your testimony you cited leadership concerns with bearing on the VA contracting and procurement process. In addition to these concerns, are there structural or policy barriers that have played a role in your experience with VA?
3. Has the KBES been tested and deployed? If so, where? What were the results?
4. What do you think would be the best application of the medical KBES for the VA at this time?
5. What evidence do we have that KBES could materially support the VA in its attempt to improve diagnosis and treatment of Traumatic Brain Injury?
6. Is KBES being used in military medicine now?
7. What do you recommend that VA do with your KBES technology?
8. Why do you believe that VA failed to acquire KBES after some staff had initially positively discussed its potential use in the VA system?
9. Did VA promise you a contract?
10. What would it cost and how long would it take for VA to contract with you?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Questions and Responses for Chairman Michaud: Wise Knowledge Systems
Dr. Jay Wise
For Chairman Michaud

Question 1: Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?

Response: The first most important recommendation would be to install and support individuals who have a real interest and energy for helping our veterans, rather than dismissing promising technology because ***"nobody at the VA wants to work".***

Secondly, you might consider the advantage of installing an ad hoc panel of scientists to evaluate technologies presented to the VA/VHA. These would need to be "honest third party" individuals whose central concern is the welfare of our vet-

erans. Please note that WKS was told that they did not need to go thru the evaluation procedure because we were a proved technology used in the DoD, years ago, when Wise Knowledge Systems (WKS) first contacted the VA! Had WKS had that opportunity, much of this unfortunate history might have been avoided.

Question 2: Leadership concerns and obstacles to VA contracting and procurement processes. Structural and policy barriers.

Response: Again, the policies of the VA, while not entirely understood here at WKS, seem sufficient to provide the VA/VHA with strategically sound technologies.

The key issue is that individuals such as **Dr. Paul Tibbits, CIO of the VA**, and **Ms. Lloyd of the VHA**, and others, seem both overwhelmed by the "portfolio" of technology they deal with, and the situation they ***repeatedly reported: "the VA is broken and nobody here wants to work".***

Question 3: Has IKBES been tested and deployed? If so, where? What were the results?

Response: Please see our written testimony for the documents that support the successes in application, deployment, and testing for KBES. Please **especially note** the correspondence from Joe Goodin of the Navy.

A full description of the architecture, application, and results of application of KBES is available to you on request.

KBES has received positive test validation and deployment successes in **active military operations** with the Navy SMART (Shipboard Medical Administrative Readiness Tool). We refer you to the letter from Joe Goodin of the Office of Naval Operations. Additionally KBES medical applications have received validation and praise in application in the private sector in cardiac care optimization, neonatal disease mapping, juried scientific journals (**please refer to our written testimony**), and is part of the collection at the Smithsonian Institute. As deployed, the KBES analyses are proven to be 95 percent accurate, or better, in providing decision support and optimizing medical outcomes.

Wise Knowledge Systems, Inc. has received positive praise following analysis of KBES technology by:

Paul Tibbits, M.D.—Veterans Administration
Roy Pratt—-HP
Joe Goodin—Office of the Chief of Naval Operations
The Smithsonian Institute
Dr. John Sharp—UMKC School of Medicine
Frank Sisti—Software Engineering Institute
Dr. Dale Alverson—Telemedicine Director, University of New Mexico
Ciro Rodriquez—U.S. Congress, House of Representatives
W.C. Vanderwagen, M.D.—Indian Health Service
Wendell Porth—St. Luke's Lutheran Hospital
Bill Silva—Dyncorp
Wise Knowledge Systems, Inc. clients, since 1985

Question 4: What do you think would be the best application of the medical KBES would be for the VA at this time?

Response: WKS feels that the most strategically significant and efficient se of the medical KBE at this time would be to be deployed in support of the emerging science associated with **Combat Related Traumatic Brain Injury (CRTBI).** An SOW and details for this deployment were provided, repeatedly, to **Dr. Tibbits** who agreed that there could be great benefit from KBES supporting the work on CRTBI, and then changed his focus to another project when he **"could not find a customer".**

Question 5: What evidence do we have that KBES could materially support the VA in its attempt to improve diagnosis and treatment of Traumatic Brain Injury?

Response: Please review the KBES successes reflected in our correspondence in our written testimony. KBES has successfully supported **major advances** in the treatment of very complex medical issues including Medical Readiness for our Navy.

Our private sector successes includes the improvement of the diagnosis and treatment strategies for acute myocardial infarction resulting in a **significant reduction of the length of stay and cost of cardiac care**, **and better positive outcome**; and the **mapping and strategic intervention plans for Neonatal Respiratory Distress Syndrome.**

While CRTBI is a very complex issue, WKS believes it will benefit from the robust analytic and predictive capabilities of KBES, just as the previous applications have benefited.

Question 6: Is KBES being used in military medicine now?

Response: No. Please refer to our written testimony for the explanation from the Navy.

Question 7: What do you recommend that the VA do with your KBES technology?

Response: With the license from WKS, the VA could use KBES in any situation that would be improved by accurate and responsive outcome prediction and the deployment of positive strategic actions.

KBES supports planning, decision discovery and support, in very large and complex human issues.

Medicine might be the most appropriate and urgent application, but very likely, not the only application for the VA.

Question 8: Why do you believe that VA failed to acquire KBES after some staff had initially positively discussed its potential use in the VA?

Response: WKS was told that the reason there would be no acquisition of KBES by the VA was because **"the VA is immature** (Dr. Pat Pearcy at SPAWAR, and Dr. Mike Valivullah at VA), **the VA is broken, and nobody at the VA wants to work** (Dr. Paul Tibbits, Deputy CIO of VA, Ms Lloyd VHA, and others)". WKS was told that the acquisition of the KBES technology would mean **"work"** for the VA.

Please note, in meeting, each of these individuals praised the KBES technology, saying it would help the VA medical mission, and other than Ms. Lloyd, that they would recommend a "pilot" project to Dr. Tibbits for funding.

Question 9: Did VA promise you a contract?

Response: Yes.

On multiple occasions, Dr. Paul Tibbits, Deputy CIO of VA, said he had **"no problem contracting directly"** with WKS.

Dr. Tibbits has said **"I will just go down the hall and get the money from my boss," and "I will ask SPAWAR (Dr. Pat Pearcy) to do a contract with you *now*".**

Question 10: What would it cost and how long would it take for VA to contract with you?

Response: VA contracting with WKS should be very straightforward.

WKS is **VA** a GSA veteran owned certified small business.

The VA (Dr. Tibbits and others) have said they would not use the GSA in acquisition, as "the GSA is not helping us".

The license for the WKS KBES technology is $450k, and depending on the scope of the project (looking at an estimate for CRTBI) the development cost should be circa $350k-$450k.

WKS' interest in pursuing this issue is the welfare of our veterans. Finances are of lesser concern to WKS.

If the VA will use KBES to benefit our veterans, these costs may be able to be lowered.

The typical time required to produce a medical KBES is about 6 months. CRTBI may take just a bit longer. We will know more on that once we have begun the development process.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Mr. James A. Clair, M.P.A., M.S.
Chief Executive Officer
Goold Health Systems
45 Commerce Drive, Suite 5
P.O. Box 1090
Augusta, ME 04332

Dear Mr. Clair:

Thank you for your testimony at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?
2. In your testimony, you discussed how Goold Healthcare Systems can work with VA to improve their pharmacy benefits program. Other witnesses have cited a concern that, prior to a solicitation being issued, they have little understanding of VA's goals and perspective. Have you encountered the same issues, or have you been able to communicate with VA?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Goold Health Systems
Augusta, ME.
November 23, 2010

The Honorable Michael H. Michaud
Chairman, Subcommittee on Health
Committee of Veterans' Affairs
U.S. House of Representatives
335 Cannon House Office Building
Washington, DC 20515

Dear Congressman Michaud,

I am writing in response to your October 4th letter in which you asked two questions to follow-up on the September 23rd oversight hearing on "VHA Contracting and Procurement Practices."

Listed below are your questions along with my responses:

Question 1: Are there any other recommendations for improving the contracting process at VHA that you would like to share with us?

GHS Response: I recommend that the VHA publish the means by which they monitor, audit and analyze existing VHA contracts so that the public can understand the value of the services each vendor/contractor/subcontractor provides to the VHA. A more public contract review process will help Congress, and the public, understand that the VHA is continuously monitoring, and improving, their contract oversight process.

In addition, I recommend that the VHA more earnestly seek out small companies with whom they can provide contracting opportunities. Smaller companies can very often provide services in a more efficient, nimble and cost-effective manner than their larger competitors yet can presently be eliminated from consideration due to contract requirements that favor the larger companies.

Question 2: In your testimony, you discussed how Goold Health Systems can work with VA to improve their pharmacy benefits program. Other witnesses have cited a concern that, prior to a solicitation being issued, they have little understanding of VA's goals and perspective. Have you encountered the same issues, or you have you been able to communicate with VA?

GHS Response: Goold Health Systems has never competed for work at the VA. Therefore, we don't have a perspective on the degree to which they communicate their goals and perspectives (and timelines and objectives) about the matters for which they solicit bids.

We have extensive experience competing in other public solicitations and know that the best procurements are those that are open, well-communicated and fairly judged. The best results for the public agency are when they have a wealth of qualified competitors submitting proposals at optimally competitive prices.

I want to thank you and the Subcommittee Members again for the opportunity to testify on September 23rd and to provide additional recommendations now so that the VHA procurement practices are optimally effective.

I would be pleased to answer your questions or provide any additional information.

Sincerely,

James A. Clair
Chief Executive Officer

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Gene L. Dodaro
Acting Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, D.C. 20548

Dear Comptroller General Dodaro:

Thank you for the testimony of Debra A. Draper, Director, Health Care, at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. How were the incidents mentioned in Ms. Draper's testimony discovered?
   - How were patients impacted by these incidents?
   - Could these incidents have been prevented by VAMCs following the policies GAO identified?
2. Why are committee reviews important for patient safety?
3. Why are VAMCs not always following the required committee review and approval process?
4. In her testimony, Ms. Draper mentioned VA's double signature policy related to the purchasing of supplies and equipment. Could you please elaborate on how this policy is connected to patient safety?
5. Why are VAMCs not entering information about expendable medical supplies in GIP?
6. Does VA headquarters provide sufficient guidance to VAMCs on implementing its policies on purchasing and tracking of expendable medical supplies and reusable medical equipment?
7. Will VA's new inventory management system, Strategic Asset Management, address the problems about items not being listed in VA's inventory management systems?
8. Is it a violation of VA policy to purchase instruments, such as surgical or dental instruments, with purchase cards? What about other reusable medical equipment?

