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U.S. DEPARTMENT OF VETERANS AFFAIRS CREDENTIALING AND PRIVILEGING: A PATIENT SAFETY ISSUE

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

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

ONE HUNDRED TENTH CONGRESS

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U.S. DEPARTMENT OF VETERANS AFFAIRS CREDENTIALING AND PRIVILEGING: A PATIENT SAFETY ISSUE

TUESDAY, JANUARY 29, 2008

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:09 a.m., in Room 340, Cannon House Office Building, Hon. Harry E. Mitchell [Chairman of the Subcommittee] presiding.

Present: Representatives Mitchell, Space, Walz, Brown-Waite.

Also Present: Representatives Costello, Whitfield

OPENING STATEMENT OF CHAIRMAN MITCHELL

Mr. MITCHELL. We are here today to address the fallout from events at the Marion, Illinois, Veterans Affairs Medical Center.

I was troubled to find out about a pattern of deaths at this U.S. Department of Veterans Affairs (VA) hospital that went unaddressed. I am further concerned that the system in place to catch the substandard care has no rapid response measures.

According to the VA's Office of the Medical Inspector (OMI), from the beginning of 2006 through August of 2007, nine patients at Marion died as a result of substandard care. Another 34 had post-operative complications resulting from substandard care.

The Marion, Illinois, VA Medical Center serves veterans in south Illinois, southwestern Indiana, and northwestern Kentucky.

In August of 2007, the Veterans Health Administration (VHA) noticed a disturbing pattern. Patient deaths following surgery were more than four times the average.

The VHA sent an inspection team. They suspended all surgeries at the hospital and placed the leadership at the hospital, including the Chief of Surgery, on administrative leave. The VHA responded quickly when the data became available, but that data was more than 6 months old.

The data from the National Surgical Quality Improvement Program known as NSQIP, collects information from several hundred thousand surgeries performed at VHA facilities every year. Unfortunately, NSQIP reports only become informative an average of 5 months after an incident, due to a lag in gathering and inputting the data.

When VHA responded in August of 2007 to the pattern of excessive deaths at Marion, they were using data that covered October 2006 to March 2007. This is unacceptable.

The VHA cannot respond to problems in its hospitals if it does not know what they are. There must be controls to ensure that doctors and other healthcare providers have the required credentials and are fully qualified to perform the specific medical procedures they undertake. Events at the VA hospital in Marion, Illinois, tragically show what happens when these essential controls break down.

The Inspector General (IG) and Office of the Medical Inspector found that there is a serious hole in the system. The VA does not have a way to identify all jurisdictions where a physician has been or is licensed. This is because some States do not have an electronic registry or are not willing to share records.

The VHA requires that surgeons must receive clinical privileges to perform specific procedures at the hospital. The IG and the OMI discovered that this process had been abused at Marion. In fact, the privileges were granted at Marion regardless of the experience or training.

Even more disturbing is that privileges were granted at Marion for procedures that the hospital did not even have the facilities to accommodate, such as radiology access 24 hours a day.

The events at the Marion Hospital demonstrate a failure of the VA system to quickly bring important information forward so that the VHA can respond with appropriate action. This is a real problem.

Our first witness today is Ms. Katrina Shank. She drove her husband, Bob Shank, to Marion for a routine surgery. Bob passed away within 24 hours of the procedure due to the substandard care at the hospital.

I believe that if the safeguards had been in place and administrators had been properly notified of past incidents, Bob's death could have been prevented.

I want to know why no one outside of Marion was aware of the problems until August of 2007 and what VHA is doing to make sure that this failure of information flow never happens again.

Additionally, what is VHA going to do to fix the serious quality management issues, credentialing, and privileging that has been disclosed by this tragedy?

I am afraid that once we start looking at this issue deeply, we may find what happened at the Marion Hospital is not an isolated incident.

Our veterans served honorably to protect our Nation. We have the responsibility to take care of them when they come back home.

And before I recognize the Ranking Member for her remarks, I would like to swear in all of our witnesses. I would ask at this time that all of our witnesses for all the panels if they would please stand and raise their right hand.

[Witnesses sworn.]

Thank you.

Next I ask unanimous consent that Mr. Costello and Mr. Shimkus be invited to sit at the dais for the Subcommittee hearing today. Hearing no objection, so ordered.

If Mr. Costello and Mr. Shimkus would join us, please come to the dais.

I would like to now recognize Ms. Brown-Waite for her opening remarks.

[The prepared statement of Chairman Mitchell appears on p. 30.]

OPENING STATEMENT OF HON. GINNY BROWN-WAITE

Ms. BROWN-WAITE. Thank you, Mr. Chairman, and I thank you for yielding.

When the news came out last year showing a spike in surgical deaths at the Marion, Illinois, VA Medical Center, we on this Committee were concerned. We wanted to know whether this was an isolated incident or more widespread than reported.

On September 14th, Ranking Member Buyer and I wrote a letter asking for an investigation by the Office of the Inspector General into the spike in surgical deaths.

I am asking for unanimous consent to submit a copy of this letter for the record.

[The September 14, 2007, letter to Inspector General George Opfer, appears on p. 44.]

Mr. MITCHELL. So ordered.

Ms. BROWN-WAITE. Thank you.

I hope to hear from the Inspector General this morning about the results of the investigation.

On November 6, 2007, our Senate counterparts held a hearing on this issue as well. During this hearing, the U.S. Government Accountability Office (GAO) testified that in their 2006 review of the VA's credentialing requirements, it made four recommendations that VA medical facility officials must (1) verify that all State medical licenses held by physicians are valid; (2) query the Federation of State Medical Boards' database to determine whether physicians had disciplinary actions taken against any of their licenses, including expired licenses; (3) verify information provided by physicians on their involvement in medical malpractice claims at the VA or at a non-VA facility; and (4) query the National Practitioner Data Bank (NPDB) to determine whether a physician was reported to this data bank because of involvement in a VA or non-VA paid medical malpractice claim, and also display of professional incompetence or engaged in professional misconduct.

I am interested to hear if the VA was following all of these recommendations. If they were, I would like to know how a physician who lost his license in the State of Massachusetts, but still licensed in the State of Illinois, was allowed to practice at the VA facility in Marion, Illinois.

I think it is imperative that we explore the circumstances of this situation to prevent similar cases in the future. To do this, several questions still need to be answered.

How current are the national databases available to maintain licensing standards and how is information on licensing actions disseminated to other States?

The current NPDB system does not inform the agency of actions taken against a license, although I understand that they are in the process of developing a prototype to do this. The question is, has VA enrolled in this prototype?

Committee Members have been told repeatedly that the VA has one of the best healthcare systems in the Nation. The VA healthcare system is one that many other hospitals and healthcare systems are trying to emulate.

However, when the VA maintains credentialing for a practitioner whose license has been revoked in another State, we must question the quality of care being provided to our Nation's veterans.

Also, it is apparent that the scope of privileging and the commensurate appropriateness of staffing support has not been afforded the professional due diligence of responsible senior management. VA's premier healthcare delivery system is marred by some senior managers asleep at the wheel.

When veterans come to VA hospitals and outpatient clinics, they should not have to worry about whether or not their physician has a valid license to practice medicine. Veterans should not have to worry about whether the State of Massachusetts or any other State has revoked the license of a doctor practicing in Illinois for quality of care issues.

Our veterans trust that the VA does its part to ensure practitioners in VA medical facilities are the best trained and most qualified individuals to care for them. For the VA to do anything less is simply unacceptable.

Thank you, Mr. Chairman, and I look forward to hearing the witnesses that we have before us today. I yield back.

[The prepared statement of Congresswoman Brown-Waite appears on p. 31.]

Mr. MITCHELL. Thank you.

At this time, I would call on Mr. Costello.

OPENING STATEMENT OF HON. JERRY F. COSTELLO

Mr. COSTELLO. Mr. Chairman, thank you, and thank you for allowing me to participate in this hearing today, and thank you for calling the hearing, both yourself and the Ranking Member.

I would ask unanimous consent, Mr. Chairman, that my statement, my full statement be entered into the record.

Mr. Chairman, as we will hear today from our witnesses, both the IG and an internal investigation that was conducted by the VA, one is that the IG's report indicates that there are three patients who died as a result of substandard care administered by medical officials at the Marion facility. And as the internal investigation at VHA will reveal is that, as the Secretary informed me yesterday, that there are nine deaths that occurred as a result of substandard care at the Marion facility.

From my briefing yesterday with some of the witnesses that you will hear from today and my conversation with the Secretary yesterday, it is clear to me that the VA facility in Marion was grossly mismanaged during this period of time. And as you noted, the IG report covered a period of one fiscal year and the investigation that is being done internally by the VA covers a 2-year period. But it is clear that there was gross mismanagement on the part of those running the facility at Marion.

I want to say for the record that Marion, Illinois, and the facility are in the congressional district that I am privileged to represent. I know most, if not all, of the employees who work at the facility

and that they are good, dedicated, hardworking professionals. The mismanagement was on the part of the top administrators at the facility, not on the part of the nurses and other professional staff.

It is worth noting, too, that the nine deaths that the internal investigation revealed resulted from substandard care, that all of these patients were under the care of two specific physicians.

In addition to gross mismanagement, it is very clear that there was a lack of oversight on the part of the VHA concerning this facility and the practices of these physicians.

And it is my hope that as a result of this hearing and as a result of the investigation by the Inspector General and the internal investigation that, one, that we will see prompt action on the part of the VA to institute management at the facility that will follow procedures, follow practices, and implement standards that already exist; two, that we will see aggressive oversight by VHA of not only the Marion facility but all of the facilities under the jurisdiction of the VHA, and also that it is very clear that national policies need to be developed and implemented for all of the facilities so what happens at the VA facility and what has happened there during this period of time does not happen ever again in Marion or any other facility.

Finally, it is my hope, and I expressed this to the Secretary yesterday, that the VHA will immediately contact the families of the nine patients who died as a result of substandard care at this facility, that they will not only inform them but assist them in filing claims against the VA and against the Federal Government; two, that the VHA releases all of the information regarding this investigation to the public.

Many of my constituents, and I think Mr. Whitfield's constituents, Mr. Shimkus, those who are served by this VA facility, are wondering is this problem unique to the facility in Marion or this is a problem throughout the VHA at every facility.

And so it is my hope that they will release all of the information concerning this investigation and then, lastly, begin the process to implement policies to make sure that checks and balances are being performed and that we get back to providing the quality care that the VA has been noted for in the past.

So I again thank you, Mr. Chairman. I thank the Ranking Member and all of the Members of the Subcommittee for allowing me to participate.

[The prepared statement of Mr. Costello appears on p. 32.]

Mr. MITCHELL. Thank you.

Mr. Walz.

OPENING STATEMENT OF HON. TIMOTHY J. WALZ

Mr. WALZ. Thank you, Mr. Chairman and Ranking Member Brown-Waite.

Ms. Shank, I am sincerely sorry for your loss, and I can be fairly certain that there is probably any place in the world you would rather be than right here and I am sure you would rather be there with your husband.

And we are not here on a witch hunt, but we are sure here to understand and recognize that the human tragedy in this cannot be overlooked.

To give you the respect that you and your husband have earned, to look you in the eye and to talk about what we are going to do to make sure that this never happens again, I wished every Member of Congress could be here because I fail to ever see a politician who does not support our veterans, and then we hear about tragedies like this.

It is not time for the platitudes. It is not time to say, oh, it will be okay or we are sorry, a mistake was made. We know we are in the business, and I have often sat here and talked to people from the VA. I am a staunch supporter of the thousands and thousands of people who work in the VA with the sole purpose of caring for our veterans.

But I am also one of their harshest critics whenever we do not get it right. These are people who deserve our highest sacrifices ourselves. They deserve the highest and the best quality care that they can receive. I have often said it, this is a zero sum game, not a single veteran or their family should have to sit where you are at and testify what you are about to say. It should be our responsibility to make sure that never happens.

And I take that very seriously. I know the Members of this Committee take it very seriously. And our goal is to make sure that we do not just provide that lip service, that we make things right. But I know no matter what we do, none of those things will ease the pain of your loss, but I praise you for your courage to come here because what you are doing will ensure no one else sits where you are at.

So I thank you for that, and I yield back to the Chairman.

Mr. MITCHELL. Thank you.

Mr. Space.

Mr. SPACE. Thank you, Mr. Chairman.

I have no statement other than to express my sorrow for your loss, and as a Member of this Committee, my commitment to make sure that it does not happen anywhere in this country again. And thank you for your courage in coming today.

Mr. MITCHELL. I ask unanimous consent that all Members have 5 legislative days to submit a statement for the record. Hearing no objections, so ordered.

At this time, I would like to recognize Congressman Ed Whitfield of Kentucky who is here to introduce his constituent, Ms. Katrina Shank.

Congressman Whitfield.

OPENING STATEMENT HON. ED WHITFIELD

Mr. WHITFIELD. Chairman Mitchell and Ranking Member Brown-Waite and other Members of the Subcommittee, we thank you so much for having this important hearing on VA credentialing and patient safety.

I would also just mention I left a hearing a few minutes ago with Congressman Shimkus and he is the Ranking Member on a Subcommittee that is issuing subpoenas related to the Food and Drug Administration this morning or he would be here. So he asked me to convey that message to you and that he appreciates this hearing as well.

I would just say that all of us have certainly been shocked, disappointed, and upset about revelations of substandard care at the Marion VA Hospital.

And I have the privilege this morning of introducing a constituent of mine, Katrina Shank, from Murray, Kentucky. I know it is very difficult for her to be here today.

And I know that the testimony that she is going to provide will assist you as you make decisions about ways that we can guarantee good healthcare for our veterans. Our Nation's veterans deserve the best and in my mind, that certainly means competent, medical care that our Nation can offer.

I had the opportunity to meet with Ms. Shank yesterday and she told me about how her husband, Bob, who served in the military had gone to Marion for a routine gallbladder surgery and he never left the hospital and died just a day or so later from what was clearly substandard care that was given to him at the hospital.

So I want to thank her very much for her courage. Certainly all of us offer our sincere condolences, but we do thank her for being here today and look forward to her testimony.

And, once again, I want to thank you all for your efforts to nationwide ensure that our veterans have quality and competent medical care. Thank you very much.

Mr. MITCHELL. Thank you.

At this time, I would like to recognize Ms. Shank for 5 minutes.

STATEMENT OF KATRINA SHANK, MURRAY, KY (WIDOW)

Ms. SHANK. Mr. Chairman, ladies and gentlemen of this Subcommittee, my name is Katrina Marie Shank.

I am sitting before you today because I am the widow of Robert (Bob) Earl Shank III of Murray, Kentucky, who passed away August 10, 2007, after a routine laparoscopic gallbladder surgery at the Veterans Administration hospital in Marion, Illinois.

Bob was a United States Air Force veteran who served his country from July 30, 1975, to July 13, 1977, discharged with the service character of honorable.

I met my husband in July 1997 when he started working at the Maytag plant that I was hired into in September 1995. We were co-workers and friends for 6½ years prior to our marriage on June 25, 2004.

Bob was a reliable, hard worker and was promoted to group leader in our department, a position he held for several years.

Upon the closure of the Maytag plant on December 26, 2006, we relocated to Murray, Kentucky, on January 27, 2007, to be closer to my family and to establish a start to our retirement today down near Kentucky Lake.

Bob was an outdoorsman. He enjoyed hunting, fishing, golfing, and four-wheeler riding. We thought that if we were going to have to start all over, then we could be somewhere and could enjoy retirement together.

Bob helped raise six children of which only one was his own. When I met him, the first older three children were already young adults and out on their own. My children were still small and he wanted to be the dad, but he did not have to be.

He was a man that took respect very seriously before he asked me to marry him. He did not ask my father for my hand in marriage. He respected my children enough as individuals that he asked each of them for permission to marry me. That says a lot about a man's character to want to raise another man's children, not once, but twice, when he could have started living a life without children still at home.

He was the type of man that if you needed something that he had, without any questions asked, it was yours. He was always trying to help the next person out.

We both wound up back in the VA system after we lost private insurance when the Maytag plant closed. Before that, since we had the private insurance to pay for our healthcare, we opted not to use the facility and the benefits in hopes this would help with the overcrowding of the VA, giving the next veteran a better chance at receiving the help and care that they needed, where that might be the only option many of our veterans have for healthcare.

In turn, I now have reservations and fears of returning to the VA hospital for my personal healthcare.

On June 26, 2007, we traveled to Marion VA for an ultrasound of his entire abdomen in which only the upper right quadrant was scanned. The technician found the gallbladder and did not continue to scan on the rest of the abdomen. The test revealed that his gallbladder was full of stones and that surgery to remove the gallbladder was the course of action to be taken.

I started my new job on July 26, 2007. And in fear of putting my job in jeopardy so soon after hiring in, I was unable to attend his first meeting with Dr. Mendez on August 2, 2007.

Bob was originally scheduled for surgery in September. But before he left the hospital that day, there was a cancelation for August 9, 2007. He was asked if he would like to have that appointment instead. Naturally, in a desperate attempt to be relieved of his pain, he accepted this earlier appointment.

But I wonder would he still be here today had his surgery not been moved up. Chances are he might have even had a different surgeon given the investigation that we know now would have started prior to the surgery being performed in September instead of August.

With the same fear of losing my job, I almost did not accompany Bob to the surgery that day. One of my parents was going in my place instead. Thank God above that I found the courage and strength to approach my new boss with my situation and asked for the time off that I needed for his surgery.

The first time I met Dr. Mendez was about Bob's surgery when he came to me and said something had gone wrong during the surgery, that my husband just would not wake up. Maybe he had a heart attack. Maybe he had a stroke. I just do not know what happened. We are taking him up to ICU where he can be cared for. I have another patient waiting on me.

We left outpatient surgery and went to ICU. We were standing in the hallway when they wheeled my husband by. Going into ICU as they passed, the nurse was manually bagging him to keep him breathing.

The next time I saw my husband as the doctor pulled me by the hand through a crowded room full of nurses and doctors to his bedside, he lay there motionless with tubes coming out of his body, hooked to IVs and machines, as he was already placed on life support.

Throughout the course of the night, I was approached by Dr. Mendez several times to hear him comparing my husband to a car that needed routine checkups and blamed my husband for not taking care of his body. He also at one point told me that my husband had liver damage that we knew nothing about and that had caused his problems.

The autopsy performed on my husband did not reveal any liver damage. The doctor was covering his own tracks.

As my husband lay there with his blood pressure still dropping, another doctor had questioned Dr. Mendez about taking him back into surgery to find out where the blood was going. Dr. Mendez's response was, I have this under control. He waited several hours before taking him back into surgery to explore where he was losing blood from. Standing in the hallway talking to Dr. Mendez, he told my sister and me I have to try something. I either let him lay here and die or I kill him on the operating table, but I have to try something.

By the time he took him in, Bob's blood pressure was so low his blood was not spurting with his heartbeat. It was just an oozing effect making it difficult for Dr. Mendez to determine where the blood was coming from.

I believe had he gone back into surgery sooner when it was suggested by the other doctor, my husband would have had a better chance for survival.

The autopsy revealed his bile duct had been cut and he had a two centimeter laceration to his liver. The sutures that were placed in my husband's body had a knot at one end of the stitch and not at the other end. The heart attack and/or stroke the doctor blamed my husband's death on was not supported by the autopsy either.

As I left the hospital after my husband passed away, I had an overwhelming feeling that there was more to this story. Something just did not seem right. The nurses had a look in their eyes that they knew something but just could not tell me what it was.

I returned to the hospital on August 16, 2007, to sign papers for release of information to obtain a copy of his medical record and an autopsy report. To this day, we still do not have a complete set of records.

While I was there, I saw the Chaplain who had sat and prayed with me through the night and one of the nurses that took care of my husband in ICU, again with that same look on their faces and their eyes that told me there was more to my husband's story and they just could not tell me.

Before my children and I left the hospital that day, a hospital employee, which I had contact with shortly after Bob's passing, pulled me to the side. As he looked around and over our shoulders as if to make sure no one could ever overhear, he told me you need to hire an attorney, that my husband was Dr. Mendez's third patient death recently, one of which the man's wife worked at the hospital.

Dr. Mendez had up and resigned from the hospital Monday morning and did not even have the decency to come to the hospital to resign. He sent them an e-mail instead. That was August 13, 2007, just 3 days after Bob passed away.

As my mouth and my heart fell to the floor, I was shocked and instantly angry. As the pieces of the untold story were now falling into place, this seemed to be the coward's way out and that he was on the run because he knew he had done something to Bob. In my mind, him fleeing was his admission of guilt to what happened to my husband.

As I look back on the day of August 9, 2007, on our trip up from Murray, Kentucky, to Marion, Illinois, about a 2-hour drive, we did not discuss his operation. We were at ease knowing that he was finally going to get the relief from his pain that he so desperately needed and had waited for. And we did not foresee any problems or complications and assumed he would be returning home with me the next day, August 10, 2007.

However, he passed away that Friday morning instead, but finally we were able to bring him home on August 16, 2007, in a wooden urn that now sits on top of our entertainment center. A picture of him cropped out of our wedding photo is overlooking his urn. Alongside are two of his Air Force pictures placed underneath two trophy ducks that he had hung on the wall himself when we moved into our new apartment to start living the rest of our lives together and looking forward to our retirement.

I speak to my husband's ashes and picture every night before going to bed. I stand there with tears rolling down my face telling him how the day has gone and how much he had missed out on. I always end my conversations with I love you and I miss you and goodnight, my love, and give him a goodnight kiss on the outdoor scenery of the urn where my husband now rests in peace.

No other veteran's family should have to go through the heartache and the pain that mine and Bob's families have had to endure. So in closing, I ask why my husband's life had to end this way? Why was this allowed to happen given Dr. Jose Viezaga-Mendez's track record? How did the system fail my husband and several other veterans at the hands of this doctor? How many other veterans are going to have to lose their lives before we as a country can offer them more reliable healthcare?

I want to thank you for this opportunity to have our voices heard and our questions answered. Although my husband did not die during battle for our country, I ultimately believe that through us, he is still fighting for the safety of his comrades in arms and the future healthcare of our American veterans.

[The prepared statement of Ms. Shank appears on p. 32.]

Mr. MITCHELL. Thank you very much.

Any questions?

[No response.]

Mr. MITCHELL. Thank you. We appreciate it.

At this time, I would like to welcome panel number two to the witness table. Dr. John Daigh is the Assistant Inspector General for Healthcare Inspections for the VA Office of the Inspector General.

Dr. Daigh's team has recently completed an extensive investigation of the quality of care at the Marion VA Medical Center, and we look forward to hearing his view on VA's credentialing and privileging systems.

Dr. Daigh, will you please introduce your team.

Dr. DAIGH. Yes, sir. On my right is Dr. Clegg who is a statistician in my office. Dr. Andrea Buck, Dr. George Wesley, Dr. Jerry Herbers are internists who work in my office.

Mr. MITCHELL. Thank you. You have 5 minutes for your testimony.

STATEMENT OF JOHN D. DAIGH, JR, M.D., CPA, ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY GEORGE WESLEY, M.D., DIRECTOR, MEDICAL ASSESSMENT, OFFICE OF HEALTHCARE INSPECTIONS; JEROME HERBERS, M.D., ASSOCIATE DIRECTOR, MEDICAL ASSESSMENT, OFFICE OF HEALTHCARE INSPECTIONS; ANDREA BUCK, M.D., SENIOR PHYSICIAN, OFFICE OF HEALTHCARE INSPECTIONS; LIMIN CLEGG, PH.D., MATHEMATICAL STATISTICIAN, OFFICE OF HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. DAIGH. Thank you, sir. Mr. Chairman, Ranking Member, Congressmen, Ms. Shank, I would like to express my sorrow and disappointment at the care Ms. Shank so unfortunately described this morning.

We make a conscious daily effort to make a positive difference in the quality of medical care that is provided to veterans in the hope that events like this can be avoided.

I am appalled at the medical care that is described in our report yesterday. Quality medical care results from careful planning and attention to detail.

The peer review, credentialing, privileging, patient adverse event notification policies were among the policies that the Marion faculty simply did not comply with.

The question I was most asked during my briefing yesterday was, is there another facility with similar unrecognized quality of care problems waiting to be discovered. I answered that if I knew of a medical center with similar problems, that I would ensure that prompt action was taken.

I would like to add some context to that response. In all of the prior testimony that I have given before this Subcommittee, I have unequivocally said that I believe veterans are getting excellent quality healthcare. I am less certain of that assertion today than I have been in the past.

In June of this year, we published a report on the deficiencies at Martinsburg, West Virginia, which resulted in the death of a veteran who was in need of intubation.

In August of 2007, we published our follow-up report to the experience of the surgery service at Salisbury, North Carolina, for which I appeared before this Subcommittee some time ago.

In December of 2007, we reported on significant management deficiencies in the ICU in San Antonio.

And today, we report on the issues at Marion.

This collection of reports is unusual in my experience and in the experience of the men and women who work with me and who have been at the IG's Office for many years. And it erodes the confidence, my confidence, that veterans are receiving the best possible care.

I am also concerned about the effectiveness of Veteran Integrated Services Networks (VISNs) to monitor and supervise their regional medical facilities. We have, over the last year, seen VHA struggle to comply with directives from VA Central Office (VACO) to set business rules appropriately on the computerized medical record.

On our current ongoing review of VHA peer review processes, which is a result of the discussions we had at our Salisbury hearing, that data will demonstrate lack of VISN oversight of this process.

I believe that veterans are receiving quality care throughout the VA system based upon our ongoing hospital reviews, our CAP reviews. However, my confidence that the proper controls are in place has been shaken by the reports of the last several months.

Our recommendations in this Marion report are designed to improve some of the system-wide issues that we believe require correction and to address specific issues at Marion. In our report, we made 17 recommendations, which I would like to summarize.

One, and the Under Secretary of Health concurred in all of these recommendations, one is that patients who have received substandard care be informed of their rights for benefit claims either through the tort system or other applicable laws.

Two, that administrative reviews be conducted to determine whether or not senior officials within Marion should, in fact, receive some administrative disciplinary action.

Three, to develop and implement a national quality management directive which goes to the issue of there being 150 hospitals out there, each of which have a different management system in place, to address the data which should be collected and acted upon to ensure veterans receive quality care.

Three, to improve the credentialing process, and there are a number of specific issues which can further delineate how to improve the privileging process.

The most important aspect of that is to match the privileges, that is the procedures, both diagnostic and therapeutic, that a physician is allowed to perform at a hospital with the total capabilities of that hospital to support that care so that you do not do surgeries that you do not have the ICU staff, and other relevant staff, to support.

In addition, we are concerned about the NSQIP reporting system. This is the first serious review we have undertaken of NSQIP data. We are concerned about the sampling methodologies.

We would like to review with the VHA algorithms used to produce a forecast of expected mortality and we believe that there needs to be a review of the reporting process undertaken once data from that algorithm is obtained.

And then we made a series of specific recommendations regarding Marion leadership, that they follow specific procedures.

With that, I would like to end my statement and am pleased to take questions either by myself or with my staff.

[The prepared statement of Dr. Daigh appears on p. 34.]

Mr. MITCHELL. Thank you. Thank you.

I do have a couple questions. Do you believe that the VHA, or does the VHA, control the complexity of procedures performed at a facility?

Dr. DAIGH. I think that in general, the privileging process is viewed as a local process at an individual hospital. The view has been they are best determined and able to figure out what ought to be done at their hospital.

And I believe that it is time for VHA to exert from the Central Office more control of that. And I believe that the Under Secretary of Health, through our report, has agreed that action should be taken to supervise that process more closely.

Mr. MITCHELL. And along with that, does the current VHA policy define what kind of documentation is needed to establish a provider's current competence to perform a particular procedure?

Dr. BUCK. No, sir, it does not. It specifies that they need to determine current competence, documents reviewed and rationale for conclusions reached, but does not specify what constitutes evidence of current competence.

Mr. MITCHELL. And what responsibility does the VISN have with respect to credentialing and privileging?

Dr. BUCK. VHA Handbook 1100.19, which is the Credentialing and Privileging Handbook for VHA, does not specify any VISN responsibility for credentialing and privileging.

Mr. MITCHELL. And one of the issues here is that the VA's Central Office did not learn of the excessive deaths following surgery until months after the fact.

Can the VA rely on the system that is in place as its backdrop or does it need to do something else?

Dr. DAIGH. I think that in response, also, to your opening statement where the concern was a timely response to events like this, I think that it is the leadership and the people who work in a hospital who have to timely respond to issues that are ongoing. They have to track mortality rates. They have to review cases of individuals who die. They have to track infection rates. And they need to, in real time, address those issues. At Marion, that was not happening.

I think NSQIP is not designed, and I think it is beyond its expectation, that it should in real time identify outliers. It is a catch-all, but it can never be a real-time program, I believe.

The time required and the effort expended to collect the data elements, 200 some data elements to put into the program, and then the time to actually crank and do the statistical analysis does, in fact, take several months. So that is not what we should be relying on.

We need to rely on the Chief of the service, the Chief of Staff, the nurses who are there looking at these cases, the leadership at the hospital, and throughout VHA to make sure that these issues are picked up and addressed timely.

Mr. MITCHELL. Thank you.

And one last question. The VHA issued a new policy yesterday on the peer review process for reviewing potentially problematic outcomes.

Are you aware of this and did you see any new policy before it was issued?

Dr. DAIGH. I am aware that they issued a policy yesterday. We did not comment and I did not see the policy before it was issued. Oftentimes we do see these policies before they are issued. We will, however, not be deterred from reviewing the policy and making comments back to VHA in light of our view of what peer review ought to be.

Mr. MITCHELL. And along with that, would you expect the VHA to want your input or the IG's input on a new policy, particularly in light of what happened at Marion?

Dr. DAIGH. I would hope that they would. We would require, in closing our recommendations that have to do with peer review, that we see such policy and agree that such policy is appropriate to deal with the issues that we have defined. So there is a process in place to ensure that we do address it. So I will just answer it that way.

Mr. MITCHELL. Thank you.

Dr. DAIGH. Yes, sir.

Mr. MITCHELL. Ms. Brown-Waite.

Ms. BROWN-WAITE. Thank you, Mr. Chairman.

And I sit there and I look at the table and we have five doctors there. I take it you all are physicians; is that correct?

Dr. DAIGH. Dr. Clegg is a statistician.

Ms. BROWN-WAITE. Okay. Four doctors and a statistician.

Probably one of the toughest battles I ever had in the Florida Senate was when I went up against doctors and said I think that the public should know when there are disciplinary actions taken, including in another State, and also malpractice claim settlements in excess of, at the time I believe it was in excess of $100,000. It was either $75,000 or $100,000.

I was threatened. It was a very difficult time, but it was the right thing to do. And guess what? In Florida, we have what is called "Physician Profiles." You can go online and find information out about any physician.

Now, we all know that physicians get sued. Some specialties get sued more than others. But the reason why this drastic step was necessary was because doctors do not stand up and say Dr. X, Y, or Z is bad and dangerous for the patient. I am sorry, doctors, but that is the truth. Peer review is a joke.

I am convinced that if more States had the availability of this process, that we would have weeded out bad doctors who either lose their license or have disciplinary action taken, that perhaps Bob Shank would still be here today and that we would not have had to put his widow, Katrina, through this.

You know, I have to ask. When I read the report, this is the Office of the Medical Inspector General, and was told that some staff felt that when they voiced patient safety concerns, including those about rapid expansion of surgical scope of services, their concerns were dismissed as unimportant.

Nurses who took their concerns to the Chief of Surgery were told that is the way the Chief of Staff wants it. One senior nurse took concerns directly to the Director and was told "my hands are tied."

So even when there are nurses that recognize patients are being put in jeopardy, they are not listened to. And it is not just in the VA unfortunately and we all know that. It is not just in the VA.

Doctors, when is your profession truly going to do no harm by being able to stand up and say, "That doctor is a danger to the public?" He might be your golfing buddy. He might be somebody who attends Christmas parties with you or holiday parties with you. But if he is a bad doc, he does not belong in there, especially in surgery.

Would you come forward with some recommendations how we can better protect the patients? Because I can tell you that other legislators in other States were not successful when they tried to mirror the legislation I put in place. They were beaten down by the medical societies.

Please, and you do not need to answer it now, please come forward with some recommendations so that patients can be better protected and give doctors the necessary backbone that it takes to protect the patient.

Dr. DAIGH. Yes, ma'am, we will do that.

Mr. MITCHELL. Mr. Walz.

Mr. WALZ. Well, thank you, Mr. Chairman, and thank you all for being here today.

And I said it many times and I say it again that we are all here to make sure that the care for our veterans is improved, but I also hear us talking a lot and I see Ms. Shank sitting behind us, and I am wondering right now if she has heard anything that makes her have any confidence that this is not going to happen again.

And as we hear these things, there are a few questions that I sure want to ask. The one thing is is that I am confident that Ms. Shank will get a peer review on this by a jury of her peers at some point who will make some decisions on this. And I trust the justice system, but when they hear her story, I think we will find out how that will work.

But in the meantime, we have work to do. And I am, of course, a big supporter of the Office of Inspector General. I consider it to be a critical component in the quality of care. I consider it to be a critical component in oversight. And I know that the VA facilities who are delivering the quality of care, which there are many and many providers doing that, see you as partners in doing that.

So this is a group that I am glad that is here this morning. I am going to read a couple statements that came from your report.

You talked about the medical facility at Marion. The oversight reporting was fragmented, inconsistent, making it extremely difficult to determine the extent of oversight, patient quality, or corrective actions needed to improve.

And then there was another statement that talked about inadequate quality management measures in place for tracking, trending, evaluation of data relating to patients undergoing cardiac catheterization.

That type of data is longitudinal. It takes time to get that. You have your statistician here in Dr. Clegg.

My question is, why did we not spot it earlier? Why after the fact do we see this? Why if this was an ongoing problem?

And I guess in answering that, my goal, and I think the goal of this Committee, is to make sure that the Office of Inspector General, we have many hearings on this and it is very frustrating for many of us, do you have the personnel necessary to make sure you can review all these records and do you have the budgeting and the personnel necessary to do it because, unfortunately, we have heard it time and time again one of the largest government agencies has the lowest per capita number of inspector generals?

I guess what I am trying to see, is there a correlation between not having the resources necessary and catching this before Ms. Shank has to come here and testify? So, please, go ahead.

Dr. DAIGH. I think there is a correlation. I have 60 people working for me. There are over 150 hospitals. There are half a hundred nursing homes. So I do believe that with more resources we could do a more effective job.

We look at each facility on a once every 3 year basis. We focus on quality of care issues and procedures that are in place. And I would like to think that if there were defects like are at Marion and we were there, we would find them.

We have found them in the past and reported them. With my last testimony, I indicated hospitals where we have done that.

We were at Marion in 2005 and we did not find any problems with their quality procedures at that time. There were some changes, I believe, in the Marion leadership and in the organization of the hospital that I think may well have led to the current problem, but I cannot be sure that we did not miss something there.

So, yes, I think with more resources, I could do more. Thank you.

Mr. WALZ. If you know offhand or if somebody knows here, what did we do this year for the 2008 budget? Is it going to get better or is it going to stay flat or is it going to get worse for the Office of IG as it shakes out?