9. What gaps has GAO identified in VA's requirements for tracking medical equipment in its inventory management systems?
10. Why is oversight of VA's policies on purchasing and tracking important for patient safety?
11. Is VA doing enough oversight of VAMCs' purchasing and tracking policies?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

U.S. Government Accountability Office
Washington, DC.
November 8, 2010

The Honorable Michael H. Michaud
Chairman
Subcommittee on Health
Committee on Veterans' Affairs
House of Representatives

Subject: Responses to Questions for the Record; Hearing Entitled *Veterans Health Administration Contracting and Procurement Practices*

Dear Mr. Chairman,

This letter responds to your October 4, 2010, request that we address several questions for the record related to the Subcommittee's September 23, 2010, hearing on the Veterans Health Administration's contracting and procurement practices. Our responses to the questions, which are in the enclosure, are based on our ongoing work on the Department of Veterans Affairs' oversight of compliance with its policies for purchasing and tracking expendable medical supplies and reusable medical equipment. Our response to these questions is based on work we performed in accordance with generally accepted government auditing standards.

If you have any questions about our responses or need additional information, please contact me on (202) 512–7114 or at draperd@gao.gov.

Sincerely yours,

Debra A. Draper
Director, Health Care

Enclosure

Questions for the Record Submitted by the Honorable Michael H. Michaud for Debra A. Draper, Ph.D., M.S.H.A., Director, Health Care U.S. Government Accountability Office

Veterans Health Administration Contracting and Procurement Practices Subcommittee on Health, Committee on Veterans' Affairs U.S. House of Representatives September 23, 2010

Question 1: How were the incidents mentioned in Ms. Draper's testimony discovered?

Response: The incident in which an incorrect expendable medical supply item was purchased and subsequently used in dialysis machines, which resulted in the potential cross-contamination of veterans' blood, was discovered by VA medical center (VAMC) staff on October 21, 2009 during an annual, routine maintenance inspection of the VAMC's dialysis machines. Initially the incident was presumed to be the result of a defect in the machine. On October 26, 2009, the VAMC staff contacted the manufacturer and during discussions with the manufacturer determined that an incorrect expendable medical supply item had been purchased and was in

use in the machines. That incorrect item allowed veterans' blood to pass into the machine during treatment and resulted in potential cross-contamination with the blood of veterans who were subsequently treated using these machines.

Another incident, which involved the improper reprocessing [1] of an auxiliary water tube, a type of reusable medical equipment (RME) used with a colonoscope, was discovered by VAMC staff in March 2009. Initially, in response to a VA patient safety alert that was issued on the auxiliary water tube in December 2008, officials from the VAMC checked their inventory management systems and concluded—incorrectly—that the tube was not used at the facility because it was not listed in the facility's inventory management systems. However, during an in-depth inspection of the facility's reprocessing activities, which consisted of searching all clinical areas of the VAMC for RME, VAMC staff determined that the auxiliary water tube was, in fact, being used at the facility.

- **How were patients impacted by these incidents?**

According to VAMC staff, the incident in which an incorrect expendable medical supply item was purchased and subsequently used in dialysis machines potentially exposed 83 veterans to infectious diseases, such as Human Immunodeficiency Virus (HIV), Hepatitis B, and Hepatitis C. As of June 2, 2010, the VAMC reported that testing for 82 of the 83 veterans had been completed and that no veterans had acquired infectious diseases as a result of this incident. The VAMC found that one of the 83 veterans identified was dialyzed on an uncontaminated machine and therefore this veteran was not notified or tested for these infectious diseases.

According to VAMC staff, the incident that involved the improper reprocessing of an auxiliary water tube potentially exposed 2,526 veterans to infectious diseases, such as HIV, Hepatitis B, and Hepatitis C. As of August 17, 2010, the VAMC reported that it had successfully notified 2,523 of the 2,526 veterans of possible exposure to infectious diseases and that there were 17 new positive test results. VA reports that these results are not necessarily linked to RME issues and is continuing its evaluation.[2]

- **Could these incidents have been prevented by VAMCs following the policies GAO identified?**

The incident in which an incorrect expendable medical supply item was purchased and subsequently used in dialysis machines may have been prevented had the VAMC followed VA's purchasing policies. VA policy requires that a designated VAMC committee review and approve proposed purchases of any expendable medical supplies that have not been previously purchased by the VAMC. However, the incorrect item that was used in conjunction with the dialysis machines was not reviewed and approved by a VAMC committee. If the item had gone through the Committee review and approval process, a clinical representative on the Committee may have recognized that it was inappropriate for use in dialysis machines and not approved the purchase. Furthermore, VA policy requires that all approvals for purchases of expendable medical supplies must be signed by two officials, the official placing the order and the official responsible for approving the purchase. However, the staff member working in the dialysis department purchased the incorrect item without obtaining the signature of an approving official. An approving official may have recognized that the item was inappropriate for use in dialysis machines and not approved the purchase.

The incident that involved the incorrect reprocessing of an auxiliary water tube may have been recognized 3 months earlier, and fewer veterans would have been potentially exposed to improperly reprocessed RME, had the auxiliary water tube been listed in one of the facility's inventory management systems. However, VA policy does not currently require information about RME valued under $5,000 that is not purchased on a recurring basis to be entered into an inventory management system. This incident does not indicate a lack of compliance with VA's requirement for entering information on RME into an inventory management system, because the auxiliary water tube is valued at less than $5,000 and is not purchased on a recurring basis. However, this incident exposed a gap in VA policy with regard to tracking RME. In part because the item was not listed in the facility's inventory management system, personnel incorrectly concluded that the item was not in use.

Question 2: Why are Committee reviews important for patient safety?

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[1] Reprocessing refers to the steps by which RME is prepared for reuse and includes cleaning and disinfecting or sterilizing the medical equipment.

[2] The VAMC reported that it was unable to contact the remaining three veterans.

Response: The Committee review and approval process is important for patient safety because Committees review and approve proposed purchases to evaluate the cost effectiveness of the purchase, as well as its likely impact on veterans' care. Therefore, without this review, the VAMC has no assurance that expendable medical supplies and RME that are purchased are appropriate or safe for use on veterans. For example, the Committee that reviews and approves proposed RME purchases often includes a representative from the department responsible for reprocessing the RME. This individual serves on the Committee to determine whether the VAMC has the capability to reprocess the RME correctly and to ensure that staff is appropriately trained to do so. Proper reprocessing of RME is important to ensure that veterans are not exposed to infectious diseases during treatment.

Question 3: Why are VAMCs not always following the required Committee review and approval process?

Response: We are unable to determine why VAMCs do not always follow VA's required Committee review and approval process. However, we found several instances at the VAMCs we visited in which clinical department staff placed orders for expendable medical supplies or surgical instruments, a type of RME, directly with the vendor instead of following this process. In these cases, officials outside the clinical departments may not be aware that the supplies have been ordered.

Question 4: In her testimony, Ms. Draper mentioned VA's double signature policy related to the purchasing of supplies and equipment. Could you please elaborate on how this policy is connected to patient safety?

Response: While one purpose of this policy is to prevent fraudulent purchases from occurring through segregating purchasing responsibilities, such as completing a purchase order and approving a purchase order, this policy is also connected to patient safety as it helps VAMCs identify whether proposed purchases are correct and appropriate for the clinical department making the purchase.

Question 5: Why are VAMCs not entering information about expendable medical supplies in the Generic Inventory Package (GIP)?

Response: We are continuing to evaluate why VAMCs are not entering information about expendable medical supplies in GIP. Based on our preliminary work we have found that officials from one VAMC we visited incorrectly believed that VA policy does not require expendable medical supplies used in only one clinical department to be entered into GIP. In contrast, officials from another VAMC correctly believed that VA policy requires them to enter information about all expendable medical supplies in GIP regardless of whether they are used facility-wide or only in a limited number of clinical departments. However, this facility had difficulty ensuring that supplies that are ordered by clinical department staff on a recurring basis are actually entered into GIP.

Question 6: Does VA headquarters provide sufficient guidance to VAMCs on implementing its policies on purchasing and tracking of expendable medical supplies and reusable medical equipment?

Response: We are continuing to evaluate whether VA headquarters provides sufficient guidance to VAMCs on implementing VA's policies on purchasing and tracking of expendable medical supplies and RME; however, we found that in some cases these policies lack clarity or appear to contradict each other. For example, VHA Handbook 1761.02 states that purchase cards are not authorized for purchasing equipment, while VHA Handbook 1730.01 states that "national policy allows purchase cards to be used for repair and equipment purchase."[3]

Question 7: Will VA's new inventory management system, Strategic Asset Management, address the problems about items not being listed in VA's inventory management systems?

Response: Because Strategic Asset Management (SAM) is not expected to be operational until March 2011, we cannot determine if the problems we identified would be fully addressed by the implementation of SAM. However, it does appear that this system will address the problem of inconsistent naming of RME in VA's inventory management systems as it is expected to help standardize names for all expendable medical supplies and RME. Inconsistent naming of RME in VA's inventory management systems makes it difficult for VAMCs to locate a specific type of RME in response to a manufacturer or FDA recall or patient safety alert.

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[3] See VHA Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009) and VHA Handbook 1730.01, *Use and Management of the Purchase Card Program* (Aug. 27, 2008).

Question 8: Is it a violation of VA policy to purchase instruments, such as surgical or dental instruments, with purchase cards?

Response: According to a VA headquarters official, it is not a violation of VA policy for clinical department staff to purchase instruments using purchase cards because instruments are not considered to be "equipment" for purposes of VA's purchasing and tracking policies, even though they are a type of RME. However, we have found that this may contribute to a potential patient safety concern because at some VAMCs, purchases made by clinical department staff using purchase cards were not always reviewed and approved as required by a Committee and that the department responsible for reprocessing the instruments may be unaware of the purchases. To prevent this problem from occurring, some VAMCs we visited have developed policies that prohibit clinical department staff from purchasing instruments using purchase cards.

- **What about other reusable medical equipment?**

  We have found that VA's policies on purchasing equipment appear to contradict each other. VHA Handbook 1761.02 states that purchase cards are not authorized for purchasing equipment, while VHA Handbook 1730.1 states that "national policy allows purchase cards to be used for repair and equipment purchase."[4]

  VA headquarters officials told us that clinical department staff is not permitted to purchase RME using purchase cards. However, VA headquarters officials also told us that some VAMC staff members may be granted the authority by a VAMC Committee to use purchase cards to purchase RME.

Question 9: What gaps has GAO identified in VA's requirements for tracking medical equipment in its inventory management systems?

Response: We are continuing to evaluate VA's requirements for tracking medical equipment and expendable medical supplies in its inventory management systems. Through our preliminary work, we have identified, for example, a gap in VA's requirements for tracking medical equipment in the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS)—VA's inventory management system for equipment. VA policy only requires RME costing $5,000 or more and with a useful life of 2 years or more to be entered in AEMS/MERS. Certain RME costs less than $5,000 and would therefore not be required to be entered in AEMS/MERS. This means that VAMCs' inventory of medical equipment could be incomplete. This gap has important patient safety implications. For example, in response to a VA patient safety alert that was issued on the auxiliary water tube in December 2008, officials from one VAMC checked their inventory management systems and concluded—incorrectly—that an auxiliary water tube, a type of RME, was not used at the facility. However, in March 2009, the VAMC discovered that the tube was in use and was not being reprocessed correctly, potentially exposing veterans to infectious diseases.

Question 10: Why is oversight of VA's policies on purchasing and tracking important for patient safety?

Response: Oversight of VAMC's compliance with VA's policies on purchasing and tracking is important for patient safety because compliance with these policies can help prevent patient safety incidents. For example, compliance can help prevent the purchase of incorrect medical supplies and the purchase of RME that VAMC staff members are not trained to reprocess or that the VAMC cannot reprocess correctly because it lacks the appropriate equipment. Compliance with these policies can also help ensure that VAMCs do not use expired supplies and that they are able to identify supplies and equipment that are the subject of a patient safety alert or a recall in a timely manner.

Question 11: Is VA doing enough oversight of VAMCs' purchasing and tracking policies?

Response: We are continuing to evaluate the oversight of compliance with VA's purchasing and tracking requirements by VA headquarters, selected Veterans Integrated Service Networks, and selected VAMCs.

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[4] See VHA Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009) and VHA Handbook 1730.01, *Use and Management of the Purchase Card Program* (Aug. 27, 2008).

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Honorable George J. Opfer
Inspector General
Office of the Inspector General
U.S. Department of Veterans Affairs
801 I Street, N.W.
Washington, D.C. 20002

Dear Inspector General Opfer:

Thank you for the testimony of Belinda J. Finn, Assistant Inspector General for Audits and Evaluations, at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. During OIG's audit of oversight over patient transportation contracts, you found that contracting officers cited staff shortages and heavy workloads as a factor contributing to the issues you unearthed surrounding these contracts. Were there other factors as well? Are shortages in contracting officers a common problem within VHA, and if so, how can this issue be addressed?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

U.S. Department of Veterans Affairs
Office of Inspector General
Washington, DC.
November 15, 2010

The Honorable Michael H. Michaud
Chairman
Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is in response to your October 4, 2010, letter following the September 23, 2010, hearing on *VHA Contracting and Procurement Practices.* Enclosed is our response to the additional hearing question.

Thank you for your interest in the Department of Veterans Affairs.

Sincerely,

/s/Richard J. Griffin for
GEORGE J. OPFER
Inspector General

Enclosure

Questions From the Honorable Michael Michaud
For Belinda Finn, Assistant Inspector General for Audits and Evaluations
Office of Inspector General, U.S. Department of Veterans Affairs
Before the Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives
Hearing on *VHA Contracting and Procurement Practices*

Question 1: During OIG's audit of oversight over patient transportation contracts, you found that contracting officers cited staff shortages and heavy workloads as a factor contributing to the issues you unearthed surrounding these contracts. Were there other factors as well? Are shortages in contracting officers a common problem within VHA, and if so, how can this issue be addressed?

Response: Our current work shows that contracting staff inexperience is also a challenge and that staff could benefit from training. With the loss of institutional knowledge resulting from retirements, VA's acquisition workforce has been strained to keep pace with the increased amount of and complexities associated with outsourced work in support of VA's mission. In response to this challenge, VA created an Acquisition Academy to address the growing acquisition workforce challenge facing the Department to help meet required certification standards for the acquisition workforce.

Our audits and reviews frequently report that contracting officers staffing shortages are an issue. The total staff authorized for Veterans Integrated System Network (VISN) contracting activities is 2,111 full time equivalents (FTEs). In June of 2010, the vacancy rate was approximately 28 percent; by September 30, 2010, the vacancy rate was just under 10 percent.

VA has developed a workforce modeling tool to determine whether staffing levels are sufficient to meet the demands of the workload. However, to remain useful this tool needs constant maintenance including the monitoring of current contract workload and staffing levels. Indications are that the information in this tool has not been kept current. Also, VA's Electronic Contract Management System (eCMS) has a workload data tool that provides the functionality needed for the purpose of monitoring workload and staffing levels. VA and Veterans Health Administration acquisition management need to decide which tool is best suited to monitor workload, determine appropriate staffing, and commit the resources to maintain and monitor workload and staffing levels.

To address staff shortages, VA can aggressively pursue options to recruit staff trained in acquisition support activities or provide more opportunities for VA staff to assume these mission-critical responsibilities. In addition, VA should consider evaluating the adequacy of the training provided at the VA Acquisition Academy to VISN contracting officers, Contracting Officers Technical Representatives, and other acquisition support staff. During 2010 audit work, we performed a survey of VISN Network Contract Managers (NCMs). Nine out of 16 NCMs, who reported taking training at the Academy, responded that the training contracting officers receive from the Academy did not adequately prepare them to support the needs of program officials and comply with acquisition laws, regulations, and VA policy. When asked to explain why the training was not adequate, NCMs recommended that training needed to be more tailored to the VA environment. NCMs also responded that there was a need for health care contract training.

Another step that could improve the development of VA's acquisition workforce is to ensure the entire VA procurement force is trained and uses the same acquisition support information system. Use of eCMS is mandated, however the system is not fully utilized and information within the system is often incomplete. VA can develop specific performance measures that align with the performance related to the use, quality, and completeness of the information in eCMS. VA's ability to obtaining reliable information and transparency over all acquisitions and to assess how well these acquisitions complied with laws, regulations and policies is key to helping identify systemic weaknesses in acquisition practices and to tailor training requirements to address deficiencies in the future.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 4, 2010

Honorable Eric K. Shinseki
Secretary
U.S Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, D.C. 20420

Dear Honorable Shinseki:

Thank you for the testimony of Frederick Downs, Jr., Chief Procurement and Logistics Officer in the Veterans Health Administration, and Dr. Andrea Buck, National Director of Medicine, at the U.S. House of Representatives Committee on Veterans' Affairs Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices," which took place on September 23, 2010.

Please provide answers to the following questions by Monday, November 15, 2010, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Does the VA have any policies in place that limit the dispensing of the initial supply of expensive brand name drugs that have high discontinuation rates? If yes, can you define, by therapeutic drug class or NDC, the types of drugs that have less than 30-day or 90-day supplies? If not, can you explain your rationale?
2. As you know, pharmacy high-cost users account for a disproportionately high percentage of a plan's drug expenditures. Are there any programs in place to identify, monitor then manage, the drug utilization for these members? Please explain.
3. Management of narcotic use is a balance between pain management and potential abuse. Are there programs in place to identify, monitor then manage VA patients using chronic pain medication? Please explain.
4. Prescription refills of maintenance medications are a routine event in most cases. However, issues can arise for non-maintenance medications. Can you please explain how early refills for non-maintenance drugs are presently managed?
5. How do you respond to the concerns that GAO and OIG raised in their testimony? What steps has VHA taken to address contracting and procurement weaknesses and deficiencies that GAO and OIG have identified over the years?
6. What are the different ways that vendors can get their products to veterans? Are there multiple ways to do this and what is VHA doing to ensure that there is transparency this process?
7. Would VA be willing to share de-identified pharmacy and medical claims data for an independent review, providing the entity performing the reviews signed a Non-Disclosure and HIPAA Business Associate Agreement?
8. In his testimony, Mr. Downs noted that "as new technologies become available, VHA staff members from clinical, logistics and acquisition disciplines form a team to carefully review potential applications before determining which advances to adopt". This is contrary to what we heard at a recent Health Subcommittee hearing on wireless health technologies. We heard about the lack of transparency and the difficulties that companies face in informing VHA about their products. Can you explain this disconnect?
9. How does the VHA Procurement and Logistics Office prioritize procurement requests from the program office?
10. What coordination exists between the VHA Procurement and Logistics Office and the VHA policy/program offices?
11. In his testimony, Mr. Downs referred to VHA's use of the Generic Inventory Package and how VHA tracks over 1,300 expendable inventories consisting of 928,816 line items. Is there a threshold, such as a dollar amount, that dictates which expendable equipments are entered into the Generic Inventory Package?
    a. What is the difference between the GIP and the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS)? Do the two programs overlap in function?
12. GAO identified gaps in VA policies regarding entering information on expendable medical supplies and RME into VA's inventory management systems. Does VA have plans to address those gaps so that VAMCs will have an accu-

rate record of the medical supplies and medical equipment they use? If so, how does VA plan to do so?

13. Please describe VA's current oversight to ensure that VAMCs comply with VA's policies for purchasing and tracking of expendable medical supplies and reusable medical equipment. Does VA plan to strengthen its oversight and, if so, what steps does VA plan to take to do this?
14. What role do the VISNS currently have in overseeing VAMC compliance with VA's policies on purchasing and tracking of expendable medical supplies and reusable medical equipment? Please describe any plans VA Central Office has to change or enhance this oversight.
15. How will SAM enhance VA's ability to oversee purchasing and tracking of expendable medical supplies and reusable medical equipment by VAMCs?
16. Could you explain the relationship between the VHA Procurement and Logistics Office and the central VA National Acquisition Center? Under what circumstances does a local VA medical center obtain goods through the VHA Procurement and Logistics Officer versus the VA National Acquisition Center?
17. How does VA central office monitor VISNs to ensure that they are adequately overseeing VAMC compliance with VA's policies on purchasing expendable medical supplies and reusable medical equipment?
18. What oversight do VAMC acquisition and Materiel Management (A&MMS) departments receive from the VISN and VA central office regarding compliance with 1) VA's prime vendor program; 2) small business programs and socioeconomic goals; 3) the Federal supply schedule program; and 4) general purchasing and acquisition policies.
19. What steps is VA taking to standardize certain types of reusable medical equipment, such as using the same type of colonoscopes, across VAMCs?
20. 20) How will VAMCs be impacted by VHA's new acquisitions and contracting policy requiring all items over $3,000 to be purchased by a VISN-level contracting officer, which goes into effect on October 1, 2010?
21. When are VAMCs required to make purchases from prime vendors?
22. Please describe the process by which VAMCs may negotiate prices under the Federal supply schedule program. To what extent are VAMCs successful at negotiating lower prices under the Federal supply schedule program.
23. Please describe the extent to which VAMCs met the prescribed small business programs and socioeconomic goals in fiscal year 2008 and 2009? What steps have VAMCs taken to meet these goals?
24. Could you explain the process of how VA medical centers obtain and provide Durable Medical Equipment (DME) to veteran patients?
25. Is there a dollar threshold for local medical center acquisitions? Could the local VA medical center make acquisitions using government purchase cards?
26. The VHA Operations Quality Assurance Office provides direct oversight to VHA acquisition activities and conducts annual site visits to Service Area Offices. Has the VHA Operations Quality Assurance Office identified the same weaknesses that GAO and OIG have found over the years? Also, GAO and OIG have independence and can expose problems without any fear or recourse. What assurances does the VHA Operations Quality Assurance Office have that they will not face any retribution from their oversight activities and that their findings will be taken seriously?
27. Does VHA use competitive bidding in the procurement of DME such as beds, wheelchairs, walkers?
28. It is my understanding that the Prosthetics and Clinical Logistics Office (P&CLO) generally oversees DME procurement and utilization, but medical facilities administer the home oxygen and respiratory services locally to provide eligible VA patients home oxygen and respiratory services, is that correct? If so, could you explain why home oxygen and respiratory services are administered locally, whereas other DME purchases are overseen and administered by the Prosthetics and Clinical Logistics Office?
29. It is my understanding that VHA uses several contracting mechanisms for acquisition of pharmaceuticals, medical and surgical supplies, prosthetics, information technology. For example VA uses the Federal Supply Schedule (FSS), Blanket Purchase Agreements (BPA), National Contracts, etc, when procuring pharmaceuticals for veterans. Could you explain to the Committee what mechanisms are used to purchase medical and surgical supplies, prosthetics, and medical information technology? What office or offices in VHA oversees these acquisitions?
30. As you are aware, VA and DoD have made substantial progress in increasing joint procurement activities since December 1999. This was done to eliminate

redundancies in purchases. Could you please provide the Committee with an update of current joint DoD–VA procurement activities? How do VA and DoD collaborate to make medical acquisitions?