Dr. DAIGH. Our budget in 2008 went up. Our budget in 2009 is back below where we were before. So there is uncertainty as to what our long-term funding is. In that we just recently got a budget, it is uncertain whether we should hire individuals now and then have to fire them in several months. So that is a quandary that our leadership is dealing with.

Mr. WALZ. But we see leadership make a very intelligent and I guess professional judgment that more resources could have had some effect. I obviously understand some of this is subjective. And with that statement being made and, of course, we are going to give you those necessary resources.

So if you are Ms. Shank sitting behind you, what should she leave with? Should she leave with, well, Congress says they are going to fix this, but the person who said we could have caught this is not going to get the resources necessary to catch it? Is that the conundrum we are in right now?

Dr. DAIGH. Yes.

Mr. WALZ. Okay. Thank you.

Mr. MITCHELL. Thank you.

Mr. Space.

Mr. SPACE. Thank you, Mr. Chairman.

I recognize that all medical procedures, even marginally invasive ones, carry with them a certain recognized risk. But I guess the thing that concerns me about the Marion incident or incidents, in the case, the case of Mr. Shank, are the allegations of a cover-up, the suggestion that the original problems were blamed upon a heart attack or stroke, and then the subsequent statement by Ms. Shank that she still has not received all the medical records. That bothers me. And I think it is consistent with really a thread that we have seen in other aspects of the VA generally.

And my question of you, Doctor, is whether or not your investigation revealed any evidence of a cover-up by any specific employees at the Marion facility, whether medical records have been forthcoming, or, alternatively, whether Ms. Shank has had a difficult time obtaining them, and, third, whether any of your recommendations pertain to transparency and honesty in the provision of records and statements regarding condition. Was that looked into as a part of your investigation?

Dr. DAIGH. Well, sir, we did not talk with Ms. Shank. We did review the records surrounding that case. And for privacy reasons, which sort of sound silly here, but we have properly considered the outcome of this case and are very saddened by it.

With respect to whether she has gotten the medical records or not that she has requested, I simply do not know the answer to that. You would have to ask VHA whether there is a problem in her getting the records that she has requested.

With respect to the issue of whether local individuals told her stories that were an attempt to cover up or hide what actually happened on a minute-by-minute basis, I am sorry. We have no insight as to those specific facts.

I do think it would be revealing, though, to have Dr. Buck talk for a minute about the issue of what data one is supposed to submit as a physician for privileging and credentialing and then how that tracks through its difficulty in the system with respect to some of the doctors that are talked about here.

Dr. BUCK. Initially during the credentialing process, a physician actually submits an application in which they are supposed to disclose any pending actions against their licenses or any previous restrictions on their privileges or any present or former malpractice claims.

The VA is supposed to obtain primary source documentation. I think this goes to Representative Brown-Waite's initial comments regarding the GAO report. That information is obtained from malpractice carriers or previous institutions in the case of malpractice claims.

This information then is supposed to be evaluated and considered in the Professional Standards Board. Now, this is a group of other physicians at the facility.

What happens at this level is that the individuals review the information and then make a determination or recommendation for credentialing or privileging a person at the facility.

The credentialing process is about having these particular things addressed. The privileging process is about what a provider and an

institution are competent to do. And that includes both specific aspects.

So that is why some component of privileging is facility specific. That does not abrogate VHA's responsibility overall for the credentialing and privileging process. However, there are components to privileging that are inherently facility specific.

These determinations are made. They go through the Professional Standards Board. They are signed off by the Service Line Chief, the Chief of Staff, and the Medical Center Director. These are the procedures that are in place.

Now, what happened at Marion is that much of the information that was collected was not critically evaluated. There were discrepancies in what providers placed on their applications and what were actually obtained through primary source verification.

And the Professional Standards Board failed to critically evaluate this information and to document current competence and the rationale for the conclusions reached in the credentialing and privileging process.

One of the examples mentioned in the report is a provider, who at his previous institution, did not have privileges to perform colonoscopy. He came to Marion, and was granted privileges to perform colonoscopy with no discussion in the minutes regarding this individual provider's competence to perform this procedure.

A nurse develops a report of contact within 2 months of this person starting employment at the facility that says he could not recognize the anatomy of the colon or perform the procedure properly in one case. And as a result of this, we could find no evidence that official action was taken against the provider's privileges or that this information was considered.

Information collection is less of a problem than information evaluation.

Mr. SPACE. Thank you, Doctor.

Very briefly, has a determination been reached by you concerning whether, I am getting back to the specific case of Mr. Shank, whether the applicable standard of care was violated in this case relating to his treatment or condition?

Dr. DAIGH. Yes. Mr. Shank is one of the cases we identify as not meeting the standard of care.

Mr. SPACE. Thank you.

Mr. MITCHELL. Ms. Brown-Waite.

Ms. BROWN-WAITE. Thank you very much.

I guess I would ask this to Dr. Daigh. Did Dr. Mendez indicate or anywhere in the credentialing process, were you told that he had restrictions in Massachusetts and that this also apparently had been disclosed in December of 2004?

Dr. DAIGH. I am going to ask Dr. Buck again to respond. Dr. Buck and Dr. Wesley went and met with Dr. Mendez and we subpoenaed documents from Massachusetts. So I will ask her to respond to your question.

Dr. BUCK. It is true that there is a letter dated in 2004 which discloses that there was an active investigation ongoing in Massachusetts.

The initial provider's application asked questions regarding whether there has been any disciplinary action taken against the

license or whether there are pending administrative claims that might suggest there was problems with quality of care, somewhat vaguely worded questions.

The actual complaint came from a malpractice carrier that essentially limited liability coverage, which in Massachusetts, is a reportable event to the State Licensing Board. This was reported and triggered an investigation of some malpractice claims in that State. And that is, in fact, what started in 2004 but was not resolved for quite some time. It was actually two additional cases were added in 2005 and it continued on for at least 2 years.

Ms. BROWN-WAITE. But I think the question is, the VA was aware of this possible problem that was out there from 2004. Did anyone follow-up on this to see the outcome?

Dr. BUCK. Well, the VA actually received documentation from the Massachusetts board that there were no disciplinary actions against this provider at the time of his hire because they report only final disciplinary actions, not pending ones.

The actual information that he provided did indicate that there were some possible restrictions.

Ms. BROWN-WAITE. Well, I do not think, with all due respect, Dr. Buck, I do not think you answered my question. Did anybody at the VA follow-up on this? If there was something pending there and the outcome was not yet resolved, did anybody at the VA follow-up to see what was the conclusion of that?

Dr. BUCK. They had information that were not followed up on.

Ms. BROWN-WAITE. Okay. If I may ask Dr. Daigh just two questions. I know that the Marion facility is a very small facility. During your investigation, did you determine why the employees at that medical center never called the IG hotline or made complaints outside of the facility about patient care issues? Could it be that there was a fear of retribution if anyone was a whistle blower?

Dr. DAIGH. It is hard for me to know what is in the mind of individuals at Marion. We did during this timeframe, however, get a call from Marion to our hotline regarding one of the surgeons. The call, however, had nothing to do with their clinical care, but spoke to their use of language.

We sent that request back to be acted upon. The facility held a Board of Investigation and made some findings as a result of that.

So we have as a group thought about this a great deal and we simply do not have an answer for that, why they did not call us, the OMI, the newspaper. I just do not know.

Once, however, there were several deaths in a row in August and the NSQIP team arrived, then clearly everyone was upset at that point and began to talk.

Ms. BROWN-WAITE. Let me just extend a comment to my colleague, Mr. Walz. We have an obligation, I believe, to make sure that the funding for the Inspector General not only is the same as it was in 2008, and from what Dr. Daigh believes, the President's budget will have it reduced even more, I think it is our obligation here, and I know everyone agrees with me, to fight for additional funding because that is the way that I believe that these kind of constant problems can be resolved, by having adequate funding for the Inspector General.

Mr. Walz, I know how passionate you and every Member of this Committee is about veterans. And I think that is something that on both sides of the aisle we feel very strongly about.

Thank you, Mr. Chairman.

Mr. MITCHELL. Thank you.

And thank you all very much for your testimony.

Dr. DAIGH. Thank you, sir.

Mr. MITCHELL. I welcome panel three to the witness table. Dr. Gerald Cross is the Principal Deputy Under Secretary for Health at the Department of Veterans Affairs. Dr. Cross, we welcome you, and your insight. I would like to ask you to introduce your team before you begin your statement.

STATEMENT OF GERALD M. CROSS, M.D., FAAFP, PRINCIPAL DEPUTY UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY KATHRYN ENCHELMAYER, M.D., DIRECTOR OF QUALITY STANDARDS, VETERANS HEALTH ADMINISTRATION; JOHN PIERCE, M.D., MEDICAL INSPECTOR, VETERANS HEALTH ADMINISTRATION; NEVIN WEAVER, DIRECTOR OF WORKFORCE MANAGEMENT AND CONSULTING, VETERANS HEALTH ADMINISTRATION; AND HON. PAUL J. HUTTER, GENERAL COUNSEL, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. CROSS. Good morning, Mr. Chairman and Members of the Subcommittee. And I thank you for the opportunity to discuss the recent reports from the VA's Office of the Inspector General and the Medical Inspector on the quality of surgical care provided at Marion.

I am accompanied by Dr. Kate Enchelmayer, who is the Director of Quality Standards; Dr. John Pierce, VHA Medical Inspector; Nevin Weaver, VHA's Chief Officer of Workforce Management and Consulting; and Paul Hutter, our General Counsel.

These reports were issued yesterday and I understand that the Committee has already received them. As the Committee Members know, these investigations yielded troubling results.

Mr. Chairman, my heart goes out to the patients who received substandard surgical care and the families affected at Marion. I am angry that such a thing could have happened at one of our hospitals. And on behalf of the VA and again to the family that I spoke to before, I apologize to those patients and to their families.

But let me assure all of you that VA management did not sit idly by once we learned of the problems at the Marion facility. We first learned the extent of the problem on August 30, 2007, and major surgeries were stopped that same day.

On September 14, we removed the Hospital Director. We removed the Chief of Staff and we removed the Chief of Surgery from their positions. Since then, a new leadership team has been in charge, ensuring quality of care to our veterans.

Yesterday, we began calling all veterans who we believe may have been harmed by any substandard care, surgical care at Marion. And in accordance with our ethics policy, we will set up appointments within the next 2 weeks to review their care with them

and we will help them and their families in their efforts to receive compensation.

We have set up a toll-free number for patients and their families who are concerned about the care they received at Marion.

And, finally, we are working diligently to ensure that the issues that arose at Marion are not present in other facilities. We will do all we can to prevent problems like this from occurring anywhere in the future and we are determined to quickly correct any problems that we uncover.

Mr. Chairman, there were four significant areas in which Marion employees failed to comply with regulations and VHA directives and procedures. Those were leadership, credentialing, privileging, and quality management.

I believe the bottom line is this was a failure of leadership. To remedy this, we have initiated an Administrative Board of Investigation to review both quality in care issues and the conduct of individual employees.

The Board is empowered to recommended specific disciplinary actions against individuals. They can make such recommendations on any employee they choose at any level of responsibility.

The employees at Marion have been assured that whatever the Board's findings, the former Director and Chief of Staff will not return to the facility.

Regarding credentialing and privileging, we are undertaking a full review of our credentialing and privileging processes and we will increase our vigilance to make sure the representations our facilities make to us are accurate and complete.

We have chartered a group to link the level of support services provided at a facility with the complexity of procedures that can be performed at that facility.

We have created a work group on surgical processes to review our current strategies for improving quality, to examine the way in which we analyze surgical results, and to define a quality assessment process all hospitals can use to better assess their quality of care.

In quality management, we have already established a new directive to augment our reviews and have more to follow. And this will be for our facilities and will require external reviews of care and other changes.

Mr. Chairman, we have learned a hard lesson from these events. Among the lessons we have learned are the value of prompt and decisive action. We must link the capabilities of hospitals to the complexity of procedures they perform. We must strengthen the peer review system, especially at small hospitals. And, finally, we have learned the meaning of President Reagan's statement, trust, but verify.

Let me close with sincere apologies to all who have received any substandard care at the Marion surgical program, to their loved ones, to the Marion community, and to all of America's veterans and their families.

Mr. Chairman, I thank you and the Committee for your time.

[The prepared statement of Dr. Cross appears on p. 39.]

Mr. MITCHELL. Thank you.

Dr. Cross, between October 1 and December 31, 2006, Marion had seven deaths following surgery when the expected number according to NSQIP was two. We have been told that as a ratio, this is the highest deviation from the expected deaths ever reported. That information did not come to the attention of the Central Office until August. This is clearly unacceptable.

The VA cannot rely solely on local facilities to identify and deal with their own problems. What is the VA doing to make sure management can respond to serious problems in a timely fashion?

Dr. CROSS. Mr. Chairman, you are absolutely right. We cannot wait for NSQIP to give us those results. NSQIP was very helpful in this case as a backup system to give us that kind of information ultimately when the people close to the local facility did not do what they should have.

First and foremost, we need to demand of our leaders that they take their responsibilities and carry them out effectively. I do not believe that happened at Marion.

But beyond that, we have to put policies in place now to make sure that, particularly in things like peer review, that it is not just left up to the local facility, particularly at a small facility like Marion, but that we have external reviews that are done elsewhere. And, indeed, it is my intention that those external reviews, a portion of them will be done outside the VA entirely.

Mr. MITCHELL. How do you know that there are no more Marions out there? If you rely strictly on NSQIP for this conclusion, as you said, we know it is out of date. So how do we know that there are no more Marions out there?

Dr. CROSS. That is a question that I have thought long and hard about, Mr. Chairman, and my staff has as well.

First of all, let me point this out. We found the problem. We took action on the problem, and it was rather decisive action, at removing the entire leadership of the facility.

But that system that found the problem is also in place elsewhere. We have looked at that data. The data does not suggest that we have a problem similar to Marion elsewhere in our system. But that is not enough.

We are taking further action. We have already met with our National directors and pointed out the lessons learned as we knew them at the time last year in regard to Marion.

We are putting in place training and other measures to make sure that at all levels of our organization people understand what to look for to make sure that this does not happen.

Mr. MITCHELL. Under what conditions will Marion be permitted to reestablish its surgery program?

Dr. CROSS. I have been asked several times again when will surgery be resumed at Marion. And I have assured everyone that we have no timeline and no pressure to move that forward.

I think that we really need to reassess what is done at Marion. I told you we have established a surgery group to look at the complexity of surgery and the type of facility at which that is done.

I think that we will have to reconsider similar facilities to Marion and Marion itself as to what their future is in regard to a surgery program.

Mr. MITCHELL. Limiting privileges at individual hospitals to those procedures that the hospital itself has the services to support, is a great idea. But we have heard that Marion granted privileges to physicians apparently without any review at all. Even if the hospital can support a procedure, our veterans need to know that the doctor has the experience and skill to perform those procedures.

What is the VHA going to do to ensure the policies about experience and review of qualifications are followed at the local facilities?

Dr. CROSS. Well, we have a number of revisions and ideas on how we can do that. I am going to ask Kate Enchelmayer to support me in expanding on this answer.

Ms. ENCHELMAYER. Thank you, Dr. Cross.

We actually recognized quite early on that it is the medical staff leadership that is responsible for the review and the documentation of an individual's competency.

So we actually implemented back, actually last July, training and have required all medical staff leaders at each facility to take this training that reinforces their responsibilities in this process and their responsibility in reviewing the competency of practitioners as it comes forward for initial appointments and initial privileging, as well as ongoing monitoring. We are reinforcing requirements of the Joint Commission and making sure that the leadership understands that they do have this responsibility.

We also, in October, put in a requirement. We have an electronic credentialing system, VetPro, which consolidates everything, all the information, all the primary source information, as well as all the secondary source that we do get from the Federation of State Medical Boards and the National Practitioner Data Bank.

And we actually are now mandating that service chiefs who are the frontline making the recommendations for granting these privileges actually document in this electronic record themselves their recommendations, including requiring a competency statement of them so that they will be able to incorporate this information. But it does put all the information directly in front of them as they are making these recommendations.

So these are some of the actions we have taken, as well as we will be looking at the complexity work group as it comes forward. And we have been discussing a number of other activities.

Mr. MITCHELL. I have one last question. The VHA issued a new policy statement yesterday on the peer review process and reviewing potentially problematic outcomes.

Who reviewed this before it was issued and did the Medical Inspector review this? We just heard earlier the IG did not. Is it standard practice not to include the IG in statements like this and do you not think it would be essential to get the IG's involvement in this after they just got through investigating?

Dr. CROSS. Mr. Chairman, I am willing to get a good idea from anybody who will give it to me, and if the IG has some ideas. Here is what we did.

We actually had a meeting with them earlier this week and discussed the basic findings and what actions we were planning on taking. That was very valuable to me in writing and approving that directive that came out. That directive is one of several that

we have underway. They are going to get more and more specific in terms of the external peer review component.

And, again, I am happy to work with the IG on this. I meet with them frequently. We have an excellent relationship. I take their ideas very seriously and will continue to do so.

Dr. PIERCE. Sir, I was involved in that peer review directive being redone.

Mr. MITCHELL. Thank you.

Ms. Brown-Waite.

Ms. BROWN-WAITE. Thank you very much.

Dr. Cross, I am seeing far too much of you with all due respect. Those of us who sit on the Oversight panel are very concerned about this continuing process where I believe veterans are harmed and/or the once great VA healthcare system is substantially impaired.

When you said that the Chief of Staff was removed and the Chief of Surgery also was removed, what does removed mean? Are we just rearranging the deck chairs? Does anybody at VA ever lose their job for gross negligence?

Dr. CROSS. You bet. And what it means in terms of removed in this case is that they were taken away where they had no further responsibility——

Ms. BROWN-WAITE. Is that like the witness protection plan?