31. In Mr. Downs' testimony, he noted that all acquisition personnel previously reporting to the VISN or medical center directors have now been realigned under the VHA Procurement and Logistics Office. When did this change take place and what are some improvements that you have observed as a result of this change?
32. In 2006, Secretary Nicholson signed VA Directive 1663 which established specific policies and procedures for the award of sole-source health care resource contracts to VA affiliated institutions. An OIG audit issued in September 2008, showed that VHA entities were not complying with the Directive.
    a. What actions have you taken since the OIG Audit was issued to ensure compliance with this Directive?
    b. What percentage of health care resource contracts awarded by VHA in FY 2009 and FY 2010 complied with the Directive?
    c. Given the significant potential cost savings identified by the pre-awards, what actions have you taken to ensure that all proposals for contracts with an estimated value $500,000 or more are referred to the OIG for a pre-award?
33. To optimize the performance of VA's acquisition system, the former Secretary of Veterans Affairs established a Procurement Reform Task Force in June 2001 and a final report was released in May 2002. It is my understanding that the VA began implementing recommendations made by the Task Force. Were the recommendations fully implemented? Have there been any new initiatives to improve VA's medical acquisition system?.
34. I understand you signed an executive decision memorandum April 29, 2010, which directed the Chief Acquisition Officer to implement the Acquisition Transformation Initiative at VA. Under this initiative, VA is to establish a strategic acquisition center to implement strategic sourcing initiatives for VA and handle contracting requirements exceeding field purchasing thresholds. However, I recently learned VHA is moving forward to increase its contracting workforce by an additional 400 FTE, and is currently advertising senior executive positions for VHA's three Service Area Offices. How does VHA's actions in this regard comport to Secretary Shinseki's direction to the Chief Acquisition Officer? What is the rationale and justification behind such an increase given the new strategic acquisition center will provide contracting support to VHA above a notional threshold for field purchases? Will this not complicate the Chief Acquisition Officer's ability to implement the Secretary's Acquisition Transformation Initiative?
    a. Another key change is that all acquisition authorities will flow from the Chief Acquisition Officer in the Office of Acquisition, Logistics, and Construction to the Heads of Contracting Activities who will be directly accountable to the Chief Acquisition Officer for ensuring compliance with enterprise policies, processes, and systems.
        i. What actions are being taken by VHA to ensure that the proper flow of information from the Chief Acquisition Officer to the Head of Contracting Activities in VHA?
        ii. What actions are being taken by VHA to ensure the HCA's implement these policies, processes, and systems, and are held accountable?
35. I'm interested in some general statistics about the contracts that VA awards. How many contracts did VHA award in fiscal year 2009? What percentage of the contracts were competitive versus sole-source contracts? What was the percentage of performance-based contracts?
36. In 2010, OIG's Office of Contract Review conducted pre-award reviews of 32 health care resource proposals. These reviews identified $39 million in potential cost savings that could be realized during negotiations.
    a. What is the amount spent annually on contracts awarded on a sole-source basis to VA affiliated institutions?
    b. What actions have you taken or are you planning to take to ensure that the cost savings identified in the pre-award reports are realized by negotiating lower prices?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 15, 2010.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Questions for the Record
Chairman Michaud
House Veterans' Affairs Subcommittee on Health Oversight hearing on
"VHA Contracting and Procurement Practices"
September 23, 2010

Question 1: Does the VA have any policies in place that limit the dispensing of the initial supply of expensive brand name drugs that have high discontinuation rates? If yes, can you define, by therapeutic drug class or NDC, the types of drugs that have less than 30-day or 90-day supplies? If not, can you please explain your rationale?

Response: There is not a national policy; however, Veterans Integrated Service Networks (VISNs) and facilities are not prohibited from having policies and procedures in place to limit initial supplies of medications. These regional and local policies and procedures are typically based on drug safety, cost, and utilization patterns. Each VISN Pharmacist Executive (VPE) and Chief of Pharmacy has access to a business analysis tool for data mining to assist in identifying regional and/or local patterns in drug utilization where limits on initial dispensing of certain medications may be required. The following are known examples where VISNs and/or facilities have implemented initial supply limits: atypical antipsychotics, pain medications, warfarin, growth factors, oncology medications, cholinesterase inhibitors, erythropoiesis-stimulating agents, and non-formulary brand name medications.

Question 2: As you know, pharmacy high-cost users account for a disproportionately high percentage of a plan's drug expenditures. Are there any programs in place to identify, monitor then manage the drug utilization for these members? Please explain.

Response: VA prescription drug costs per patient include all patients receiving drugs from VA pharmacies. In contrast, other prescription benefits plans report per member per month or per member per year, which underestimates costs because members that do not use the benefit are counted in the calculation. Patients served by other prescription benefit plans are typically younger with fewer chronic diseases than patients served by VA; therefore their prescription costs would be expected to be lower than VA's costs. Despite these differences, VA's costs are significantly lower than other health plans. VA closely manages drug utilization for all patients, not just high-cost users, to ensure safe, effective and appropriate medication use.

According to a presentation entitled "*Overview and Update on DoD Pharmacy*" presented at the 2010 Military Health System Conference, the pharmaceutical cost per Department of Defense eligible beneficiaries aged 65 and older was $1,927 in fiscal year (FY) 2009, compared to $686 in the same age group in VA during the same time period. According to the Pharmacy Benefit Management Institute (PBMI) 2009 Prescription Drug Benefit Cost and Plan Design Survey, completed by 417 employers representing 7,041,676 members, the average net prescription drug cost per retiree per month extrapolates to $1,770 per member per year. In comparison, the VA average prescription drug cost per unique patient in FY 2009 was $697 and VA's cost is a gross cost; it does not subtract first party co-payments. According to Express Scripts, the overall per member per year drug cost was $911 based on the 36 million lives in the commercial client groups. In comparison, the VA average prescription drug cost per unique patient in FY 2009 was $697; again, other plans have younger, healthier patients than VA's patients and include all members, and unlike VA, patients are included regardless of whether or not they use the prescription benefit.

VA Pharmacy Benefits Management Services (PBM) monitors utilization and conducts safety and efficacy reviews using a central drug utilization analysis database. The results of these analyses are then used to assess future needs. One of the ways the database is utilized is to identify potential areas for managing drug costs through cost-avoidance initiatives. These are developed nationally, and may be im-

plemented at the VISN or local medical care facility level. The intent of the program is to actively pursue pharmacy efficiencies and appropriateness of use for selected pharmaceuticals and reduce the variance in drug cost per patient across the system while assuring no negative impact on the quality of care. The program was formally initiated in FY 2007 and has resulted in substantial cost avoidance and a subsequent reduction in the variance in drug cost per patient. The program documented cost avoidance of $264 Million in FY 2007, $354 Million in FY 2008, $191 Million in FY 2009 and $112 Million projected for FY 2010. As a result of these efforts, the variance in cost per patient has decreased substantially between VISNs. VA's average cost of a 30-day equivalent outpatient prescription changed from $13.03 in FY 1999, to $12.64 in FY 2009, a 3.0 percent decrease over a 10-year period.

Question 3: Management of narcotic use is a balance between pain management and potential abuse. Are there programs in place to identify, monitor then manage VA patients using chronic pain medication? Please explain.

Response: VHA appreciates the important balance between meeting the needs of Veterans with pain by providing access to opioid analgesic medications and concerns about patient opioid misuse, abuse, and addiction and public safety concerns related to diversion. VHA has been in the forefront of efforts to address this issue and has developed a comprehensive approach for promoting safe and effective use of opioids.

In October 2009, as directed by Congress, VHA published a comprehensive policy for pain management (VHA Directive 2009–053). The policy articulates standards for pain assessment and treatment including parameters for safe and effective prescribing of opioid analgesics. Earlier in 2007, VHA launched a comprehensive Opioid-High Alert Medication Initiative to address concerns about safe prescribing of opioids in both inpatient and outpatient settings. Parameters of safe prescribing were established, and a comprehensive approach to dissemination and implementation of these standards was undertaken. A recent Health Analysis and Information Group (HAIG) Pain Management Survey documented a high level of implementation of these standards across VHA facilities.

A key to safe and effective use of opioids for the management of pain is the education and training of both prescribers to assure their competencies in this practice area and the education of patients and families about benefits and risks of opioid analgesics. In 2010, VHA and DoD collaborated in the publication of a Chronic Opioid Therapy Clinical Practice Guideline (CPG) that articulates state-of-the-science practice recommendations for the use of this class of medications. The CPG specifically addresses the balance of promoting effective use of these medications for the management of chronic pain and strategies for evaluating and mitigating risk. Supporting the CPG is a comprehensive, web-based educational program available on the VHA's Learning Management System (LMS). Both the CPG and LMS course on opioid therapy recommend the use of a Opioid Pain Care Agreement as a key resource for promoting education of patients and family members about the potential benefits and risks of chronic opioid therapy, for establishing the parameters of safe prescribing of opioid therapy, and for generally promoting well-informed shared medical decision-making involving prescribers and patients. Currently under review in the VA Central Office concurrence process, is a VHA Directive, a national standard Opioid Pain Care Agreement and supplemental patient educational tools to be used for these purposes. Finally, this comprehensive approach is supported by a variety of additional educational efforts including workshops at national pain management leadership conferences and regularly scheduled educational teleconferences.

Through the national Pharmacy Benefits Management Services (PBM), VHA also conducts semi-annual opioid prescription reviews that identify patients who obtain prescription fills from more than one facility either within Veterans Integrated Service Networks or VISNs ("Multi-site") or between VISNs ("Multi-VISN"). After contacting providers and patients, locally designated personnel identify the one site that will fill future opioid prescriptions. Local personnel may take additional steps as indicated to address any patient drug-seeking or other aberrant drug-related behaviors. These prescription reviews have reduced the number of Multi-site and Multi-VISN opioid prescription fills since their inception in late 2002.