Dr. CROSS. I am going to ask Nevin Weaver to give you the details.

We are part of the government. We do have to follow the government safeguards that have been put in place. But we made sure within minutes, within hours that those individuals were removed from the facility and had no longer any relationship to the Marion facility.

I will ask Mr. Weaver to comment.

Ms. BROWN-WAITE. Sir, I think the question is, are these two individuals, the previous Chief of Staff for the hospital and Chief of Surgery, in any position in the VA today overseeing or performing any medical practices?

Dr. CROSS. No.

Mr. WEAVER. Yes. Let me talk a little bit about that. We did take 12 personnel actions that are in process. We have a combination of people who have reassigned, people who were actually removed.

And as you mentioned about the Director and the Chief of Staff, they are going to be a part of our Administrative Investigative Board which has begun yesterday. And we will be reviewing their involvement and then taking appropriate actions.

Ms. BROWN-WAITE. I certainly hope that none of these actions will be taken against the nurses who actually spoke up but who felt that (A) nobody cared what they said, and (B) that there was a lot of intimidation going on at that facility.

Have you all looked into that and do you have any remedies for other situations where quality of care is really necessary?

I find it also amazing that the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) gave their approval to this facility in August of 2007 while all this was going on. This is just absolutely amazing.

Dr. CROSS. Let me clarify one thing I told you earlier. The individuals were put on administrative leave.

Mr. WEAVER On detail.

Dr. CROSS. And the Administrative Board of Investigation is the thing that will now determine their responsibility and disciplinary actions, whatever that may be.

In regard to the Director and the Chief of Staff, I said in my opening statement that they would not be returning to the facility regardless of the findings.

Furthermore, the individuals have been placed at the VISN headquarters, which is, I think, over a hundred miles away from Marion, to just do routine administrative duties on a day-to-day basis while this investigation continues.

Ms. BROWN-WAITE. So it is basically administrative leave with pay and they are doing something administratively, not medically? Is that what I understand you to say?

Dr. CROSS. That is my understanding, yes.

Ms. BROWN-WAITE. Okay. Dr. Cross, you know that we have had hearings in the past on bonuses. As a matter of fact, we had one last year.

Can you tell this Committee if any of the senior management at Marion received bonuses and, if so, how much?

Dr. CROSS. I do not have that information.

Ms. BROWN-WAITE. Mr. Chairman, I would like to ask unanimous consent to have that information supplied to the Committee.

Mr. MITCHELL. Without objection.

[The information was provided in the response to Question 1 of the Post Hearing Questions for the Record letter from VA dated March 3, 2008, which appears on p. 56.]

Ms. BROWN-WAITE. I appreciate that very much.

The other thing is, and this will be my last question, there are about 20 other facilities in the VA, somewhat similar size to Marion.

Why are you waiting until March to check these facilities?

Dr. CROSS. We are not waiting until March to check those facilities. What we are doing, we started the credentials review that Ms. Kate Enchelmayer can comment on last year. And that is a credentialing review of all the staff at all those facilities across the Nation. And that has been underway now for some time.

I would like to ask Kate to comment on that.

Ms. ENCHELMAYER. Certainly. Thank you.

We actually, the 7th of October, went into our VetPro, our electronic credential system, and extracted approximately 17,000 names of the 56,000 licensed, independent practitioners. These are individuals who responded to supplemental questions that they had allowed a license to lapse or had a licensure action. They had responded to the questions about administrative claims or medical malpractice against them.

They also have had documented reports of information from the licensing boards or NPDB, reports given to us as we queried the NPDB, and also responses from the Federation of State Medical Boards.

That information was compiled and distributed to each individual facility. Each individual facility has already done a review

of these individuals. They have looked at the information that we had available, looked at the documentation and the consideration of these people as they were appointed to the facility or reappointed to the facility and privileges granted.

This has gone through VISN. It has had a VISN review. And we are in the process of actually collating information on the dollar figures that we have gotten over the many years of the National Practitioner Data Bank and the reports there. We have dollar figures. We have the reports. We have the information.

We are also looking at the licensure action information. We know that we have no physician or licensed independent, practitioner who is working for us who has a revoked license or has surrendered a license for cause after written notification of a revocation——

Ms. BROWN-WAITE. May I stop you right there?

Ms. ENCHELMAYER. Certainly.

Ms. BROWN-WAITE. I have found that when physicians know that they are being brought up on disciplinary action, what they do is they hand their license in at the State they are in, which in most States, will stop the disciplinary action. So they have voluntarily surrendered that license in another State. I see you shaking your head in agreement with me.

Ms. ENCHELMAYER. We have the requirement. The other half of the requirement is that if they surrender their license after written notification of a potential revocation for cause, then they cannot work for us until that license is fully reinstated. And that information is confirmed with the State Licensing Board, so we are at the mercy of the State Licensing Board to give us the information that we are requesting.

But we do have the requirement that if it is a voluntary surrender, once they are notified that the action is pending, they may not work for us until that license is fully restored.

Ms. BROWN-WAITE. Ma'am, the point at which someone realizes that disciplinary actions are going to be taken or that they are going to be involved in a major lawsuit, at that point, and you know it as well as I do, at that point, it is I am going to move to Florida or I am going to move to California and I am voluntarily giving up my license in this State. So you need to peel that onion apart a little bit more than just——

Ms. ENCHELMAYER. We are working very hard at that.

Ms. BROWN-WAITE [continuing]. If they have disciplinary actions.

Ms. ENCHELMAYER. We are working very hard at that. We implemented again back in October related to the medical malpractice issues that you have raised, we have implemented a VISN level review based on certain triggers in the medical malpractice payment process.

If a practitioner has three or more medical practice payments period, they must be reviewed by the Chief Medical Officer (CMO) at the VISN level to review the process that the facility has used in their review and the documentation of that process.

The second trigger on medical malpractice payment is if they have two or more malpractice payments totaling a million dollars or more, and the third trigger point is a medical malpractice payment of $550,000, a single malpractice payment.

And this is based on National Practitioner Data Bank data of all physicians who have been reported to them since the founding of the data bank in 1990. And that is the 85 percent cut point for the physicians of those three different categories.

So we have implemented that and those were the standards that were used by the VISNs when they reviewed the data that they were looking at back in November and December. And we are also looking at that.

To date, we have calculated that 619 practitioners out of the 56,000 licensed, independent practitioners we have would have triggered a review by the CMO based on medical malpractice payments.

Ms. BROWN-WAITE. Just one other question, Mr. Chairman, if you will.

I do hope that you will take into consideration that some specialties are sued more than others.

Ms. ENCHELMAYER. Yes.

Ms. BROWN-WAITE. Obviously orthopedic, OB/GYNs, and many times oncologists alone. So take that into consideration.

Ms. ENCHELMAYER. We are doing that right now, ma'am.

Ms. BROWN-WAITE. Okay. Thank you very much.

And I really do yield back.

Mr. MITCHELL. Thank you.

Mr. Walz.

Mr. WALZ. Thank you, Mr. Chairman.

And thanks, Dr. Cross, and your team.

Ms. Shank, when I opened with my statement, I said the least we can do is show you the respect to look you in the eye and talk about this issue which we have been doing over about the past hour.

And the one thing I can tell you as an honest assessment, you have heard it here, and this place and this Committee is a place where it is not business as usual for Congress. You heard the Ranking Member's passion on this issue and the cooperation.

I would like to tell you that I just returned recently from a fact-finding trip on the medical care our soldiers are receiving out in the field in Afghanistan and Iraq. And that trip was put together and led by Mr. Bestor on the Majority side and Mr. Wu on the Minority side. And I can tell you that politics did not enter into that at all. It was all about fact finding and seeing what is happening.

And I am pleased to tell you that the care that is provided for our soldiers down range is unprecedented in world history. And I think it is probably worth noting that a person highly responsible for that is Dr. Cross and his training of many of those physicians in the position he was in.

He came to the position he is in right now, if I am not mistaken, Dr. Cross, in July of 2007. So he took on this task and I am telling you this, Ms. Shank, to let you understand that this is not business as usual, that you coming here, nothing we say is going to make your pain any better, but the people you have here are the people who can make decisions.

You have the passion of the Chairman and the Ranking Member. You have the people here, and IG are the oversight on this, and you see the gentleman who is responsible for this in making sure

that it does not happen again answer hard questions and get quizzed on this.

So I would have to tell you that in terms of the way this place normally works, unfortunately, it does not look like this and the way it should be, that I am optimistic. But as the Ranking Member and the Chairman have said, there are issues we need to bring up.

Dr. Cross, the 17 IG recommendations on this specific issue at Marion, you concurred that those were issues?

Dr. CROSS. Yes, sir, we do.

Mr. WALZ. The only thing I am questioning, and this is where I get frustrated with business as usual, what assurance do we have that those are going to be done in a timely matter?

That is not something we were given. And I understand procedures and things. I would just ask you, Dr. Cross, to tell me how can we, in our oversight capability, be able to see that those things are hitting the benchmarks.

Dr. CROSS. We will give it to you and without hesitation. I should say that, you know, because of the relationship that we have with the OMI and the IG, we did not just start working on the recommendations this week. We actually started months ago because we in talking with the OMI and IG had some sense of what the issues were going to be and so we did not wait. We went ahead and started putting these things together at that time.

Mr. WALZ. Well, I look forward to it. It is incumbent upon us to exercise our responsibility to make sure that is happening. There is supposed to be layers in place to make sure these types of things do not happen. They obviously failed you, Ms. Shank and failed your husband, Bob. The issue at hand now is to do everything we can to make sure they do not fail in the future. And I think the questions that were asked, I am very appreciative of the hard questioning and the point of attack on this.

I can tell you something I was just notified of, that on February 13th, we will be holding a hearing in this Subcommittee on the IG's budget. And you heard the Ranking Member's commitment to making sure we get this thing right and we will be working on that.

So it is not lip service for a short time and then we brush away any of the inconveniences. This is a case of understanding that this has to be fixed.

So for all of us here today, it is an unfortunate reason that we are here, but it is also, I think, in the right spirit that we are going to move this thing forward and that responsibility is being taken. And we're going to make sure if responsibility is not taken, that it will be.

Mr. MITCHELL. One thing just before he comes back. Can we make sure that Ms. Shank gets the records that she is after?

Dr. CROSS. Yes, sir.

Mr. MITCHELL. Thank you.

Mr. WALZ. The last question that counsel asked, Dr. Cross, was on this issue and that you are going to provide those to us and those timelines of when the 17 recommendations will be. How can we expect to get that, I guess, being a little more specific?

Dr. CROSS. I am going to get them to you as fast as I can. You know, we are still drafting them and we have to make sure that it is a quality document, that we have covered the entire gamut.

We still have work to be done. I am not sure what the exact process is, but it is my hope——

Mr. WALZ. Do your staff know that I can call over and keep following up?

Dr. CROSS. Yes, sir. And I will work on that call.

[The timeline was provided in *Appendix A*, of the January 28, 2008, report, *Healthcare Inspection: Quality of Care Issues, VA Medical Center, Marion, Illinois* (Report No. 07–03386–65), which appears on p. 45.]

Mr. WALZ. Okay. Thank you.

And I yield back.

Mr. MITCHELL. Thank you.

I would just like to make one closing statement, that I joined with Mr. Costello and Mr. Whitfield and Mr. Shimkus in introducing H.R. 4463, the "Veterans Healthcare Quality Improvement Act." And I believe this bill is a first step in improving the desperate situation that the VHA is in at this time.

And what I am asking is that if you would review this and give us your input because we want to make sure that we are on the right track and we are doing the right thing.

And I also ask the Members of this Subcommittee to join on as joint sponsor.

Dr. CROSS. Yes, sir.

[The Administration views for H.R. 4463, the "Veterans Healthcare Quality Improvement Act," appear on p. 62.]

Mr. MITCHELL. And this concludes the hearing. And I want to thank all of our panelists.

And, Mrs. Shank, again, our condolences.

Thank you.

[Whereupon, at 11:43 a.m., the Subcommittee was adjourned.]

APPENDIX

Prepared Statement of Hon. Harry E. Mitchell, Chairman, Subcommittee on Oversight and Investigations

This hearing will come to order.

We are here today to address the fallout from events at the Marion, Illinois, VA Medical Center. I was troubled to find out about a pattern of deaths at this VA Hospital that went unaddressed . . . and further concerned that the system in place to catch this substandard care has no rapid response measures.

According to the VA's Office of Medical Inspector, from the beginning of 2006 through August of 2007, nine patients at Marion died as a result of substandard care. Another 34 had post-operative complications resulting from substandard care.

The Marion, Illinois, VA Medical Center serves veterans in southern Illinois, southwestern Indiana, and northwestern Kentucky. In August of 2007, the Veterans' Health Administration noticed a disturbing pattern—patient deaths following surgery were more than four times the average.

VHA sent an inspection team. They suspended all surgeries at the hospital and placed the leadership of the hospital—including the chief of surgery—on administrative leave.

The VHA responded quickly when the data became available, but that data was more than six months old.

The data came from the National Surgical Quality Improvement Program, known as NSQIP. This program collects information from several hundred thousand surgeries performed at VHA facilities every year. Unfortunately, NSQIP reports only become informative an average of five months after an incident . . . due to a lag in gathering and inputting the data.

When VHA responded in August 2007 to the pattern of excessive deaths at Marion, they were using data that covered October 2006 to March 2007.

This is unacceptable. The VHA cannot respond to problems in its hospitals if it does not know what they are.

There must be controls to ensure that doctors and other health care providers have the required credentials and are fully qualified to perform the specific medical procedures they undertake. Events at the VA Hospital in Marion, Illinois, tragically show what happens when these essential controls break down.

The Inspector General and Office of the Medical Inspector found that there is a serious hole in the system. The VA does not have a way to identify all jurisdictions where a physician has been—or is—licensed. This is because some states do not have an electronic registry or are not willing to share records.

The VHA requires that surgeons must receive a clinical privilege to perform specific procedures at the hospital; the IG and OMI discovered that this process had been abused at Marion. In fact, privileges were granted at Marion regardless of experience or training.

Even more disturbing is that privileges were granted at Marion for procedures that the hospital didn't even have the facilities to accommodate, such as radiology access 24 hours a day.

The events at the Marion hospital demonstrate a failure in the VA system to quickly bring important information forward so that the VHA can respond with appropriate action. This is a real problem.

Our first witness today, Ms. Katrina Shank, drove her husband, Bob Shank, to Marion for a routine surgery. Bob passed away within 24 hours of the procedure due to the substandard care at the hospital. I believe that if the safeguards had been in place and administrators had been properly notified of past incidents, Bob's death could have been prevented.

I want to know why no one outside of Marion was aware of the problems until August 2007 and what VHA is doing to make sure that this failure of information flow never happens again.

Additionally, what is VHA going to do to fix the serious quality management issues, credentialing and privileging that have been disclosed by this tragedy?

I am afraid that once we start looking at this issue deeper, we may find that what happened at the Marion hospital isn't an isolated incident.

Our veterans served honorably to protect our Nation. We have a responsibility to take care of them when they come back home.

Prepared Statement of Hon. Ginny Brown-Waite, Ranking Republican Member, Subcommittee on Oversight and Investigations

Mr. Chairman, thank you for yielding.

Mr. Chairman, when news reports came out last year showing a spike in surgical deaths at the Marion, Illinois VA Medical Center, we on this Committee were concerned. We wanted to know whether this was an isolated incident or more widespread than reported.

On September 14, 2007, Ranking Member Buyer and I wrote a letter asking for an investigation by the Office of the Inspector General into the spike in surgical deaths. I ask unanimous consent that a copy of this letter be submitted for the official hearing record.

I hope to hear from the IG this morning about the results of this investigation. On November 6, 2007, our Senate counterparts held a hearing on this issue as well. During this hearing, GAO testified that in their 2006 review of VA's credentialing requirements, it made four recommendations that VA medical facility officials must:

1. Verify that all state medical licenses held by physicians are valid;
2. Query Federation of State Medical Boards (FSMB) database to determine whether physicians had disciplinary action taken against any of their licenses, including expired licenses;
3. Verify information provided by physicians on their involvement in medical malpractice claims at a VA or non-VA facility; and
4. Query the National Practitioner Data Bank to determine whether a physician was reported to this data bank because of involvement in VA or non-VA paid medical malpractice claims, display of professional incompetence, or engaged in professional misconduct.

I am interested to hear if the VA was following all of the recommendations. If they were, I would like to know how a physician who lost his license in the state of Massachusetts, but was still licensed in the state of Illinois, was allowed to practice at the VA facility in Marion, IL.

It is imperative that we explore the circumstances of this situation to prevent similar cases in the future. To do this, several questions need answering.

How current are the national databases available to maintain licensing standards, and how is information on licensing actions disseminated to other states?

The current NPDB system does not inform the agency of actions taken against a license, although I understand that they are developing a prototype to provide Proactive Disclosure Services. Has VA enrolled in this prototype?

Committee Members have been told repeatedly that the VA has one of the best healthcare systems in the nation. The VA healthcare system is one that many other hospitals and healthcare systems are trying to emulate.

However, when the VA maintains credentialing for a practitioner whose license has been revoked in another state, we must question the quality of care being provided to our Nation's veterans.

Also, it is apparent that the scope of privileging and the commensurate appropriateness of staffing support have not been afforded the professional due diligence of responsible senior management. VA's premier healthcare delivery system is marred by some senior managers asleep at the wheel.

When veterans come to VA hospitals and outpatient clinics, they should not have to worry about whether or not their physician has a valid license to practice medicine.

Veterans should not have to worry about whether the state of Massachusetts has revoked the license of a doctor practicing in Illinois for quality of care issues.

Our veterans trust that the VA does its part to ensure practitioners in VA medical facilities are the best trained and most qualified individuals to care for them. For the VA to do anything less is unacceptable.

Thank you for calling this hearing, Mr. Chairman. I look forward to the witness testimony.

Prepared Statement of Hon. Jerry F. Costello,
a Representative in Congress from the State of Illinois

Chairman Mitchell and members of the Subcommittee on Oversight and Investigations, I would like to thank you for giving me the opportunity to be a part of this hearing addressing the issue of ensuring the quality of healthcare practices within the Veterans Health Administration (VHA).

First, I want to give my condolences to the families affected by the tragedy at the Marion VA Medical Center, including the wife of Mr. Robert Shank III, Mrs. Katrina Shank, who is here today to testify.

As the representative of the congressional district which includes Marion, Illinois, I know that much of the staff at the Medical Center does good work providing healthcare for Veterans. For this reason I am all the more troubled that faulty leadership at the Medical Center and significant institutional problems have resulted in the tragic deaths of at least nine individuals in the past two years and in significant health problems for numerous others. The system has failed these veterans, and their families, who have given a part of their lives to the service of this country. While it is too late to help these veterans, we must make sure that these problems are corrected to restore the integrity of the VHA system.

The report addresses four major problems that were found at the facility: quality management, the credentialing process, the privileging process, and a lack of leadership by senior staff. In all of these cases there was a combination of exceedingly poor management in parts of the facility and a lack of sufficient, systemwide rules ensuring checks on the quality of health care. As such, both the Marion VAMC's practices and VA Department rules relating to quality healthcare assurance need to be reviewed and strengthened accordingly. In addition, while the credentialing of health care providers can be viewed as a problem of the health care system as a whole, there is much that the VHA can do to address this problem.

While I am pleased that the VA discovered and investigated the problems at the Marion VAMC, this must be the first step in reevaluating and reforming fundamental procedures in the VHA. Representatives Shimkus, Mitchell, Whitfield and I have recently introduced legislation to address many of these issues. The Veteran's Health Care Quality Improvement Act would:

1. require greater disclosure of a physician's history of malpractice lawsuits and status of being licensed
2. establish within the VA, as well as in each Veteran Integrated Services Network (VISN), a Quality Assurance Officer responsible for ensuring quality healthcare is provided
3. require a complete review of VA policies and procedures which ensure quality care

While I will work to enact this legislation into law, it is seriously troubling that these controls were not already standard practice within the VHA.

As these investigations demonstrate, there clearly needs to be a substantial revamping of the credentialing and privileging processes, as well as other institutional changes within the VHA to assure quality healthcare. I look forward to the panel's testimony regarding their investigations. I also hope to hear suggestions of how reliable controls can be implemented in our medical centers and outpatient clinics so that our Veterans receive the quality healthcare that their country owes them.

Mr. Chairman, I again thank the Subcommittee for allowing me to participate today, and I look forward to the testimony of the witnesses.

Prepared Statement of Katrina Shank, Murray, KY (Widow)

Mr. Chairman, Ladies and Gentlemen of this Committee:

My name is Katrina Marie Shank; I am sitting before you today because I am the widow of Robert (Bob) Earl Shank III of Murray, Kentucky, who passed away August 10, 2007, after a routine Laparoscopic Gallbladder Surgery at the Veterans Administration Hospital in Marion, Illinois.

Bob was a United States Air Force Veteran, who served his country from July 30, 1975–July 13, 1977, discharged with a service character of "Honorable."

I met my husband in July 1997, when he started working at the Maytag plant that I was hired into in September 1995. We were co-workers and friends for six and a half years prior to our marriage on June 25, 2004.

Bob was a reliable hard worker and was promoted to group leader in our department, a position he held for several years. Upon the closure of the Maytag plant on December 26, 2006, we relocated to Murray, Kentucky, January 27, 2007, to be

closer to my family, and to establish a start to our retirement together down near Kentucky Lake. Bob was an outdoorsman; he enjoyed hunting, fishing, golfing, and four-wheeler riding. We thought that if we were going to have to start all over then we would be somewhere we could enjoy retirement together.

Bob helped raise six children of which only one was his own. When I met him the first (older) three children were already young adults and out on their own. My children were still small and he wanted to be "the dad that he didn't have to be."

He was a man that took respect very seriously; before he asked me to marry him, he did not ask my father for my hand in marriage, he respected my children enough as individuals that he asked each of them for permission to marry me. It says a lot about a man's character, to want to raise another man's children, not once, but twice, when he could have started living his life without children still at home.

He was the type of man that if you needed something that he had, without any questions asked, it was yours. He was always trying to help the next person out.

We both wound up back in the VA system after we lost private insurance when the Maytag plant closed. Before that, since we had the private insurance to pay for our health care, we opted not to use the facilities and benefits, in hopes this would help with the overcrowding of the VA; giving the next veteran a better chance at receiving the help and care they needed, where that might be the only option many of our veterans have for health care. In turn I now have reservations and fears of returning to the VA for my personal healthcare.

June 26, 2007, we traveled to the Marion VA for an ultrasound of his entire abdomen, in which only the upper right quadrant was scanned, the technician found the gallbladder and didn't continue the scan on the rest of the abdomen; the test revealed that his gallbladder was full of stones and that surgery to remove the gallbladder was the course of action to be taken.

I started my new job on July 26, 2007, in fear of putting my job in jeopardy so soon after hiring in, I was unable to attend his first meeting with Dr. Mendez on August 2, 2007. Bob was originally scheduled for surgery in September, but before he left the hospital that day there was a cancellation for August 9, 2007 he was asked if "he would like to have that appointment instead," naturally in a desperate attempt to be relieved of his pain he accepted that earlier appointment. I wonder "would he still be here today had his surgery not been moved up; chances are he might have even had a different surgeon, given the investigation that we now know would have started prior to the surgery being performed in September instead of August."

With the same fear of losing my job I "almost" did not accompany Bob to surgery that day, one of my parents was going in my place instead, "Thank the good Lord above that I found the courage and strength to approach my new boss with my situation and ask for the time off that I needed for his surgery."

The first time I met Dr. Mendez was after Bob's surgery when he came to me and said "something had gone wrong during surgery, Mr. Shank just wouldn't wake up, maybe he had a heart attack, maybe he had a stroke, I just don't know what happened; we are taking him up to ICU where he can be cared for, I have another patient waiting on me."

We left out-patient surgery and went to ICU, we were standing in the hallway when they wheeled my husband by, going into ICU. As they passed, a nurse was manually bagging him to keep him breathing; the next time I saw my husband as the doctor pulled me by the hand through a crowded room, full of nurses and doctors to his bedside. He lay there motionless, with tubes coming out of his body hooked to IV's and machines; as he was already placed on life support.

Throughout the course of the night, I was approached by Dr. Mendez several times listening to him compare my husband to a "car" that needed routine checkups and blamed my husband for not taking care of his body. He also at one point told me that Bob had liver damage we knew nothing about, and that had caused his problems. The autopsy performed on my husband did not reveal any liver damage (the doctor covering his own tracks).

As my husband lay there with his blood pressure still dropping, another doctor and I questioned Dr. Mendez about taking him back into surgery, to find out where the blood was going; Dr. Mendez's response was "I have this under control." He waited several hours before taking him back into surgery to explore where he was losing blood from. Standing in the hallway talking to Dr. Mendez, he told my sister and me, "I have to try something, I either let him lay here and die, or I kill him on the operating table, but I have to try something." By the time he took him, Bob's blood pressure was so low, his blood was not spurting with his heart beat; it was just an "oozing" effect making it difficult for Dr. Mendez to determine where the blood was coming from. I believe had he gone back into surgery sooner when it was

suggested by the other doctor, my husband would have had a better chance for survival.

The autopsy revealed his bile duct had been cut and he had a 2cm laceration to his liver, the sutures that were placed in my husband's body had a knot at one end of the stitch and not at the other end. The heart attack and/or stroke the doctor blamed my husband's death on, was not supported by the autopsy either.

As I left the hospital after my husband passed away, I had an overwhelming feeling that there was more to this story; something just didn't seem right. The nurses had a look in their eyes, that they knew something but just couldn't tell me what it was.

I returned to the hospital on August 16, 2007, to sign papers for release of information, to obtain a copy of his medical records and autopsy report (to this day we still do not have a complete set of records). But while I was there, I saw the Chaplain, who sat and prayed with me through the night, and one of the nurses that took care of my husband in ICU, again with that same look on their faces, and in their eyes that told me there was more to my husband's story and they just couldn't tell me. Before my children and I left the hospital that day a hospital employee (which I had contact with shortly after Bob's passing) pulled me to the side, as he looked around and over our shoulders as if to make sure no one could over hear, he told me "You need to hire an attorney, that my husband was Dr. Mendez's third patient death "recently"; one of which, the man's wife worked at the hospital, Dr. Mendez had up and resigned from the hospital Monday morning and he didn't even have the decency to come to the hospital to resign, he sent them an e-mail instead." (August 13, 2007, just 3 days after Bob passed away). As my mouth and my heart fell to the floor I was shocked and instantly angry, as the pieces of the untold story were now falling into place; this seemed to be the coward's way out and that he was on the run cause he knew he had done something to Bob. In my mind, him fleeing was his admission of guilt as to what happened to my husband.

As I look back on the day of August 9, 2007, on our drive up from Murray, Kentucky, to Marion, Illinois (about a two hour drive) we didn't discuss his operation. We were at ease knowing that he was finally going to get the relief from his pain that he so desperately needed and had waited for. We did not foresee any problems, or complications, and assumed he would be returning home with me the next day, August 10, 2007. However, he passed away that Friday morning instead, but finally we were able to bring him home August 16, 2007, in a wooden urn that now sits on top of our entertainment center. A picture of him cropped out of our wedding photo is overlooking his urn; alongside are two of his Air Force pictures placed underneath two trophy ducks that he had hung on the wall himself, when we moved into our new apartment to start living the rest of our lives together and looking forward to our retirement. I speak to my husband's ashes and picture every night before going to bed. I stand there with tears rolling down my face telling him how the day had gone and how much he missed out on each day. I always end my conversation with, "I Love You and I Miss You, Goodnight My Love," and give him a goodnight kiss on the "outdoor" scenery of the urn, where my husband now "Rests In Peace."

No other veteran's family should have to go through this heartache and pain that mine and Bob's families have to endure!!! So in closing I ask why my husband's life had to end this way? Why was this allowed to happen, given Dr. Jose Viezaga-Mendez's track record? How did the system fail my husband and several other veterans at the hands of this Doctor? How many other veterans are going to have to lose their lives before we, as a Country, can offer them more reliable health care?

I want to thank you for this opportunity to have our voices heard and our questions answered. Although, my husband did not die during battle for our Country, I ultimately believe that through us he is still fighting for the safety of his comrades in arms and the future health care of our American Veterans.

Prepared Statement of John D. Daigh, Jr., M.D., CPA,
Assistant Inspector General for Healthcare Inspections,
Office of Inspector General, U.S. Department of Veterans Affairs

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today on the credentialing and privileging process of the Department of Veterans Affairs. As a way of explaining to you the importance of the credentialing and privileging process, I would like to review our findings from the Office of Inspector General (OIG) report *Healthcare Inspection, Quality of Care Issues, VA Medical*

Center, Marion, Illinois. I am accompanied by Dr. George Wesley, Dr. Andrea Buck, Dr. Jerome Herbers, and Dr. Limin Clegg.

INTRODUCTION

The Veterans Health Administration's (VHA's) National Surgical Quality Improvement Program (NSQIP) identified the VA Medical Center (VAMC) at Marion, Illinois, as having a mortality rate that was over four times the expected rate as calculated by VHA during the first two quarters of fiscal year (FY) 2007 (October 1, 2006, through March 31, 2007). In response, a NSQIP review team was sent to the Marion VAMC on August 29, 2007. By the end of its 2-day visit this team had identified concerns with the quality of surgical care provided patients and deficiencies related to medical center leadership and the Surgery Service, including quality management (QM) processes, such as peer reviews and credentialing and privileging of physicians. As a result of this review, inpatient surgery was suspended at the Marion VAMC, and the Under Secretary for Health and Congress asked the Office of Inspector General (OIG) to perform a comprehensive review of these concerns.

The OIG Office of Healthcare Inspections (OHI) immediately initiated a review making numerous site visits to Marion VAMC and the Veteran Integrated Services Network (VISN) 15 in Kansas City, Missouri. We reviewed all Marion VAMC NSQIP surgical mortality cases for FY 2007 and selected morbidity cases and ancillary services, such as respiratory therapy and intensive care unit capabilities, necessary to permit the safe performance of inpatient surgery. We retained distinguished surgeons and an anesthesiologist not employed by the Federal government to further review cases in question. We also conducted a comprehensive review of the credentials and privileges of the Marion VAMC surgical staff and a review of NSQIP processes and data.

OHI staff interviewed physicians; other clinical and administrative staff; veterans and family members; and VHA leadership at Marion VAMC, VISN 15, and VA Central Office in Washington, DC. OHI also interviewed staff at the NSQIP Denver Data Analysis Center (DDAC), the NSQIP Boston Coordinating Center, and the Information Service Center at Birmingham, AL. Records were subpoenaed from state medical licensing boards and other institutions. The Federation of State Medical Boards (FSMB) was contacted to determine the extent of information provided VHA, as was the Department of Health and Human Services concerning VHA inquiries regarding the National Practitioner Database (NPDB).

INSPECTION FINDINGS—QUALITY OF CARE IN SELECTED CASES

Overall, we concluded that the Surgical Specialty Care Line at Marion VAMC was in disarray. Based on a review of 29 deaths that occurred among veteran patients who underwent surgery at the Marion VAMC in FY 2007, we concluded that there were specific problems with actual quality of care provided to veteran patients. These problems included pre-operative, intra-operative, and post-operative quality of care issues. In the report we discuss three mortality cases as examples of those which did not meet the standard of care. A veteran suffered a traumatic rupture of his spleen requiring urgent surgery. Sufficient blood transfusions were prepared for this patient, but they were administered too late to be effective. The second example involved the care provided for a patient whose heart disease placed him at increased risk for surgery. This patient, who died 1 day after surgery, received inadequate intra- and post-operative care. The third case involved a death following elective gallbladder surgery, with clear evidence of inadequate management of the patient's ventilation and post-operative instability.

OHI also identified examples of non-fatal complications resulting from poor care involving other patients treated by surgeons at Marion VAMC. In one case, we found that Marion VAMC failed to appropriately diagnose and treat a young Operation Iraqi Freedom Marine veteran following the onset of severe abdominal pain. Areas of deficiency related to this case included availability and use of consultants and the transfer of his care to his home state. He also faced substantial barriers to ongoing specialty care in the private sector due to the lack of specialty surgeons participating in TRICARE. Other cases discussed in this report include a veteran who received substandard care by an orthopedic surgeon managing a knee infection following total knee replacement surgery, and a urologist who perforated both the bladder and the sigmoid colon of another veteran patient while attempting to incise a urethral stricture.

We also substantiated allegations of poor medical care involving two patients treated by non-surgical providers. One case involved allegations relating to the follow-up of a patient with a thoracic aortic aneurysm, and the other the medical management of a patient with hypotension.

QUALITY MANAGEMENT

Quality Management is designed to monitor quality and performance improvement activities, compliance with selected VHA directives and appropriate accreditation standards, as well as Federal and local regulations. The ability of Marion VAMC to effectively respond to quality of care concerns was hampered by an ineffective QM Program. We found that failure to comply with VHA QM policies resulted in deficiencies in the peer review process, tracking and collecting service line or medical provider performance data, reporting adverse events and occurrences, and mortality assessments, among others.

We concluded that the oversight reporting structure for QM reviews at Marion VAMC was fragmented and inconsistent, making it extremely difficult to determine the extent of oversight of patient quality or corrective actions taken to improve patient care. This occurred partially because QM responsibilities were split between multiple groups at the facility with little or no management oversight. Likewise, Surgery Service leadership was ineffective, including communication between the NSQIP nurse, surgical providers, and the Chief of Surgery, allowing multiple QM processes within the care line to fail.

An important component of the QM Program is the peer review process. VHA defines peer review as a protected, non-punitive, medical center process to evaluate the care at the medical provider level. The peer review process includes an initial review by an individual peer to determine if the most experienced practitioners would have managed the case in a similar fashion (Level I), might have managed one or more aspects of the care differently (Level II), or would have managed the case differently (Level III) in one or more prescribed categories. At Marion VAMC, surgical peer review results from February 2007 through August 2007 resulted in 131 Level I findings, 4 level II findings, and no Level III findings. These results appear inconsistent with OHI review findings of the mortality and morbidity cases discussed in this report. Also, it was not clear how cases at Marion VAMC were identified for peer review, and cases were not presented in a timely manner. Local policy states that reviews should be completed in 30 days, although some cases took as long as 5 months.

VHA policy requires that standardized trending of patient deaths occur at each medical facility. The results are required to be presented in a regular forum in order to identify unusual patterns or trends. Although VHA policy does not designate the frequency for presentation of death reviews, standard practice is to aggregate and report results quarterly. We found that Marion VAMC reviews are compiled annually. If there were a trend in mortality, an annual review would not address issues in a timely manner. For example, the latest review at Marion VAMC was presented in April 2007, but it was limited to deaths that occurred during FY 2006. As such, the spike in deaths reported by NSQIP that occurred during the 1st and 2nd quarters of FY 2007 would not have been compiled and assessed for unusual patterns or trends until almost a year later.

We also found that Marion VAMC had inadequate quality management measures in place for tracking, trending, and evaluation of data relating to patients undergoing cardiac catheterization. The facility also failed to adequately document nursing staff and provider competencies to perform services in the cardiac catheterization laboratory.