In addition to the Multi-site and Multi-VISN opioid prescription surveillances, the PBM has recently implemented semi-annual Large Dose opioid prescription reviews that identify patients who have been prescribed aberrantly large doses of opioids, defined as the top 10 largest quantities of opioids in each VISN. Locally designated personnel evaluate the Large Dose patient cases for appropriateness in terms of quality of care and safety using a protected peer review process.

Question 4: Prescriptions refills of maintenance medications are a routine event in most cases. However, issues can arise for non-maintenance medications. Can you please explain how early refills for non-maintenance drugs are presently managed?

Response: In VA, all refills are managed by the facility where the prescription was originally written. The VA computer system automatically builds a 10 day early window into the request process for all refillable prescriptions. This has the effect of generally ensuring that patients receive the next refill in plenty of time. In all cases, the patient must request a refill; they are not automatically sent. This is done to avoid waste by sending patients prescriptions that have been discontinued or modified by their provider and to prevent unsafe conditions resulting from the stockpiling of unneeded medications. Requests for refills beyond the 10-day window are handled on a case-by-case basis by local pharmacy staff members based on the unique situations encountered by patients. In some cases, a partial quantity may be dispensed to bridge the patient's supply until receipt of the regularly scheduled refill or until the next medical appointment. Requests for early fills for controlled substances are generally referred to the patient's provider as running out of these medications can signal a change in medical condition or potential misuse.

Question 5: How do you respond to the concerns that GAO and OIG raised in their testimony? What steps has VHA taken to address contracting and procurement weaknesses and deficiencies that GAO and OIG have identified over the years?

Response: The acquisition concerns raised by GAO and OIG during their testimony are valid. VHA has taken several steps to address acquisition deficiencies including: realigning VHA's acquisition workforce and establishing a VHA Compliance/Quality division responsible for tracking, reviewing and addressing recommendations.

The purpose of the realignment was to provide decision makers with the appropriate authority to execute strategic procurement programs, improve procurement oversight and create the best opportunity for stewardship. The realignment created a regional infrastructure with three service area office's being responsible for regions of 6–8 Networks or Program Offices. Each Service Area Offices (SAO) includes the following staff: SAO Director, SAO Deputy Director, Quality Reviewers, Training Officers, Data/Program Analysts, Finance/Budget Specialists and an Administrative Officer dedicated to regional management of the Networks. At the national level, the VHA Procurement & Logistics Office (P&LO) monitors the metrics established for each SAO to determine if the SAO regions are compliant with procurement regulations and guidelines. This robust system drastically improved the oversight and monitoring of procurement functions.

In addition, the National VHA Quality/Compliance team is responsible for ensuring that the recommendations made by the OIG/GAO are instituted and all Networks comply with the requirements. This team tracks the OIG/GAO audits and monitors the associated recommendations. This team is also responsible for conducting random internal audits to ensure continued compliance.

Question 6: What are the different ways that vendors can get their products to Veterans? Are there multiple ways to do this and what is VHA doing to ensure there is transparency in this process?

Response: A vendor can get their products to Veterans by identifying and responding to procurement opportunities in their product or service area by visiting the FedBizOpps (FBO) Web site at www.fbo.gov. The FBO site is the Federal Civilian and Military Government single point of entry for business opportunities over $25,000. A vendor can also establish a General Service Administration (GSA) Federal Supply Schedule (FSS) contract. Federal agencies can use Government-wide Acquisition Contracts (GWACs) and GSA FSS contracts to make purchases for commonly used products and services. These opportunities are typically not advertised on the FBO Web site, they are normally competed among pre-qualified vendors under contract. VHA ensures transparency by advertising procurement opportunities above $25,000 and competing procurements, to the maximum extent possible.

Question 7: Would VA be willing to share de-identified pharmacy and medical claims data for an independent review, providing the entity performing the reviews signed a Non-Disclosure and HIPAA Business Associate Agreement?

Response: VA can provide de-identified health care claims data upon request through FOIA. These are very large files and a focused request would be more appropriate. VA can provide fee claims data, although at this point approximately 5 percent of claims are received electronically and it is unlikely that a review of this very small percentage of claims would realize any significant result.

Given the potential volume for these files, there will likely be costs to the VA to provide these data.

Representatives from the Chief Business Office would be more than happy to meet with any vendor to discuss tools they may have that could improve our health care claims processing.

Question 8: In his testimony, Mr. Downs noted that "as new technologies become available, VHA staff members from clinical, logistics and acquisition disciplines form a team to carefully review potential applications before determining which advances to adopt". This is contrary to what we heard at a recent Health Subcommittee hearing on wireless health technologies. We heard about the lack of transparency and the difficulties that companies face in informing VHA about their products. Can you explain this disconnect?

Response: VHA's statement is accurate. As new technologies become available, VHA staff members from clinical, logistics, and acquisition disciplines form a team to carefully review potential applications before determining which advances to adopt. There are many standards that must be met and verified before we can allow health information to be broadcast via various wireless mediums. As such, some wireless health technologies present unique challenges to the VA as one of our primary concerns is to protect Veterans' health information. This does not mean VHA is not pursuing these technologies; however, the team must validate that the technology meets VHA's predetermined requirements before recommending a potential wireless technology solution. Additionally, VHA is not able to review every vendor's technological solution; but VHA makes a concerted effort to meet with as many vendors as possible.

Question 9: How do VHA Procurement and Logistics Office prioritize procurement requests from the program office?

Response: Procurement requests from the program offices are prioritized based on the needs of the requesting service. VHA acquisition staff work with their respective customers to establish priorities given: (1) When the procurement is needed and (2) dollar value and complexity of the procurement.

Question 10: What coordination exists between the VHA Procurement and Logistics Office and VHA policy/program offices?

Response: On all issues impacting VHA acquisition, the VHA Procurement and Logistics Office (P&LO) closely coordinates with the appropriate VHA policy/program offices. When an acquisition policy, process, procedure or other change within acquisition is anticipated, P&LO identifies the appropriate stakeholders and develops a plan of action including determining the impact on: (1) Leadership; (2) stakeholders; (3) resource management; (4) budget/finance; (5) personnel; and (6) operations. This information is communicated with the appropriate offices; and the identified implementation team works with the VHA policy/program offices to accomplish the established objectives.

Question 11: In his testimony, Mr. Downs referred to VHA's use of the Generic Inventory Package and how VHA tracks over 1,300 expendable inventories consisting of 928,816 line items. Is there a threshold, such as a dollar amount that dictates which expendable equipments are entered into the Generic Inventory Package?

Response: No, there is not a threshold to determine which expendable equipment is entered into the Generic Inventory Package (GIP).

Question 11(a): What is the difference between the GIP and the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS)? Do the two programs overlap in function?

Response: The GIP is the inventory system utilized for consumable supplies. To date, VHA tracks over 1,300 expendable inventories consisting of 928,816 line items. The Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) is utilized to maintain equipment inventory and maintenance information for Non-Expendable (NX) Items (Equipment items which have been formally classified as NX and assigned a category stock number by the cataloging division of Office of Acquisition, Logistics, and Construction). The two programs do not overlap in function.

Question 12: GAO identified gaps in VA policies regarding entering information on expendable medical supplies and RME into VA's inventory management systems. Does VA have plans to address those gaps so that VAMCs will have an accurate

record of the medical supplies and medical equipment they use? If so, how does VA plan to do so?

Response: Yes. P&LO is currently collaborating with the VACO Medicine Program office (responsible for programmatic oversight of reusable medical equipment processes), and the VACO Real Time Location System (RTLS) Program office in identifying and pursuing supply and equipment tracking technology, which will address those gaps which have been identified. It is expected that the technology ultimately adopted will be in collaboration with the Strategic Asset Management (SAM) initiatives so that this technology can be integrated with and incorporated into VA's overall SAM system, anticipated to begin national deployment in Fiscal Year 2013.

Question 13: Please describe VA's current oversight to ensure that VAMCs comply with VA's policies for purchasing and tracking of expendable medical supplies and reusable medical equipment. Does VA plan to strengthen its oversight and, if so, what steps does VA plan to take to do this?

Response: P&LO currently monitors and reports performance achievements in the management of consumable and NX items for all facilities and at a VISN and national level. This oversight is based upon established performance thresholds for effective management of consumable supplies based upon GIP data reports and NX inventory compliance reports. In addition to these reports, the Office of Business Oversight—Management Quality Assurance Section conducts assessment reviews of facilities, comparing actual records and business processes at a site to those requirements contained within VA and VHA policy and directives. P&LO currently has an initiative under way to enhance the Logistics Operations Team by building an assessment and compliance team, which will be charged with ongoing assessment and assistance activities directed to all facilities.

Question 14: What role does the VISNs currently have in overseeing VAMC compliance with VA's policies on purchasing and tracking of expendable medical supplies and reusable medical equipment? Please describe any plans VA Central Office has to change or enhance this oversight.

Response: VISNs, through the network Chief Logistics Officer (CLO) with programmatic oversight responsibility are expected to ensure compliance with VA and VHA level policy on tracking of expendable supplies and NX equipment. P&LO currently has an initiative under way to enhance the Logistics Operations Team by building an assessment and compliance team, which will be charged with ongoing assessment and assistance activities directed to all facilities. Additionally, P&LO is pursuing an initiative directed towards a standardized network level Logistics organization, to include staffing requirements designed to enhance overall program oversight.

Question 15: How will SAM enhance VA's ability to oversee purchasing and tracking of expendable medical supplies and reusable medical equipment by VAMCs?

Response: The SAM initiative is designed to centralize the consumable and NX equipment asset data from all field level sites to a centralized database, utilizing nationally standardized item nomenclature. Standardizing the data will enhance VA's ability to track and monitor all assets within the system in a consistent manner.

Question 16: Could you explain the relationship between the VHA Procurement and Logistics Office and central VA National Acquisition Center? Under what circumstances does a local VA medical center obtain goods through the VHA Procurement and Logistics Officer versus the VA National Acquisition Center?

Response: The National Acquisition Center (NAC) has responsibility for National Contracts and Blanket Purchase Agreements, in support of National Standardization, which are established under the Federal Supply Schedule Program. All of these programs are open to VA medical centers. Most of these contracts and agreements include other Government agencies such as the Department of Defense, Indian Health Service and Bureau of Prisons. Most of the solicitations for these contracts and agreements are competitive, best value procurements. Essentially, the NAC establishes National contracts that can be utilized by the Networks under P&LO. The local VA Medical Centers (VAMCs) do not obtain goods or services through P&LO instead the procurements are accomplished through the Network procurement activities that report to the P&LO infrastructure. The VAMC procurement activity makes the determination of whether to use the NAC or local procurement process

based on whether the requirement is National in scope or whether this requirement presents an opportunity for National standardization.