CREDENTIALING

Credentialing refers to the process by which health care organizations screen and evaluate medical providers in terms of licensure, education, training, experience, competence, and health status. The credentialing process is done for a medical provider's initial appointment in VHA and every 2 years following. Credentialing occurs at the VISN 15 level in a centralized credentialing office. VISN 15 also queries the FSMB and the NPDB to obtain information regarding any disciplinary actions taken against a provider's medical license and any paid malpractice claims. Even though credentialing is centralized to VISN 15, credentialing decisions must still be approved at the medical center by the Professional Standards Session of the Clinical Executive Board (Marion VAMC's term for the Professional Standards Board or PSB). Credentialing is done through VetPro, VA's credentialing and privileging system.

We found deficiencies in the credentialing of physicians. For example, the PSB at Marion VAMC failed to document consideration of important credentialing information such as malpractice claims identified through the NPDB, the health status of a surgeon who recently had a visual problem, and information on previous performance problems contained in provider references. OHI also found discrepancies in the number of malpractice claims reflected in primary source documents from malpractice carriers and the initial application of a medical provider without evidence

that this discrepancy was addressed by the PSB, the Chief of Staff, or the Chief of Surgery Service. Other examples include not completing documentation related to verification of licensure, registration, and board certification requirements in a complete and timely manner. In one instance, a physician was granted privileges on May 3, 2007, even though the Chief of Staff did not complete reporting requirements until August 27, 2007.

VHA does not require physicians to have a medical license in the state in which they are employed with VA. As a result, a surgeon at Marion VAMC can hold a medical license issued by a state other than Illinois. It is also common for VA physicians to simultaneously hold licenses from more than one state, and to let licenses lapse and apply for new ones throughout their career. Being able to identify which state or states a physician is or has been licensed in is critical in obtaining information regarding any disciplinary actions taken against a physician's medical license for credentialing purposes. VHA currently has no means of identifying all states in which a physician holds a license to practice medicine if that physician does not disclose those licenses on his or her initial application.

We found the existence of undisclosed medical licenses in both surgical and non-surgical providers. For example, OHI reviewed credentialing and privileging files for 14 non-surgical providers and found that 2 providers held licenses not listed on the initial application. In one of these examples, the medical provider had not disclosed a license in a state where disciplinary action was ultimately taken against that license. We also discovered an instance where VHA received a disciplinary alert from the FSMB concerning a Marion VAMC medical provider's license, but they failed to fully evaluate the alert for more than 9 months after receiving it.

PRIVILEGING

We found significant deficiencies in the privileging of physicians, which is the process by which physicians are granted permissions by the medical center to perform various diagnostic and therapeutic procedures. For example, multiple instances were discovered in which physicians were privileged to perform procedures without any documentation of current competence to perform those procedures. In one instance, a surgeon received privileges to perform colonoscopies at the Marion VAMC. His privileges from his previous institution did not include colonoscopies. On February 22, 2006, a report of contact written by the Operating Room (OR) nurse manager described an incident in which a technologist reported to her that this surgeon had difficulty identifying colon anatomy and in maneuvering the colonoscope. We were informed that the surgeon was asked not to perform colonoscopies at the Marion VAMC. Although no documentation was identified of any action taken against his privileges, there were no records indicating that the surgeon performed colonoscopies after that date.

In another example, we could not find documentation that the PSB considered current competence of a surgeon to place a central line. On November 1, 2007, the Acting Medical Center Director at Marion requested an administrative board of investigation (ABI) to examine the surgeon's treatment of a complication arising from central line placement. The physician placed a central line, and the patient, who was receiving mechanical ventilation at the time, developed a tension pneumothorax. The ABI found that, while both the surgeon and another physician involved in the care of the patient were privileged to perform needle decompression of a tension pneumothorax, neither could articulate the proper procedure to the ABI. The ABI recommended that the facility evaluate processes in place for requesting and approving provider privileges.

Not only did the facility fail to document consideration of the current competence of a physician to perform certain procedures, the PSB also failed to consider professional performance data in its decision to re-privilege physicians at the institution. For example, as early as May 19, 2006, the Medical Center Director was notified of serious problems with documentation of patient encounters. Multiple e-mails document that this problem was ongoing. On November 20, 2006, the Quality Assurance Session of the Clinical Executive Board identified that a specific physician had an increased number of post-operative infections. On April 24, 2007, the OIG referred a complaint against this physician to Marion VAMC for review of allegations of inappropriate conduct and tardiness. On June 20, 2007, Marion VAMC notified the OIG that an ABI substantiated multiple reports of vulgar language and prolonged waiting times for patients resulting from numerous factors, including physician tardiness. The ABI recommended appropriate progressive disciplinary or other administrative actions related to the physician's behavior. On May 10, 2007, his service chief received peer reviews conducted on this physician's cases which identified clinical care issues in 8 of 12 cases reviewed. Nevertheless, the physician was

re-privileged without reference to aggregated data from the peer reviews, the results of the ABI, or the physician's problems with documentation.

In part, privileging is facility specific because, regardless of the expertise of the physician involved, the availability of services at a facility may limit the appropriateness of performing those procedures at that facility. OHI found that facility leadership did not limit provider privileges based upon medical center capabilities. For example, the Marion VAMC Surgical Specialty Care Line Operational Planning Guide reflected interest in establishing a specialty surgery program in part to decrease fee basis costs. As a result, in January 2006, Marion VAMC hired a general surgeon to perform surgery in that specialty, even though he was not board certified in general surgery or the specialty surgery at the time he was hired. He also received special pay based on the facility's recruitment and retention difficulties related to hiring surgeons in that specialty. Also, Marion VAMC did not have in-house 24-hour coverage in respiratory therapy, pharmacy, and radiology. Because of that, OR staff expressed concern about performing such complex procedures at Marion VAMC. Clinical staff at the facility acknowledged that they felt pressured to perform more complex procedures in order to reduce fee basis costs.

FACILITY LEADERSHIP

Problems identified in the areas of quality management and credentialing and privileging, as well as the quality of care issues identified in specific cases, are a reflection of facility leadership. The Marion Medical Center Director, Chief of Staff, Chief of Surgery, Associate Chief Nurse, and Associate Director for Patient Care/Nursing Services have specific responsibilities for the performance of quality management activities in the surgical specialty care line. OHI found that there were significant warnings of many of these very problems that were available to medical center senior management well before the NSQIP site visit and the subsequent suspension of inpatient surgery. These took the form of a detailed external review of the Surgery Service by a consultant nurse occurring in October 2006, and a similar review performed by the Chief of Surgery Service of a large midwestern VAMC. Likewise, we found internal reports of contact and e-mails detailing frontline nursing surgical staff problems with many aspects of the Surgery Service. It appears that most of this information, with the possible exception of the aforementioned Chief of Surgery Service's report, was not disseminated to other VHA managerial entities such as VISN 15 or VA headquarters in Washington, DC.

NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM

NSQIP data are collected locally at each VAMC and analyzed centrally in the DDAC. The Marion VAMC NSQIP data were abstracted and entered by the same NSQIP Surgical Clinical Nurse Reviewer (SCNR) for the 1st and 2nd quarters of FY 2007, during which the Marion VAMC had elevated Observed-to-Expected mortality ratios which triggered the NSQIP team site visit. During her tenure as the Marion SCNR from September 1998 until her retirement in April 2007, there is no evidence to question her technical competence as the NSQIP SCNR.

We concluded that NSQIP offers an opportunity of providing evidence-based monitoring and improvement in VA quality of surgical care. NSQIP could improve by developing an operations manual for the DDAC, reviewing and adopting the state-of-the-art statistical methodologies, detailing its risk-adjustment methodology in a technical report, taking more advantage of the VA computerized medical records system in its data collection and edits, and evaluating evidence of its tangible improvement in VA quality of surgical care. NSQIP would enhance the utility of its risk-adjusted and unadjusted surgical outcome measures by taking its sampling scheme into account in their estimation to reflect the actual outcome experience of the VA surgical patient population.

RECOMMENDATIONS

The following recommendations are based on the findings of the report.

Recommendation 1: The Under Secretary for Health develop and implement a national quality management directive that ensures a standardized structure and mechanism throughout VHA for collecting and reporting quality management data.

Recommendation 2: The Under Secretary for Health develop and implement a mechanism to ensure that VHA's diagnostic and therapeutic interventions are appropriate to the capabilities of the medical facility.

Recommendation 3: The Under Secretary for Health explore the feasibility of implementing a process to independently identify all state licenses for VA physicians.

Recommendation 4: The Under Secretary for Health develop and implement formal policies and procedures to ensure that Federation of State Medical Boards' Dis-

ciplinary Alerts are timely addressed by medical facilities, VISNs, and VHA headquarters.

Recommendation 5: The Under Secretary for Health conduct reviews to determine appropriate administrative actions against Marion VAMC leadership and other staff responsible for the problems cited in this report, to include the Medical Center Director, the Chief of Staff, the Chief of Surgery, the Associate Director for Patient Care/Nursing Services, and the Associate Chief Nurse of the Surgical Service.

Recommendation 6: The Under Secretary for Health issue guidance that clearly defines what constitutes evidence of current competence for use in the privileging process.

Recommendation 7: The Under Secretary for Health consider the issues which are identified in this report for modifications to NSQIP and other related programs.

Recommendation 8: The Under Secretary for Health confer with the Office of General Counsel regarding the advisability of informing families of patients discussed in this report about their right to file tort and benefit claims.

Recommendation 9: The Under Secretary for Health ensure that Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses.

Recommendation 10: The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider National Practitioner Database results and document consideration of those results.

Recommendation 11: The Under Secretary for Health ensure that Marion VAMC appropriately credentials providers with references executed in accordance with VHA Handbook 1100.19 and documents consideration of discrepancies in provider disclosures and information obtained from references.

Recommendation 12: The Under Secretary for Health require the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board to consider the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19.

Recommendation 13: The Under Secretary for Health require the Marion VAMC Chief of Staff to sign and complete the certification correctly on VA Form 10–2850, *Application for Physicians, Dentists, Podiatrists and Optometrists.*

Recommendation 14: The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification.

Recommendation 15: The Under Secretary for Health require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed and rationale for the conclusions reached with respect to privileging process.

Recommendation 16: The Under Secretary for Health require that the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the re-privileging of medical providers.

Recommendation 17: The Under Secretary for Health ensure that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competency evaluations for staff, and evaluates the privileging of catheterization laboratory providers in according with VHA policy.

Comments

The Under Secretary for Health concurred with our findings and recommendations and submitted appropriate action plans. We found the Department's improvement plans acceptable and will follow up until all recommendations are implemented.

Mr. Chairman, thank you again for the opportunity to testify on this important issue. We would be pleased to answer any questions that you or other members of the Committee may have.

Prepared Statement of Gerald M. Cross, M.D., FAAFP,
Principal Deputy Under Secretary for Health,
Veterans Health Administration, U.S. Department of Veterans Affairs

Good morning, Mr. Chairman and members of the Subcommittee. Thank you for the opportunity to discuss the reports from VA's Office of the Inspector General (OIG) and the Office of the Medical Inspector (OMI) regarding surgical care pro-

vided at the Marion, IL VA Medical Center (VAMC). I am accompanied by Ms. Kate Enchelmayer, Director of Quality Standards, Dr. John Pierce, Veterans Health Administration (VHA) Medical Inspector, Nevin Weaver, VHA's Director of Workforce Management and Consulting, and Paul Hutter, VA's General Counsel. These reports were issued yesterday and I understand the Committee has already received them. As the Committee members know, these investigations yielded troubling news.

Last year, VA provided treatment to almost 5.5 million veterans, the vast majority of whom received exemplary care. The events at Marion represent an unfortunate exception to our established record of high quality care. As part of that care, the VA review process detected the problems at Marion, and our response has been sure and swift. Our Department is committed to continually improving our care to make the VA health care system a model of excellence for health care around the world. VA is determined to do the right thing for our patients and their families.

In that spirit, I will now outline VA's initial response to the problems VA identified at Marion, the conclusions of the two independent investigations, and our subsequent actions.

The Marion VAMC opened in 1942 and now provides care to almost 44,000 veterans annually. The Marion VAMC serves 27 counties in southern Illinois, eight counties in southwestern Indiana, and 17 counties in northwest Kentucky. It is a general medical and surgical hospital that operates 55 acute care beds. The last full survey by the Joint Commission was completed on August 31, 2007. There were no major issues identified, and the Marion VAMC was re-accredited.

The National Surgical Quality Improvement Program (NSQIP) gathers aggregate data from surgical outcomes to determine whether there are significant deviations in mortality and morbidity rates for surgical procedures. VA developed NSQIP almost 15 years ago as part of our effort to monitor and improve the quality of surgical care. The American College of Surgeons (ACS) has incorporated its own version and now enrolls new private sector hospitals in the ACS' program. VA's NSQIP feeds back mortality and morbidity data on a quarterly basis to VA Surgical Chiefs, Directors, and VISN CMO's. Beginning in Fiscal Year 2007, the National Director of Surgery of the NSQIP Executive Committee reviews NSQIP information on a quarterly basis. Prior to that time, the information had been reviewed by the board yearly. It was decided that NSQIP would be a better tool if the data were acted upon more frequently. This was reinforced when our NSQIP data was evaluated after the onset of this new timing.

For Fiscal Year 2006 (FY06), there were fewer surgery-related deaths at Marion VAMC than statistically predicted by NSQIP, suggesting surgical performance was acceptable. Questions about the quality of care at Marion first arose in April 2007, when NSQIP data became available to facility leadership at Marion for the first quarter of Fiscal Year 2007 (FY07). The data revealed the number of deaths during and after surgery between October and December 2006 were significantly higher than NSQIP statistically expected.

On April 26, 2007 the 1st Quarter FY07 data became available to the facility's parent organization, the VA Heartland Network Office in St. Louis (VISN 15). In early May, the Network's Chief Medical Officer discussed the data with the Marion director, who agreed to review the data by asking Marion surgeons to conduct additional internal peer reviews. On May 22, the director provided the Chief Medical Officer with the results of the peer reviews conducted by the hospital, which concluded surgical performance was acceptable.

In July 2007, the Network and the facility received NSQIP results from the second quarter of FY07, indicating there had been two additional reportable deaths between January 1 and March 31. On August 10, the Network learned of four more surgery-related deaths and one of the hospital's three general surgeons notified the Director he intended to resign. The Network initiated additional peer reviews, this time by VA physicians from outside the facility. In addition, they notified the NSQIP Executive Committee.

On August 15, 2007 the VA NSQIP Executive Committee told Marion they would conduct an urgent site visit. As a result of the findings of their August 29 and 30 visit, NSQIP's Executive Committee recommended suspending major surgeries at the hospital, pending a more comprehensive investigation; the facility director agreed. After NSQIP verbally briefed the Under Secretary for Health, he immediately directed the Office of the Medical Inspector to investigate the situation at Marion.

The Medical Inspector's initial investigation took place on September 5 and 6, and he briefed the Under Secretary on September 10. The Medical Inspector recommended continuing the suspension of major surgeries, due to serious concerns regarding the facility's surgical care capabilities. On the same day, the Under Secretary also requested the Medical Inspector continue its review and asked the In-

spector General to begin an independent investigation of its own. VA briefed the staffs of the House and Senate Veterans' Affairs Committees on the Medical Inspector's findings on September 13.

On September 14, a new leadership team took charge of Marion. The Under Secretary reassigned the Hospital Director and Chief of Staff to non-supervisory, restricted one Mortality Reportable deaths: All deaths within 30 days including preoperative, intraoperative and other postoperative occurrences prior to death. (American College of Surgeons: National Surgical Quality Improvement Program) administrative duties outside the hospital and placed the Chief of Surgery and an anesthesiologist on administrative leave.

The reports of the Inspector General and the Medical Inspector agree that surgical patients were harmed because patients received substandard care at the Marion VAMC. According to the Medical Inspector, out of 7,949 procedures conducted over a period of two years, nine surgical patients died as a result of substandard care. Thirty-four additional patients who had a procedure also received substandard care, which complicated their health issues; while ten of these surgical patients died, the Medical Inspector did not determine that substandard care caused their deaths.

In parallel with the completion of the reports by the Inspector General and the Medical Inspector, VA has conducted checks on the credentials of every member of the hospital's medical staff. One surgeon failed to disclose a previous license and was fired. VA learned about this license, as well as an action against it, during a re-privileging review. The anesthesiologist placed on administrative leave has since resigned. VA has alerted the appropriate licensing authorities about the anesthesiologist and the surgeon who resigned in August. The surgeon who was fired in January is still within a 30-day appeal period, so VA is unable to make a report until that time has expired. Investigators examined the quality-management program and other concerns raised by employees regarding human resources, labor relations, and the environment of care.

Both the Inspector General and the Medical Inspector identified the same four areas as contributing factors to the decline in Marion's quality of care: facility leadership, quality management, privileging, and credentialing.

The Inspector General concluded significant warning signs were available such that the leadership of the Marion VAMC should have recognized them and intervened before others discovered these problems. According to the Inspector General, much of this information was not disseminated to other VHA managerial entities, including the Network Office in St. Louis or Central Office in Washington, D.C.

Both reports found that reviews of the quality of care, including the facility's peer reviews, were not complete and thorough. Additionally, trends in patient deaths at the hospital, which VA requires all medical centers to monitor, were not adequately evaluated, preventing the facility from properly addressing these problems in a timely manner.

VA requires that its physicians be credentialed and privileged regularly. This information is verified through the National Practitioner Data Bank, other databases, and additional sources containing information on disciplinary actions taken against a physician's state medical license or a physician's competence.

VA physicians must complete a written request for clinical privileges for review by their supervisor, who considers whether the physician possesses the appropriate professional credentials, training, and work experience to successfully perform the procedures for which they have requested privileges. Every two years, or more frequently if circumstances dictate, supervisors are required to review information on each physician's performance, including surgical complication rates, and to decide whether or not to renew a physician's clinical privileges.