Question 17: How does VA Central Office monitor VISNs to ensure that they are adequately overseeing VAMC compliance with VA's policies on purchasing expendable medical supplies and reusable equipment?

Response: P&LO is establishing a methodology to monitor Network compliance with VA policy on purchasing supplies and reusable medical equipment. P&LO's initiative to enhance the Logistics Operations infrastructure, as referenced in 13 and 14 above, will increase the level of oversight and monitoring related to the request, review, and approval processes. Additionally, the acquisition realignment initiative will enhance compliance with the appropriate sourcing related to this issue.

Question 18: What oversight do VAMC acquisition and Materiel Management (A&MMS) departments receive from the VISNs and VA central office regarding compliance with 1) VA's prime vendor program; 2) small business programs and socioeconomic goals; 3) the supply schedule program; and 4) general purchasing and acquisition policies?

Response: *VA's prime vendor programs:* Network and VAMC Logistics program offices are provided with VA Medical/Surgical Prime Vendor (MSPV), Pharmaceutical Prime Vendor (PPV) and Subsistence Prime Vendor (SPV) reports of compliance related to commitment versus actual expenditures, as well as, order fill rates and invoice/payment processes. P&LO receives compliance reports from the NAC, reviews and disseminates these reports to identify out of line situations and requests appropriate corrective action on the part of the network Chief Logistics Officer, who is expected to effect the corrective action through program oversight communication with the deficient VAMC Logistics Manager.

Small business programs and socioeconomic goals: VHA socioeconomic spend goals are incorporated into the annual P&LO performance metrics, as well as the performance plans of VISN leadership. These metrics are monitored throughout the year by VA Central Office leadership and VISN Directors.

The supply schedule program: Oversight of the VA Federal Supply Schedule (FSS) program fall within the auspices of the VA Office of Acquisition, Logistics and Construction (OALC). The National Acquisition Center is a strategic purchasing arm of the VA, and maintains and administers the FSS program.

General purchasing and acquisition policies: It is the responsibility of OALC to develop, communicate, and enforce policies to ensure VA complies with Federal laws, policies, and regulations governing procurement and logistics activities. VHA does not create acquisition policy, but rather institutes standard operating procedures to ensure uniformity of contracting efforts and practices throughout the VISNs and operating locations.

Question 19: What steps is VA taking to standardize certain types of reusable medical equipment, such as using the same type of colonoscopes, across VAMCs?

Response: VA chartered an Integrated Procurement Team (IPT) to address lease versus purchase options as a way to standardize gastrointestinal (GI) endoscopes across VAMCs. The IPT recommended leases as the best method to ensure standardization of GI endoscopes across VAMCs. Leases allow upgrade to current generation technology through lease amendments as new technology becomes available, ongoing refresher training for personnel on care and handling of the equipment, and continuous maintenance for the endoscopes at a fixed price. This allows facilities the flexibility to trade up or trade out as needed without having to maintain an inventory of GI endoscopes of varying age. However, the lease must be amended at an increased cost to add or substitute a newer model.

The lease recommendation from the IPT team was accepted and the medical facilities in the field have received instruction from the Deputy Under Secretary for Health for Operations and Management to implement standardization of endoscopes through leasing as early as possible in the current fiscal year.

Question 20: How will VAMCs be impacted by VHA's new acquisitions and contracting policy requiring all items over $3,000 to be purchased by a VISN-level contracting officer, which goes into effect on October 1, 2010?

Response: VAMCs will be minimally impacted by requiring purchases above $3,000 to be completed by the Network Contracting Activities (NCA). The purchasing agents previously responsible for these purchases were realigned under the NCA. Therefore, the workload for these purchases will be readily absorbed by the NCA.

Question 21: When are VAMCs required to make purchases from prime vendors?

Response: VAMCs are required to make purchases from prime vendors when the items required are included under the umbrella of the prime vendor contract. Exceptions are provided for emergency or non-core list items.

Question 22: Please describe the process by which VAMCs may negotiate prices under the Federal supply schedule program. To what extent are VAMCs successful at negotiating lower prices under the Federal supply schedule program?

Response: In accordance with the Federal Acquisition Regulations (Part 8), prices found within the General Services Administration and the Federal Supply System GSA/FSS programs have already been determined to be fair and reasonable. However, VHA contracting officers do attempt to seek additional price considerations when placing orders. It is mandatory to request a price discount when orders are placed in excess of the per-contract maximum order threshold. In an effort to better leverage VA and government-wide spending, the VHA CLOs have been evaluating commonly-procured and high volume medical/surgical items purchased under the FSS program. Prices of competing vendors have been analyzed, so greater negotiating power can be achieved in the future.

Question 23: Please describe the extent to which VAMCs meet the prescribed small business programs and socioeconomic goals in fiscal year 2008 and 2009. What steps have VAMCs taken to meet these goals?

Response: In FY 2010, VHA exceeded the small business goals in all except two categories (refer to the chart below). In FY 2009, VHA exceeded the small business goals in all except two categories (refer to the chart below). In FY 2008, VHA exceeded the small business goals in all except one category (refer to the chart below). Each Network has a Small Business Liaison responsible for working with the Network Contract Activities to meet socioeconomic goals. The steps taken for VAMCs to meet these goals include: participation in small business vendor outreach and monthly National small business conferences to discuss small business concerns, and provide training on FAR Part 19 compliance and other special small business programs/initiatives.

FY 2010 VHA Small Business Accomplishments

VA–Wide Goal	SDVOSB (10%)	VOSB (12%)	8(a) (0%)	SDB (5%)	WOSB (5%)	HUBZone (3%)	SB (33.5%)	SDB + 8(a) (5%)
VHA Accomplishments	17.7%	20.2%	.7%	6.7%	3.3%	2.2%	35.1%	7.4%

FY 2009 VHA Small Business Accomplishments

VA–Wide Goal	SDVOSB (7%)	VOSB (10%)	18(a) (0%)	SDB (5%)	WOSB (5%)	HUBZone (3%)	SB (28.7%)	SDB + 8(a) (5%)
VHA Accomplishments	15.65%	18.69%	1.02%	7.24%	3.61%	2.21%	34.58%	8.26%

FY 2008 VHA Small Business Accomplishments

VA–Wide Goal	SDVOSB (10%)	VOSB (12%)	8(a) (0%)	SDB (5%)	WOSB (5%)	HUBZone (3%)	SB (33.5%)	SDB + 8(a) (5%)
VHA Accomplishments	11.67%	14.89%	1.95%	7.26%	4.53%	3.10%	38.33%	9.21%

Question 24: Could you explain the process of how VA medical centers obtain and provide Durable Medical Equipment (DME) to Veterans patients?

Response: Every VAMC has a Prosthetic and Sensory Aids Service (PSAS) that is responsible for the procurement of all devices for the personal use of a Veteran. Whenever a qualified VA clinician determines that a particular device is needed, an electronic request is sent to PSAS to determine if this is something that can be stock issued directly to the patient, mailed from stock to the Veteran, or purchased from a vendor and shipped to either the hospital, third party vendor, or to the Vet-

eran's home for installation and training. The method that is pursued is based upon the availability of the prescribed item, any fitting or training required for it, and other logistical issues such as size or timing. The provision of these items is a very personalized approach specific to the needs and preferences of each Veteran. If not stock issued the same day, all requests are initially acted upon within 5 days. VHA has been monitoring this for several years and has steadily increased the complexity and compliance standards for the delivery of goods to Veterans.

Question 25: Is there a dollar threshold for local medical center acquisitions? Could the local VA medical center make acquisitions using government purchase cards?

Response: No, there is no dollar threshold for local VA medical center acquisitions. The VAMC determines which purchases should be made by acquisition versus small purchasing based on the dollar value and complexity of the procurement.

The VAMCs are able to make acquisitions using the purchase card. However, the purchasing ability is limited by the given purchase card holder's authority. To monitor the purchase card program, centralized purchase card program managers have been established at every Network. Additionally, facility purchase card coordinators are being realigned under the purchase card managers in the acquisition chain of command.

Question 26: The VHA Operations Quality Assurance Office provides direct oversight to VHA acquisition activities and conducts annual site visits to Service Area Offices. Has the VHA Operations Quality Assurance Office identified the same weaknesses that GAO and OIG have found over the years? Also, GAO and OIG have independence and can expose problems without any fear or recourse. What assurances does the VHA Operations Quality Assurance Office have that they will not face any retribution from their oversight activities and that their findings will be taken seriously?

Response: The VHA Quality Assurance Office (QA) has been able to validate that weaknesses identified in the OIG/GAO report exist. The VHA QA office has been working with the QA staff at each Network on establishing action plans to address the deficiencies identified in the OIG/GAO audits. Additionally, the QA office works with the compliance team to identify key areas to review during internal audits.

P&LO leadership has clearly delineated the roles and responsibilities of this office. All Service Area Offices (SAOs) and staff are aware of the role of QA, and acknowledge that their quality team must work closely with QA to address all recommendations and findings. The QA office will not face retribution and their findings will be taken seriously because the QA office reports to P&LO independently of the SAOs. As such, P&LO will ensure that there is no retribution and will monitor the implementation and execution of QA recommendations as part of the SAO performance.

Question 27: Does VA use competitive bidding in the procurement of DME such as beds, wheelchairs, and walkers?

Response: The Prosthetic and Sensory Aids Service has been very aggressive in its approach to competitive bidding. For high volume or high cost items, VHA has been pursuing national contracts in conjunction with the National Acquisition Center. We analyze our extensive database to look for opportunities to use our economies of scale by securing national contracts. These national contracts not only guarantee a lower price for the government, but they also elevate the standard of care being provided to Veterans because VHA identifies what features and criteria a device must have to meet VHA's requirements. We also work closely with the Office of Small and Disadvantaged Business Utilization (OSDBU) to ensure that we are meeting small business goals to the maximum extent possible, while meeting the needs of the Veteran and the agency. Between FY 2002–FY 2009, VHA realized a cost savings of over $380 million by using National contracts.

Question 28: It is my understanding that the Prosthetics and Clinical Logistics Office (P&CLO) generally oversees DME procurement and utilization, but medical facilities administer the home oxygen and respiratory services locally to provide eligible VA patients home oxygen and respiratory services, is that correct? If so, could you explain why home oxygen and respiratory services are administered locally, whereas, other DME purchases are overseen and administered by the Prosthetics and Clinical Logistics Office?

Response: We apologize if we were unclear in a previous answer that led you to believe this. The Prosthetic and Sensory Aids Service out of Central Office creates policy covering all items and services for the personal use of the Veteran including

home respiratory care, durable medical equipment, and home and vehicle adaptations, but all of these procurements are actually handled by the local medical centers' Prosthetic and Sensory Aids Services.