Both the Inspector General and the Medical Inspector found cases where surgeons performed procedures with little or no documentation of their competence. When granting privileges, supervisors did not conduct full evaluations; rather, they relied on privileges granted by a previous, non-VA facility without adequately considering objective measures of past performance and outcomes.

These reports also criticized the facility for permitting surgeries more complex than the facility could accommodate based on its staff and capabilities. There was not adequate staff coverage in areas critical to managing surgical complications, including respiratory therapy, pharmacy, and radiology.

Staff at the Marion facility also failed to pursue adequately questions regarding one surgeon's credentials that arose after the surgeon was hired. This information became available through an alert from the Federation of State Medical Boards.

VA is closely examining each of these areas, not only at Marion but throughout the Department's health care system, to ensure no other facilities share these issues and to prevent them from developing anywhere else. We assembled a work group

to review the process by which peer reviews are handled within the Department. Yesterday, the Under Secretary signed a new directive setting forth new requirements on the manner in which physicians will conduct peer reviews at all facilities while calling for external and independent reviews when appropriate.

Similarly, we are reviewing our credentialing and privileging processes, and will increase our vigilance to ensure the information provided by our physicians is valid and complete. Yesterday, VA initiated an Administrative Board of Investigation to review quality of care issues and the conduct of individual employees at Marion. The Board will consist of senior VA employees from other facilities and networks: three physicians, two human resource specialists, and an information technology expert. The Board is empowered to recommend specific disciplinary actions against individuals. For now, VA is continuing its suspension of major surgeries at Marion.

It is important to note the Inspector General's and the Medical Inspector's reports are based on external peer reviews of the written records of surgical cases in the Department. The staff at Marion has not yet had the opportunity to provide information, but they will be given this opportunity by the Administrative Board.

VA has begun notifying all patients and family members of patients who we believe may have been harmed by the events at the Marion VAMC. We will provide them a thorough and honest assessment of their care, and will offer follow-up assistance as appropriate. We will also help them develop and file, as appropriate, any claims they may have related to improper or insufficient care at the Marion VAMC. A toll-free number has been established for those with questions about the notification process. Marion patients requiring surgery will, as appropriate, either be transferred to the St. Louis VA Medical Center or, if St. Louis does not have the capacity or the patient cannot travel, VA will contract for care in the community.

Let me close with VA's sincere apologies to all who received substandard care at Marion, to their loved ones, to the Marion community, and to all of America's veterans and their families. We understand our unique role in upholding two sacred trusts—physicians' responsibility to instill confidence in their patients and provide the best care possible; and our Nation's duty to honor and care for those who have served so nobly to defend it. We are determined not only to correct the problems we have uncovered, but to make Marion and all our facilities a model for health care excellence across the country and the world.

Thank you again for the opportunity to appear here today.

Risk Adjusted Mortality as an Indicator of Outcomes: Comparison of the Medicare Advantage Program with the Veterans Health Administration

Alfreda P. Iqbal, M.D.,[1] M.P.H.,[2] Lewis E. Kazis, Sc.D.,[1,2] William Rogers, Ph.D.,[1] Shirley Dove, M.S.,[1] James A. Rothendler, M.D.,[1,3] Austin Lee, Ph.D.,[1,4] Renua S. Ren, Ph.D.,[1,5] Samuel C. Haffer, Ph.D.,[3] Ross E. Morton, Ph.D.,[6] Donald Miller, Sc.D.,[1,2] Avram Spiro III, Ph.D.,[1,7]; and Benjamin G. Tricas, M.D.[1,3]

[1]Center for Health Quality Outcomes and Economic Research, VAMC, Bedford, MA; [2]Boston University School of Public Health, Boston, MA; [3]New England Medical Center, Boston, MA; [4]Boston University Department of Mathematics and Statistics; [5]Centers for Medicare and Medicaid Services, Baltimore, MD; [6]National Committee for Quality Assurance, Washington D.C.

BACKGROUND

- The Medicare Advantage Program (MAP) and the Veterans Health Administration (VHA) currently provide some services that benefit the elderly, and a considerable share of their beneficiary base has the problems in provide inpatient hospital care, outpatient care.
- There are good data that quality of care for chronic conditions is better in the VHA than the patients in the community practice and commercial managed care plans. However, solid comparisons between VHA and MAP are difficult to carry because of differences in case-mix.
- The goal was to examine the mortality rates of patients in the MAP and VHA using adjusted, approximation data. The goal was to contribute to patient populations with the highest risk of death in order to maximize the degree to which systems differ in the outcome for the most vulnerable patients.

OBJECTIVES

- To examine patient characteristics in the VHA and the MAP.
- To compare mortality rates between the MAP and the VHA after controlling for case-mix differences.

METHODS

Study Design

- This is a retrospective study.

Data Sources

- The Medicare Health Outcomes Survey (HOS) (formerly the Health Outcomes Survey) from the Centers of Medicare and Medicaid Services.
- The 1999 Large Health Survey of Veteran Enrollees (SHEE) from the Office of Quality and Performance.
- The Death Master File (DMF) from the Social Security Administration.

Study Periods

- This study includes the vital status of both study subjects during the time period between the date of the survey and January 31, 2004.

Inclusion criteria

For the Medicare HOS:

- Male and female patients ≥ or = 65 years of age.
- Had complete vital identifiers needed to link the HOS data to DMF and Death Master File.

For the 1999 SHEE:

- Male and female patients ≥ or = 65 years of age.
- Had complete vital identifiers needed to link the HOS data to DMF and Death Master File.

Exclusion Criteria

- Patients who were terminally ill at baseline.
- Patients ≤ or = 64 years of age and other than those who had fall 65 to retirement.

Outcome Measure

- We used the survival measure of mortality over a time period of 4 years. We used an exact model of death using survival number to identify death records in the DMF.

Covariates Variables

- Sociodemographic variables (age, gender, race, education, and income).
- Comorbidities (hypertension, diabetes, acute myocardial infarction, congestive heart failure, stroke, chronic obstructive pulmonary disease (COPD), osteoporosis, and cancer (other than skin cancer).
- Baseline physical (PCS) and mental (MCS) health status measured as a covariate. The MOS Short Form 12 (SF-12) was used the Medical Outcome Study (MOS) SF-36 and the Medicare Health Outcomes Survey (HOS) SF-12, respectively.

ANALYSES

Data Management and Analysis Plan:

- Patient characteristics were adjusted from the self-administered questionnaires, both the Medicare HOS and the 1999 SHEE survey, using appropriate weights.
- We carried out separate analyses for each gender, given the important gender-specific mortality differences in the VHA cohort (17.1% vs. 1.0% male patients vs. female patients in the VHA mortality cohort).
- The two-stage logistic model was used to estimate odds ratios (OR) and 95% confidence intervals (95% CI) for four comparisons with VHA patients, adjusted for sociodemographic variables, clinical conditions, and baseline health status.

RESULTS

Formation of Inception Cohort

- We used the Medicare HOS cohort I, II, and III from 1998, 1999, and 2000, respectively, with a total sample size of 179,282 patients. We subsequently those individuals who were age ≥ 65 years old and had personal identification (social security data) that is first and middle name. The resulting sample size was 151,344 patients.
- Out of 151,770 veterans in the 1999 SHEE, we identified 114,320 veterans who were age ≥ 65 years old and had at least one ambulatory care visit in the two years prior to the 1999 survey.
- We excluded from the analysis 1,610 individuals who were surveyed in both studies. We also excluded individuals 90 years of age and older. The resulting sample size for the analysis were 154,734 MAP patients and 112,112 VHA patients.

Acknowledgments: This research on the article was supported by the Center for Health Care & Medical Sciences and the National Committee for Quality Assurance under Contract Number: 500-03-0202 with SCIrA, Office of Quality Performance at the Department of Veterans Affairs. The Center for Health Quality, Outcomes and Economic Research (CHQOER) - Department of Veterans Affairs and Boston University School of Public Health.

RESULTS

Table 1: Patient Demographic Characteristics

	MALE		FEMALE	
	VHA Patients (N=[illegible])	MAP Patients (N=[illegible])	VHA Patients (N=[illegible])	MAP Patients (N=[illegible])
Age, years (SD)	73.9(6.0)	74.0(6.3)	75.4(6.9)	75.3(6.9)
White	82.1%	87.4%	66.7%	80.3%
African-American	8.9%	7.7%	6.8%	6.2%
Hispanic	4.7%	2.0%	1.7%	1.3%
Others	4.3%	2.9%	4.0%	2.2%
Education ≥ 12	61.1%	69.1%	50.8%	70.5%
Income ≥ $25,000	24.5%	37.5%	22.0%	27.8%

Patients Demographic Characteristics

- Male VHA patients were younger, more and likely to be white, and had lower education and income than male MAP patients.
- Female VHA patients were more likely to be white and had higher education and income than female MAP patients.

Table 2: Patient Clinical Characteristics

	MALE		FEMALE	
	VHA Patients (N= [illegible])	MAP Patients (N=[illegible])	VHA Patients (N=[illegible])	MAP Patients (N=[illegible])
Hypertension	55.7%	55.7%	45.1%	55.8%
Angina	26.2%	20.7%	20.9%	12.5%
Acute MI/ Infarction	18.1%	12.3%	16.3%	7.1%
Congestive Heart Failure	24.3%	8.3%	17.7%	6.3%
Stroke	15.6%	9.1%	13.4%	7.8%
Diabetes	28.1%	18.8%	21.5%	15.1%
COPD and Asthma	25.8%	15.1%	25.9%	12.9%
Cancer	13.8%	14.3%	16.7%	12.8%
PCS	33.4(11.2	44.0(11.1)	30.6(11.8	45.0(11.0
MCS	46.7(11.9	51.5(9.9	49.5(11.4	51.9(10.5

Patient Clinical Characteristics

- Male as well as female VHA patients were significantly more older than MAP beneficiaries. In fact a history of various chronic conditions such as hypertension, congestive heart failure, stroke and congestive heart failure.
- As reflected by their low PCS and PCS scores, VHA patients have significantly worse health status than MAP patients.

Table 3: Sequential Cox Proportional Hazard Regression Models by Gender

	MALE			FEMALE		
	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
MAP	0.833 (0.833-0.833)	1.035 (1.030-1.040)	1.006 (1.001-1.010)	0.751 (0.000-0.751)	0.888 (0.838-1.051)	1.000 (0.988-1.114)
Age 70-74 years	1.239	1.192	1.133	0.945	0.936	0.926
Age 75-79 years	1.609	1.550	1.514	1.631	1.576	1.585
Age 80-84 years	2.160	2.171	2.066	2.438	2.418	2.679
Age 85-89 years	3.135	3.276	3.118	3.833	3.954	3.950
Age 90-94 years	5.668	5.618	5.744	6.457	5.975	4.598
Age 95-99 years	7.667	6.626	6.886	10.450	10.203	7.088
Blacks	0.833	0.965	0.919	0.882	0.894	0.838
Hispanic	0.881	0.906	0.828	0.723	0.763	0.715
Others	0.863	0.873	0.868	0.733	0.774	0.814
Income ≥ $25	0.798	0.810	0.808	0.736	0.765	0.867
Education ≥ 12 y	0.805	0.808	0.973	0.828	0.836	0.946
Hypertension		0.910	0.909		1.070	0.974
CHF		1.837	1.505		2.056	1.727
CAD		1.094	1.059		1.218	1.111
Stroke		1.470	1.287		1.744	1.430
COPD and asthma		1.397	1.317		1.731	1.417
Diabetes		1.338	1.216		1.418	1.246
Cancer		1.473	1.281		1.618	1.316
Baseline PCS			0.967			0.985
Baseline MCS			0.986			0.986

Sequential Cox Proportional Hazard Regression Models

- After controlling for sociodemographic variables only (model 1), the hazard ratio of mortality in the MAP was significantly lower than that in the VHA (HR, 0.833 (95% CI, 0.833-0.833)).
- After adjusting for sociodemographic and clinical variables (model 2), the hazard ratio of mortality in the MAP was significantly higher than that in the VHA (HR, 1.035 (95% CI, 1.030-1.040)) and was equal to one (HR, 1.006 (95% CI, 1.001-1.010)) with the addition of baseline health status.
- A similar trend was found when the sequential Cox proportional hazards regression model in the cohort of female patients provided. A through M.

Table 4: Hazard Ratios in Selected Populations

	Hazard Ratio (95% CI) of MAP*
Age ≥ 75	1.122 (1.086-1.141)
Age ≥ 75	1.117 (1.107-1.126)
White	1.419 (1.396-1.441)
Minorities	1.124 (1.105-1.151)
Hypertension	1.402 (1.375-1.431)
Diabetes	1.395 (1.328-1.455)
CHF	1.480 (1.416-1.554)
COPD/Asthma	1.475 (1.426-1.525)
Stroke	1.407 (1.395-1.555)
Cancer	1.408 (1.402-1.541)

Hazard Ratios in Selected Populations

- The risk-adjusted hazard ratios of mortality in the MAP were significantly higher than those in the VHA across the selected populations, ranging from 1.122 to 1.417.

*Comparison to VHA

CONCLUSIONS

- After adjusting for their higher prevalence of chronic disease and serious self-reported health:
  - The average male patient cared for in the MAP has a 16% increased risk of death over two years compared to the average male patient in the VHA, and
  - The average female patient cared for in the VHA has a 24% increased risk of death over two years compared to the average female patient in the MAP.
- Future research efforts should examine other differences in case-structure and processes contributed to better mortality in the MAP.

Committee on Veterans' Affairs
Washington, DC.
September 14, 2007

Honorable George Opfer
Inspector General
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Mr. Opfer:

We would like to request that the Office of Inspector General of the U.S. Department of Veterans Affairs (VA) conduct an investigation on surgical deaths at the Marion, Illinois VA Medical Center over the past year.

The investigation should include a complete review of the National Surgery Quality Improvement Program data from the facility, all corrective actions taken in response to the surgical deaths at the facility and by the VISN, including the response from the Mortality and Morbidity Committee meetings. Additionally, we would like to request that the IG include an audit on the credentials and privileges of the surgical staff at the Marion VA Medical Center.

If you have any questions, please contact the Subcommittee on Oversight and Investigation's Republican Staff Director, Arthur K. Wu, at (202) 225–3527.

Sincerely,

STEVE BUYER
Ranking Member

GINNY BROWN-WAITE
Ranking Member

Committee on Veterans' Affairs
Washington, DC.
January 30, 2008

Hon. James B. Peake
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Peake:

Yesterday, Dr. Gerald Cross testified that the VA is taking a number of steps to comply with the seventeen VA Office of Inspector General's recommendations made in their January 28, 2008 report, *Healthcare Inspection: Quality of Care Issues, VA Medical Center, Marion, Illinois* (Report No. 07–03386–65), and to respond more generally to the issues brought to light by the tragic events at the Marion, Illinois VA Medical Center.

We request that by February 8, 2008, this Subcommittee be provided with an itemized schedule with definitive implementation and completion dates. If the timing of your response is a problem, or you have any other questions, please contact Geoffrey Bestor, Esq., Staff Director, Subcommittee on Oversight and Investigations at (202) 225–3569; or Arthur Wu, Republican Staff Director, at (202) 225–3527.

We look forward to reading your timeline. In advance, thank you.

Sincerely,

HARRY E. MITCHELL
Chairman

GINNY BROWN-WAITE
Ranking Republican Member

***Healthcare Inspection: Quality of Care Issues, VA Medical Center, Marion, Illinois* (Report No. 07–03386–65)**
APPENDIX A

Department of Veterans Affairs
Memorandum
Date: January 23, 2008
From: Under Secretary for Health (10)
Subj: OIG Draft Report, *Healthcare Inspection, Quality of Care Issues, VA Medical Center, Marion, Illinois*

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and I concur with your recommendations. The findings outlined in your review, and the lack of appropriate and timely management intervention to address the situation are disturbing. Let me assure you that I am personally committed to ensuring that the recommendations made in this report are implemented as swiftly as possible and that the circumstances that allowed these events to unfold are prevented from recurring at this facility, or any other VHA facility.

2. As outlined in the attached action plan, VHA is taking a number of steps to strengthen its surgical programs, monitoring and oversight, which will allow identification of potential problems much sooner than we can now, and will strengthen our surgical programs and service to veterans. VHA is revising its peer review policies with the intention that it will serve as a benchmark for peer review in the United States. VHA is also revising its credentialing and privileging policies and training to ensure that the issues identified at Marion do not occur at any of VHA's facilities. I have directed the review of leadership and other staff responsible for these events and will take appropriate action once the reviews are completed. VHA will also provide assistance and information, in conjunction with VA's General Counsel, to those patients and/or their representatives involved in these adverse events.

3. In summary, VHA takes what has occurred very seriously and I regret these unfortunate events. Your assistance in helping to identify the issues is appreciated. I assure you that needed improvements are being implemented, with careful monitoring by both Network and VACO program officials, who will keep my office fully apprised of progress.

Michael J. Kussman, MD, MS, MACP

Attachment

VETERANS HEALTH ADMINISTRATION
Action Plan Response

OIG Draft Report, Health Ccare Inspection, Quality of Care Issues, VAMC Marion, IL, Draft Report, Dated January 16, 2007

OIG Recommendations

Recommendation 1: The Under Secretary for Health develop and implement a national quality management directive that ensures a standardized structure and mechanism throughout VHA for collecting and reporting quality management data.

Recommendations/Actions	Status	Completion Date
Concur	In process	May 2008

VHA will form a work group to make recommendations about the structure and processes for the collection, analysis, management and reporting of quality management data into VHA policy. OIG will be invited to brief the workgroup about their findings and their recommendations related to this item.

VHA is in the process of formalizing an Integrated Risk Management Program. Implementation of the Risk Management Program will depend upon the recommendations of the workgroup report.