Question 29: It is my understanding that VHA uses several contracting mechanisms for acquisition of pharmaceuticals, medical and surgical supplies, prosthetics, and information technology. For example VA uses the Federal Supply Schedule (FSS), Blanket Purchase Agreements (BPA), National Contracts, etc, when procuring pharmaceuticals for Veterans. Could you explain to the Committee what mechanisms are used to purchase medical and surgical supplies, prosthetics, and medical information technology? What office or offices in VHA oversees these acquisitions?

Response: The methods used to purchase pharmaceuticals, medical and surgical supplies, prosthetics and information technology vary depending on the acquisition. VHA procures in compliance with Federal Acquisition Regulations (FAR) and VA Acquisition Regulations (VAAR). The methods used to purchase pharmaceuticals, medical and surgical supplies, prosthetics and information technology include: 1. FAR/VAAR Part 8—required sources of Supplies and Services i.e. AbilityOne, Federal Prison Industries, FSS, etc.; 2. FAR/VAAR Part 15—contracting by negotiation: best value, tradeoff or lowest price technically acceptable source selections using full and open competition; 3. FAR/VAAR Part 13—Simplified Acquisitions; 4. FAR/VAAR Part 19—Small Business Set-Asides; 5. use of contract vehicles such as Government-Wide Acquisition Contracts, Multiple-Award Contracts; 6. Prime Vendor Programs (Med/Sug, Pharmaceutical and Subsistence; 7. National Contracts and 8. utilizing unique statutory authorities under 38 U.S.C. 8127 & 8128 (Veterans First Program); 38 U.S.C. 8123 (Procurement of Prosthetic Appliances). In VHA, P&LO oversees these acquisition through SAO oversight and management of field acquisition activities.

Question 30: As you are aware, VA and DoD have made substantial progress in increasing joint procurement activities since December 1999. This was done to eliminate redundancies in purchases. Could you please provide the Committee with an update of current joint DoD–VA procurement activities? How do VA and DoD collaborate to make medical acquisitions?

Response: The need for more initiatives within the medical/surgical commodity is evident. As a formal work group of the joint VA/DoD Health Executive Council (HEC), the Acquisition and Medical Materiel Work Group meets regularly to discuss ways to increase joint contracts and sales. High on the work group's agenda are initiatives and strategies to affect the expansion of the medical/surgical joint contracts.

During the past year, DoD and VA awarded four new joint radiology contracts. These contracts were: ICAD, Aurora Advanced Breast Imaging, iCRco and Neurologica. In addition to these awards, four new offers for new joint radiology contracts were received during this year's open season from Bronchus Technology, Technical Communities, Ultrasonix and Insighttec. The VA National Acquisition Center (NAC) and the DLA Troop Support Medical work on potential joint contracts. For radiation therapy, DoD and VA awarded 10 follow-on contracts.

There are currently eighty-six joint national contracts for pharmaceutical, two Blanket Purchase Agreements, seven pending contracts (at NAC going through the award process) and thirty-one proposed contracts which may or may not come to contracting as they are currently undergoing clinical review.

A comparison of joint contract sales (in millions) is shown below. A total of 27.4 percent of all contract sales are joint/shared sales.

Commodity	FY 2010 (thru 2nd Qtr)	FY 2009 (thru 2nd Qtr)	Change (thru 2nd Qtr)
Pharmaceuticals	$86.98	$96.75	($9.77)
Medical/Surgical Supplies	$0.015	$0.016	($0.001)
Equipment	$223.5	$368.63	($145.13)
Total	$310.50	$465.40	($154.90)

Question 31: In Mr. Down's testimony, he noted that all acquisition personnel previously reporting to the VISN or medical center directors have now been realigned under the VHA Procurement and Logistics Office. When did this change take place and what are some improvements that you have observed as a result of this change?

Response: On January 27, 2009, all acquisition workforce members that reported to the Network/Program Contract Managers (NCM/PCMs) were realigned under the new acquisition organization. The improvements that have been observed since this change include: (1) Transformation into a customer-focused organization; (2) improved fiscal responsibility; (3) increased performance oversight; (4) improved ability to implement and enforce acquisition metrics; (5) increased ability to involve customers in the full acquisition cycle; (5) increased opportunity for cost savings; and (6) standardized processes and procedures throughout the Service Area Office regions. These improvements have been validated through the various Network performance metrics established and reviewed by P&LO. These metrics include: procurement action lead time (tracks the amount of time from a completed acquisition package to award); purchase cards (verify that the purchase card holders reconciliations are performed within 30 days); customer survey (measures the level of customer satisfaction) ; electronic contract management system (eCMS) compliance (ensures procurement actions above $25,000 are in eCMS); unauthorized commitments (tracks the number and dollar value of unauthorized commitments); and socioeconomic goals (identifies percent of awards in the socioeconomic categories).

The second phase of the acquisition realignment occurred on October 1, 2010. As of this date, all warranted purchasing agents realigned under the acquisition chain of command. This change will allow VHA to improve training, oversight and management of all warranted individuals with purchasing responsibilities.

Question 32: In 2006, Secretary Nicholson signed VA Directive 1663, which established specific policies and procedures for the award of sole-source health care resource contracts to VA affiliated institutions. An OIG audit issued in September 2008 showed that VHA entities were not complying with the Directive.

Question 32(a): What actions have you taken since the OIG Audit was issued to ensure compliance with this Directive?

Response: A memorandum was issued to the field by the Medical Sharing Director on August 2008, defining the review process and thresholds.

Integrated Oversight Process (IOP) Review Checklists have been developed to identify the steps as required in VA Directive 1663, which include verification of the OIG pre-negotiation review defined in VA Directive paragraph 4.b.8.

Question 32(b): What percentage of health care resource contracts awarded by VHA in FY 2009 and FY 2010 complied with the Directive?

Response: Presently, this information is not known. For future purposes, the Medical Sharing Office could generate a monthly or quarterly report and have the SAO certify that pre-negotiation reviews were conducted in accordance with the directive.

Question 32(c): Given the significant potential cost savings identified by the pre-awards, what actions have you taken to ensure that all proposals for contracts with an estimated value of $500,000 or more are referred to the OIG for a pre-award?

Response: Using the IOP Checklists as mentioned above, allows for a quality check point to ensure appropriate reviews are conducted. If an OIG review has not been completed as required, it will be noted during the pre-award Contract Review Team (over $500K) or Contract Review Board (over $5M) review.

Question 33: To optimize the performance of VA's acquisition system, the former Secretary of Veterans Affairs established a Procurement Reform Task Force in June 2001 and a final report was released in May 2002. It is my understanding that the VA began implementing recommendations made by the Task Force. Were the recommendations fully implemented? Have there been any new initiatives to improve VA's medical acquisition system?

Response: VA continues to improve its medical acquisition system through the Acquisitions Realignment. The purpose of the realignment was to provide decision makers with the appropriate authority to execute strategic procurement programs, improve procurement oversight and create the best opportunity for stewardship. The realignment infrastructure ensures increased oversight and compliance with procurement regulations. These changes should effectively address the recommendations from the 2002 Procurement Reform Task Force.

Question 34: I understand you signed an executive decision memorandum April 29, 2010, which directed the Chief Acquisition Officer to implement the Acquisition Transformation Initiative at VA. Under this initiative, VA is to establish a strategic acquisition center to implement strategic sourcing initiatives for VA and handle contracting requirements exceeding field purchasing thresholds. However, I recently learned VHA is moving forward to increase its contracting workforce by an additional 400 FTE, and is currently advertising senior executive positions for VHA's three SAOs. How does VHA's actions in this regard comport to Secretary Shinseki's direction to the Chief Acquisition Officer? What is the rationale and justification behind such an increase given the new strategic acquisition center will provide contracting support to VHA above a national threshold for field purchases? Will this not complicate the Chief Acquisition Officer's ability to implement the Secretary's Acquisition Transformation Initiative?

Response: The VHA contracting workforce increases are to supplant the lack of personnel increases over the last several years. Within many VISNs there has been no increase in contracting personnel over the past 7 years, while there has been a substantial increase in workload. Additional personnel are required at the VHA level due to workload increases created as VHA corrects deficiencies in its acquisition programs. VHA fully supports the Integrated Acquisition Model, and requires additional staff to support this initiative. P&LO used the VA OALC staffing tool to determine additional staffing needs. OALC's staffing tool validated that VHA needed to hire an additional 399 acquisition staff. However, this staff number was based only on a $7.4 billion VHA spend; the actual spend for FY 2009 was $11.3 billion. VHA will request assistance from OALC to re-run the staffing tool using the final FY 2010 amount spent, which was approximately $13 billion.

Currently, VHA has 1,575 operational acquisition staff and 194 existing 1105 purchasing staff. This is significant because in FY 2009, VHA assumed additional contracting responsibilities for VHA Central Office Programs, absorbed the workload from over 1,000 non-acquisition staff and received an increase in workload from the reduction of the use of Miscellaneous Obligations (1358s). The ongoing VHA Acquisition Realignment established the proper acquisition structure and will drastically improve VHA Acquisition Operations. We do not see this as overlapping with the Strategic Acquisition Center implementation or complicating the implementation of the Secretary's Acquisition Transformation Initiative. Instead, this further supports the agency-wide goal to improve acquisition. Essentially, VHA's realignment and potential staffing increases create an acquisition infrastructure that supports both the integrated acquisition model and Secretary's Acquisition Transformation Initiative.

With regard to the Service Area Office Director positions; these positions were originally proposed as Senior Executive (SES) positions in the PricewaterhouseCoopers Study (PWC). The study indicated that SES positions for the VHA Service Area Offices (SAO) are reasonable due to the scope, size and complexity of VHA Acquisition operations, including interactions with National Unions, VISN Network Directors, Medical Center Directors and senior health care professionals. In addition to the approval of the SES positions in August 2010, VHA also received approval to upgrade the Network Contract Managers from GS–14s to GS–15s. The actions being taken to upgrade positions and obtain additional staff will ensure succession planning and compliance with the SAO SES recommendation in the PWC study.

Question 34(a): Another key change is that all acquisition authorities will flow from the Chief Acquisition Officer in the Office of Acquisition, Logistics, and Construction to the Heads of Contracting Activities who will be directly accountable to the Chief Acquisition Officer for ensuring compliance with enterprise policies, processes, and systems.

Question 34(i): What actions are being taken by VHA to ensure the proper flow of information from the Chief Acquisition Officer to the Head of Contracting Activities in VHA?

Response: The Chief Acquisition Officer provides information directly to the Head Contracting Activity in VHA. In addition, when acquisition information is provided to the Chief Procurement and Logistics Officer (CP&LO), the CP&LO ensures that VHA's HCA is informed and advised on the potential impact on VHA acquisition activities.

Question 34(ii): What actions are being taken by VHA to ensure the HCA implements these policies, processes, and systems are held accountable?

Response: As new policies, processes and systems are implemented, the VHA Quality Assurance (QA) team develops a plan of action and/or standard operating

procedure, if necessary. The QA works closely with the SAOs to ensure that SAO and VISN staff are informed and trained on the new policies, processes and/or systems. To ensure compliance, the QA team conducts compliance reviews at the SAO level; corrective action is initiated as necessary. The SAO level QA staff implements the corrective action at the VISN level.

Question 35: I'm interested in some general statistics about the contracts that VA awards. How many contracts did VHA award in fiscal year 2009? What percentage of the contracts was competitive versus sole-source contracts? What was the percentage of performance-based contracts?

Response: The total contract actions awarded by VHA in 2009 were 71,695, of which 22 percent were noncompetitive; 25 percent were performance based and 15.65 percent were awarded to Service-Disabled Veteran Owned Small Businesses (SDVOSBs).

Question 36: In 2010, OIG's Office of Contract Review conducted pre-award reviews of 32 health care resources proposals. These reviews identified $39 million in potential cost savings that could be realized during negotiations.

Question 36(a): What is the amount spent annually on contracts on a sole-source basis to VA affiliated institutions?

Response: Annually, approximately $181 million is awarded on a sole-source basis to VA affiliated institutions. In FY 2010, 9 percent of health care resource contracts were awarded sole-source to VA Affiliated institutions; none of these institutions are SDVOSBs.

Question 36(b): What actions have you taken or are you planning to take to ensure that the cost of savings identified in the pre-award reports are realized by negotiating lower prices?

Response: VHA has created a Cost Price Work Group to identify best practices to develop training information for the VHA contracting officers. VHA has requested assistance from OALC in defining the duties, responsibilities and authorities in regard to Medical Sharing.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 19, 2010

Belinda J. Finn
Assistant Inspector General for Audits and Evaluations
U.S. Department of Veterans Affairs
Office of Inspector General
801 I Street, NW
Washington, DC 20001

Dear Ms. Finn:

Thank you for testifying at the House Committee on Veterans Affairs' Subcommittee on Health oversight hearing on "VHA Contracting and Procurement Practices" held on September 23, 2010. We would greatly appreciate if you would provide answers to the enclosed follow-up questions in writing by Friday, November 19, 2010.

Due to the delay in receiving mail, please also provide your responses to Dolores Dunn, Minority Staff Director to the Subcommittee on Health. If you have any further questions, please call (202) 225–3527.

Sincerely,

Henry E. Brown, Jr.
Ranking Member

Office of Inspector General
Washington, DC,
November 16, 2010

The Honorable Henry E. Brown, Jr.
Ranking Member
Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives
Washington, DC 20515

Dear Congressman Brown:

This is in response to your October 19, 2010, letter following the September 23, 2010, hearing on *VHA Contracting and Procurement* Practices. Enclosed are our responses to the additional hearing questions.

Thank you for your interest in the Department of Veterans Affairs.

Sincerely,

/s/ by Richard J. Griffin for
GEORGE J. OPFER
Inspector General

Enclosure

Questions from the Honorable Henry Brown, Jr.
For Belinda Finn, Assistant Inspector General for Audits and Evaluations
Office of Inspector General, U.S. Department of Veterans Affairs
Before the Subcommittee on Health, Committee on Veterans' Affairs
United States House of Representatives
Hearing on *VHA Contracting and Procurement* Practices

Question 1: Please comment on the development of the VA's acquisition workforce. What further steps would you recommend VA take to ensure it has acquisition staff with the skill sets needed to provide appropriate contract oversight?

Response: To further develop VA's acquisition workforce, VA could consider evaluating the adequacy of the training provided at the VA Acquisition Academy to Veterans Integrated Service Network (VISN) contracting officers, Contracting Officers Technical Representatives, and other acquisition support staff. During fiscal year 2010 audit work, we performed a survey of VISN Network Contract Managers (NCMs). Nine out of 16 NCMs, who reported taking training at the Academy, responded that the training contracting officers receive from the Academy did not adequately prepare them to support the needs of program officials and comply with acquisition laws, regulations, and VA policy. When asked to explain why the training was not adequate, NCMs recommended that the training needed to be more tailored to the VA environment. NCMs also responded that there was a need for health care contract training.

Another step that could improve the development of VA's acquisition workforce is to ensure the entire VA procurement workforce is trained and uses the same acquisition support information system. Use of the Electronic Contract Management System (eCMS) is mandated, however the system is not fully utilized and information within the system is often incomplete. VA can develop specific performance measures on the use, quality, and completeness of the information in eCMS. VA's ability to obtain reliable information and transparency over all acquisitions and to assess how well these acquisitions complied with laws, regulations and policies is key to helping identify systemic weaknesses in acquisition practices and to tailor training requirements to address deficiencies in the future.

Question 2: What can VA do to ensure the completeness and accuracy of information in the system? Note we have addressed how improving the eCMS program is needed to promote visibility and transparency in VA acquisition processes in our September 23, 2010 testimony.

Response: In response to the above-referenced survey, VISN NCMs identified the need to integrate eCMS with the Integrated Funds Distribution, Control Point Activity, Accounting and Procurement system (IFCAP) to ensure VA and the Veterans Health Administration (VHA) information systems are connected and compatible. In

our July 2009 audit, we recommended VA determine the feasibility of integrating eCMS with IFCAP or the Financial Management System in order to avoid or minimize the duplicate data entry and streamline the process. VA agreed to implement this integration. Once in place, we expect that the integration will help strengthen the management of VA's acquisition processes.

VA recently reported to Office of Inspector General (OIG) auditors that VA's vendor is scheduled to complete a release of eCMS in November 2010, which will provide drop down lists for improved data consistency. The release will also incorporate mandatory data elements. Furthermore, VA reported to the OIG that an Action Review and Approval process will be introduced in calendar year 2011. This feature will provide business rules to enforce compliance at selected acquisition process milestones. After these changes are implemented, VA can consult with NCMs to determine whether these improvements effectively meet their needs and if other improvements to eCMS are needed. VA can greatly benefit from fully leveraging the use of eCMS from the standpoint of relying on a standardized management tool to improve the procurement process; however, VA cannot fully realize the benefits without ensuring the tool properly integrates with existing and planned financial systems.

Question 3: In a written statement submitted for the September 23, 2010, hearing on VHA procurement, the Coalition for Government Procurement (Coalition) alleges numerous problems with the timeliness of awards at VA's National Acquisition Center (NAC). The Coalition alleges that one of the primary reasons the NAC is broken is the "inappropriate insertion of the VA Office of Inspector General (OIG) into the contracting process." The Coalition implies that the OIG has assumed primary price negotiation and decision-making responsibility for contracts negotiated by the NAC. The Coalition also asserts that it hears "frequently from its members that after receiving and accepting an offer from a Contracting Officer, the OIG will step in and make the Contracting Officer withdraw its offer." Please explain the role of the OIG with respect to contracts awarded at the NAC and address in your response whether the statements by the Coalition are accurate.

Response: We have had the opportunity to review the statement submitted for the record to the Subcommittee on Health by Mr. Larry Allen on behalf of the Coalition for Government Procurement (Coalition). As way of background information, one component of the OIG is the Office of Contract Review (OCR). This group of 25 auditors and management analysts is responsible for conducting pre-award reviews of proposals submitted to the NAC by vendors seeking Federal Supply Schedule (FSS) contracts or modifications to those contracts and proposals for sole-source health care resource contracts. These reviews provide information and recommendations to VA contracting officers for use during contract negotiations. These services have been provided to VA since 1993 under a reimbursable agreement between the OIG and VA's Office of Acquisition and Logistics.

We also note that the Coalition is not a vendor, does not contract with VA, and to our knowledge, has not participated in the contracting process with VA on behalf of any of its members. Furthermore, the OIG and the Coalition have not engaged in discussions during any pre- or post-award review.

The Coalition's assertion regarding OIG actions in the contracting process are erroneous. The OIG has never assumed primary price negotiation and decision-making authority in the award of a contract or modification. During contract negotiations, contracting officers can, and do, consult with OCR staff who conducted the pre-award review to clarify findings and recommendations or seek additional review. Any involvement by OCR during contract negotiations is at the request of the contracting officer and does not constitute "primary negotiation or decision-making authority" or "operational responsibility" as alleged by the Coalition.

The Coalition criticizes VA's decision to conduct pre-award reviews of proposals submitted by vendors to determine whether the prices offered are fair and reasonable. The basis of the criticism is that this process is the cause for delays in award. The Coalition's position is not unexpected because these reviews often find that prices offered by vendors are not fair and reasonable when compared to those paid by commercial customers. As noted in our written statement, in 2010 pre-award reviews identified over $370 million in potential cost savings if the contracting entity negotiated fair and reasonable prices. In the past 5 fiscal years, the potential cost savings identified in the pre-award reviews exceeded $1.54 billion. These reviews have consistently shown that vendors fail to provide accurate, current, and complete information with their proposals. Although it can take up to 90 days to conduct these reviews, they are necessary to ensure that VA pays fair and reasonable prices for commercial products and services.

VA's pre-award program has been cited by the Government Accountability Office (GAO) as a best practice (*Contract Management: Further Efforts Needed To Sustain VA's Progress in Purchasing Medical Products and Services,* June 22, 2004). In a separate report, *Contract Management: Opportunities To Improve Pricing of GSA Multiple Award Schedules Contracts* (issued on February 11, 2005), GAO stated:

> The more than 1,200 FSS and 330 national contracts that VA has awarded have resulted in more competitive prices and have yielded substantial savings. VA has achieved these favorable prices and savings, in part, by exercising its audit rights and access to contractor data to pursue best prices aggressively for medical supplies and services. For example, pre-award audits of vendors' contract proposals and post-award audits of vendors' contract actions resulted in savings of about $240 million during fiscal years 1999 to 2003.

In the report, GAO was critical of GSA's failure to conduct pre-award and post-award audits and its negative impact on Government pricing. GAO also noted in this report that the price negotiation tools available to contracting entities to analyze information provided by vendors and make price reasonableness determinations were not effective.

The Coalition also criticizes VA contracting officers for relying on the pre-award review during negotiations. The criticism is based on the results of a survey question asking Coalition members: "In your negotiations with the VA, what did your CO rely on." The Coalition states that many members responded "the VA–OIG Pre-Award Audit." It is understandable that the Coalition and its members see this as a negative because the use of the pre-award report often results in the negotiation of lower prices. As a result, the profits the vendor anticipates receiving by charging VA more than fair and reasonable prices for products and services are decreased. Contracting Officers should be applauded for relying on the information obtained during the pre-award review to negotiate lower pricing for VA.

The Coalition further alleges that that after receiving and accepting an offer from a contracting officer, the OIG will step in and make the contracting officer withdraw the offer. However, the Coalition did not provide any evidence to support this allegation. This scenario could not happen because the OIG does not have any authority to make a contracting officer withdraw an offer that has been accepted. Such an action could only be taken by the contracting officer or someone within the contracting officer's chain of command. In addition, if a vendor believes VA has acted inappropriately during the award process, the vendor has the right to file a protest. To our knowledge, no protest has been filed alleging inappropriate actions by the OIG during contract negotiations.