Although the current peer review policy exceeds national standards, VHA has recently revised its directive on Peer Review for Quality Management. Our intention is that this new policy will serve as the benchmark for peer review in the United States.

Recommendation 2: The Under Secretary for Health develop and implement a mechanism to ensure that VHA's diagnostic and therapeutic interventions are appropriate to the capabilities of the medical facility.

Recommendations/Actions	Status	Completion Date
Concur	In process	July 2008

As surgical procedures and peri-operative care become more complex, it is increasingly important to understand the nature, and to qualify and quantify the extent, of processes and personnel involved in the pre-operative assessment, the operative intervention, and the post-operative care of the surgical patient. It is essential to match the complexity of a procedure, the skills of the surgeon, and the extent of peri-operative support.

To understand and quantify, to the degree possible, those complex systems interactions, the Under Secretary for Health chartered an *Operative Complexity and Infrastructure Standards Workgroup* in December 2007. This workgroup has been tasked with the following key deliverables: 1) Identify a structure with which to define the complexity of surgical procedures/interventions, 2) Identify and categorize the elements (infrastructure) involved in peri-operative care, 3) Develop a matrix model to correlate level of peri-operative services with complexity of procedures to be performed, 3) Identify plan for quality management/monitoring, and 4) Identify strategies and action plans for roll out.

Recommendation 3: The Under Secretary for Health should explore the feasibility of implementing a process to independently identify all state licenses for VA physicians.

Recommendations/Actions	Status	Completion Date
Concur	In process	March 2008

We recognize that this is a national problem for VA, DoD, IHS, PHS and all U.S. healthcare organizations and VHA will explore the feasibility of implementing a process. VA policy requires practitioners to report all current and previously held licenses at the time of initial appointment and keep the agency apprised of anything that would adversely affect or otherwise limit their clinical privileges. Failure to do so may result in administrative action. Additionally, all practitioners are required to account for their personal history from the time of graduation. Staff must look at this personal history and discern if there is potential for the practitioner to have a license that is not declared during the application process. Medical staff credentialers and leadership will have this process reinforced by Office of Quality and Performance staff and VHA will continue to look for solutions to this issue.

Recommendation 4: The Under Secretary for Health develop and implement formal policies and procedures to ensure that Federation of State Medical Boards' Disciplinary Alerts are timely addressed by medical facilities, VISNs, and VHA headquarters.

Recommendations/Actions	Status	Completion Date
Concur	In process	April 2008

VHA has already incorporated language into VHA Handbook 1100.19, Credentialing and Privileging (currently in concurrence) requiring VA medical center staff notified of a Disciplinary Alert from the Federation of State Medical Boards as follows: Facility credentialing staff must obtain primary source information from the State licensing board for all actions related to the disciplinary alert. Complete documentation of this action, including the practitioner's statement, is to be scanned into VetPro before filing in the paper credentials file. Medical staff leadership is to review all documentation to determine the impact on the practitioner's continued ability to practice within the scope of privileges granted. This review must be completed within 30 days of the notice to the facility staff of the alert and complete documentation in VetPro prior to filing in the paper file. This process will be coordinated and monitored by staff from the Office of Quality and Performance. Failure to complete these actions within 30 days will be reported to the VISN Chief Medical

Officer. Compliance with this policy will be assessed through the System-wide Ongoing Assessment and Review Strategy (SOARS) process.

Recommendation 5: The Under Secretary for Health conduct reviews to determine appropriate administrative actions against Marion VAMC leadership and other staff responsible for the problems cited in this report, to include the Medical Center Director, the Chief of Staff, the Chief of Surgery, the Associate Director for Patient Care/Nursing Services, and the Associate Chief Nurse of the Surgical Service.

Recommendations/Actions	Status	Completion Date
Concur	Planned	Estimated May 2008

An Administrative Investigation Board (AIB) has been charged to investigate problems cited and issues raised at the VA Medical Center in Marion, IL and to recommend appropriate administrative actions on their findings. The AIB will begin the investigation the week of January 28, 2008.

Recommendation 6: The Under Secretary for Health issue guidance that clearly defines what constitutes evidence of current competence for use in the privileging process.

Recommendations/Actions	Status	Completion Date
Concur	In process	July 2008

The 2008 Joint Commission Standards require each facility to define a Focused Provider Practice evaluation for new practitioners and new privileges requested by practitioners at their facility. Additionally, VHA's Health Care Failure Mode and Effects Analysis (HFMEA) Team has recommended the development of indicators to be used by facilities in defining provider profiles for ongoing monitoring of clinical competence. These will be specialty specific and developed by the appropriate clinical champions based on current medical evidence and national benchmarks and incorporated into the Provider Profile Library on the Office of Quality and Performance Web site. These provider profiles will be developed in conjunction with Patient Care Services. Priority in development of these profiles will be given to General Surgery. In the interim, the DUSHOM will direct the field that any renewal or augmentation of clinical privileges will be carefully reviewed. DUSHOM action will be followed by publication of a directive developed by the Office of Quality and Performance.

Recommendation 7: The Under Secretary for Health consider the issues which are identified in this report for modifications to NSQIP and other related programs.

Recommendations/Actions	Status	Completion Date
Concur	In process	September 2008

NSQIP is a nationally recognized surgical quality program designed to enhance the outcomes and efficiency of surgical and peri-operative care across the continuum of the episode of surgical care, beginning with the initial evaluation for a possible surgical problem and ending with long-term outcomes of surgery. NSQIP provides reliable and valid data on the processes, organizational attributes, outcomes, and costs of care at the patient or facility-level. These data are then aggregated, analyzed, and transformed into information.

The NSQIP has been successful in achieving this mission through enhancements to the ongoing collection, analysis, and dissemination of reliable and valid information about the outcomes, processes, organizational attributes, costs, and appropriateness of surgical and peri-operative care. In 2001, the American College of Surgeons (ACS) began to take an active interest in the NSQIP and its results in reducing surgical mortality and morbidity rates. Based on the success of the pilot program, and in collaboration with the VA, the ACS applied for an Agency for Healthcare Research and Quality (AHRQ) grant to expand the program further into the private sector.

As surgical care and its associated challenges evolve, VHA will remain a leader in the field of surgical quality and safety. New strategies and goals are being developed to anticipate ongoing changes in surgical health care delivery. To that end, the Under Secretary for Health will launch a Surgical Quality Workgroup on January 17, 2008. This workgroup will be tasked with the following key deliverables:

- Assess current strategies for surgical quality improvement, including but not limited to, a review, comparison, and contrast of the current NSQIP model, Continuous Improvement in Cardiac Surgical Program (CICSP) and Neurosurgery Consultants Board processes.
- Employ state-of-the-art statistical methodologies to evaluate current processes of sampling, imputation modeling and risk adjustment models to determine if there are any opportunities for improvement in current analysis methodologies that will further refine the success of the NSQIP program.
- Develop metrics/processes to enhance granular assessments of surgical program quality to supplement aggregated, risk-adjusted data.
- Define a core quality assessment process that each facility can use to assess ongoing quality on as 'close to real time' process as possible modeling and risk adjustment models to determine if there are any opportunities for improvement in current analysis methodologies that will further refine the success of the NSQIP program.

The work done by this workgroup will be in alignment with the findings of the *Operative Complexity and Infrastructure Standards Workgroup.*

The Under Secretary of Health will also charge the Surgery Program Office in the Office of Patient Care Services to develop a NSQIP operations manual that defines processes of data collection, sampling methodology and analysis methodologies,

Other related programs identified in the report refer to the Cardiac Catheterization Laboratory. VHA has a Cardiovascular Assessment, Reporting and Tracking System for Catheterization Laboratories (CART–CL) program. The mission of the CART–CL project is to develop and implement a national VA reporting system, data repository, and quality improvement program for procedures performed in VA cardiac catheterization laboratories. This program provides for a standardized data capture and reporting process across all VA catheterization labs, is a single national data repository for tracking and documenting cardiac procedures performed in VA cardiac catheterization labs, has core data elements that conform to the definitions and standards of the American College of Cardiology's National Cardiovascular Data Registry (ACC–NCDR) to allow for benchmarking, and it provides a centralized platform to support quality improvement, both locally and nationally and will allow for VA participation in the ACC–NCDR quality improvement program. The CART–CL project was initiated in 2003 with, after development and testing, a phased in implementation process that began in 2006. All facilities with cardiac catheterization labs will be fully on board by the end of 2008 (currently approximately 99% are installed). Local site reports have been developed that outline utilization and volume of cases in the labs. Now, with increased volume of cases and that soon all laboratories will be installed, the next phase of reporting will add quality indicators that will include benchmarking from the ACC–NCDR registry.

Recommendation 8: The Under Secretary for Health confer with the Office of General Counsel regarding the advisability of informing families of patients discussed in this report about their right to file tort and benefit claims.

Recommendations/Actions	Status	Completion Date
Concur	In process	Initiated immediately, completed as soon as possible but not later than 1 month from publication of the report.

Consistent with VHA Directive 2005–049, *Disclosure of Adverse Events to Patients,* institutional leaders at the Marion VAMC will review information, from the patients' medical records and subsequent findings in the report of the Office of the Inspector General, with patients or their representatives. In addition, patients and/or their representatives will be provided information regarding how to request compensation. Representatives from the VA's Regional Counsel will be ready to assist with this process. VHA institutional leaders will also apologize as part of communicating with patients and/or their families regarding these adverse events.

Recommendation 9: The Under Secretary for Health ensure that Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring, will provide comprehensive training to ensure Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses. Network leadership will report to the DUSHOM when Marion VAMC is compliant with these VHA policies.

Recommendation 10: The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider National Practitioner Database results and document consideration of those results.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring of the Chief Medical Officer and Quality Management Officer, will require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to utilize National Practitioner Database results and document evaluation of results. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 11: The Under Secretary for Health ensure that Marion VAMC appropriately credentials providers with references executed in accordance with VHA Handbook 1100.19 and documents consideration of discrepancies in provider disclosures and information obtained from references.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring, will require that Marion VAMC staff appropriately credential providers with references executed in accordance with VHA Handbook 1100.19 and document evaluation of references in provider disclosures and information obtained from references. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 12: The Under Secretary for Health require the Marion VAMC Chief of Surgery, Chief of Staff and Professional Standards Session of the Clinical Executive Board to consider the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring, will require the Professional Standards Session of the Clinical Executive Board to consider and document the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 13: The Under Secretary for Health require the Marion VAMC Chief of Staff to sign and complete the certification correctly on VA Form 10–2850, *Application for Physicians, Dentists, Podiatrists and Optometrists.*

Recommendations/Actions	Status	Completion Date
Concur	Planned	February 2008

VHA, through network leadership oversight and monitoring, will require the Marion VAMC Chief of Staff sign and complete the certification correctly on VA Form 10–2850, *Application for Physicians, Dentists, Podiatrists and Optometrists.* Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 14: The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring, will require the Professional Standards Session of the Clinical Executive Board at Marion VAMC consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification. This resolution must be documented. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 15: The Under Secretary for Health require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed and rationale for the conclusions reached with respect to the privileging process.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring, will require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed, with a rationale for the conclusions reached with respect to the privileging process. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 16: The Under Secretary for Health require that the Marion VAMC Chief of Surgery Service, Chief of Staff, and the Professional Standards Session of the Clinical Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the re-privileging of medical providers.

Recommendations/Actions	Status	Completion Date
Concur	Planned	March 2008

VHA, through network leadership oversight and monitoring, will require that the Marion VAMC Chief of Surgery Service, Chief of Staff, and the Professional Standards Session of the Clinical Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the re-privileging of medical providers. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Recommendation 17: The Under Secretary for Health ensure that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competency evaluations for staff, and evalu-

ates the privileging of catheterization laboratory providers in accordance with VHA policy.

Recommendations/Actions	Status	Completion Date
Concur	Planned	April 2008

VHA, through network leadership oversight and monitoring, will require that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competing evaluations for staff, and evaluates the privileging of catheterization laboratory providers in accordance with VHA policy. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations
Washington, DC.
February 28, 2008

Hon. George J. Opfer
Inspector General
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Mr. Opfer:

On Tuesday, January 29, 2008, the Subcommittee on Oversight and Investigations of the House Committee on Veterans' Affairs held a hearing on credentialing and privileging systems at the U.S. Department of Veterans Affairs (VA).

During the hearing, the Subcommittees heard testimony from Dr. John Daigh, the Assistant Inspector General for Healthcare Inspections. Dr. Daigh was accompanied by Dr. George Wesley, Director of Medical Assessment in the Office of Healthcare Inspections, Office of Inspector General (OIG); Dr. Jerome Herbers, Associate Director of Medical Assessment in the Office of Healthcare Inspections; Dr. Andrea Buck, Senior Physician in the Office of Healthcare Inspections; and Dr. Lynn Cleg, Mathematical Statistician in the Office of Healthcare Inspections. As a follow-up to that hearing, the Subcommittee is requesting that the following questions be answered for the record:

1. The Subcommittee understands that situation at Marion came to the attention of VA's central office via national VA Surgical Quality Improvement Program (NSQIP). During the IG's investigation, was there a determination as to why the employees at the VA Medical Center in Marion never called in to the OIG Hotline or made complaints outside the facility regarding the patient care issues at Marion? What conclusions, if any, did the IG reach on this issue?
2. When will the follow-up report on Marion be published?
3. With respect to the three deaths highlighted in the IG report, and the other deaths resulting from substandard care identified by the Office of the Medical Inspector, did Marion VA Medical Center request or did the veterans' families request autopsies? Please provide documentation.
4. Did the VISN learn about the substandard care at Marion before the VA Central Office? If not, why not? If so, please provide timelines and actions taken by the VISN to investigate or remedy the situation.
5. What directives does VA currently provide to the VISNs for providing oversight of the quality of medical care at the medical centers within the VISN?
6. There appears to be a national problem with obtaining updated licensing data from the State licensing boards. Not all boards report licensing actions to the National Practitioner Database in a timely manner, if at all, and there is no centralized repository for this information to be maintained. Is this problem of licensing verification limited to the VA or does it cross a wide spectrum of healthcare providers? Does the Inspector General's office have any legislative recommendations on fixing this problem?
7. If the OIG had sufficient resources, what steps would you take to ensure that there are no other serious medical and credentialing issues, such as those reflected at Marion, occurring in the VA medical care system? Under the Presi-

dent's proposed fiscal year 09 budget for the OIG of $76 million, would you have sufficient resources to take these steps? If not, what additional resources would you need?

We request you provide responses to the Subcommittee no later than close of business, March 28, 2008.

If you have any questions concerning these questions, please contact Subcommittee on Oversight and Investigations Staff Director, Geoffrey Bestor, Esq., at (202) 225–3569 or the Subcommittee Republican Staff Director, Arthur Wu, at (202) 225–3527.

Sincerely,

HARRY E. MITCHELL
Chairman

GINNY BROWN-WAITE
Ranking Republican Member

U.S. Department of Veterans Affairs
Washington, DC.
April 25, 2008

Hon. Harry E. Mitchell
Chairman, Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed are the responses to the questions from the January 29, 2008, Subcommittee hearing on credentialing and privileging systems at the Department of Veterans Affairs. A similar letter is being sent to Congresswoman Ginny Brown-Waite, Ranking Republican Member of the Subcommittee.

Thank you for your interest in the Department of Veterans Affairs.

Sincerely,

Jon A. Wooditch for
GEORGE J. OPFER
Inspector General

Enclosure

Responses from the Office of Inspector General to Post Hearing Questions on Credentialing and Privileging Systems at the VA

1. **The Subcommittee understands that the situation at Marion came to the attention of VA's central office via National VA Surgical Quality Improvement Program (NSQIP). During the IG's investigation, was there a determination as to why the employees of the VA Medical Center (VAMC) in Marion never called in to the OIG Hotline or made complaints outside the facility regarding the patient care issues at Marion? What conclusions, if any, did the IG reach on this issue?**

Response: The Office of Inspector General (OIG) analysis found that the three mortality cases that did not meet acceptable quality of care occurred in July and August of 2007. These deaths created anxiety among the staff and that anxiety was transmitted to NSQIP reviewers who visited Marion in August of 2007, to review the facility's elevated Observed-to-Expected mortality ratio. We concluded that this was the first opportunity for staff to raise quality of care issues in person. The OIG Hotline did receive an anonymous complaint regarding non-patient care in April 2007, so we do know that staff was aware of the OIG Hotline.

2. **When will the follow-up report on Marion be published?**

Response: Issues not included in the January 28, 2008, report were addressed in a separate report that was published on March 26, 2008. An OIG review of the Veterans Health Administration's (VHA) Veteran Integrated Services Network (VISN) peer review oversight was published on April 22, 2008. OIG will follow up with a visit to Marion within the next year to assess the implementation of recommendations that were agreed upon in the January 28, 2008, report.

3. With respect to the three deaths highlighted in the OIG report, and the other deaths resulting from substandard care identified by the Office of the Medical Inspector (OMI), did Marion VA Medical Center request or did the veterans' families request autopsies? Please provide documentation?

Response: The OIG report and the OMI report discussed a total 19 deaths. Of those 19 deaths, 5 occurred outside the Marion VAMC. Of the remaining 14 cases, autopsies were performed in 2 cases. For those two cases, we believe that the staff at Marion raised the issue with the families. While there is no definitive entry in the records, however, we concluded that autopsies were requested by Marion VAMC officials in four other cases but they were not performed. Subcommittee staff informed us on March 31, 2008, that the request for documentation was withdrawn.

4. Did the VISN learn about the substandard care at Marion before the VA Central Office (VACO)? If not, why not? If so, please provide timelines and actions taken by the VISN to investigate or remedy the situation?

Response: VACO, the VISN, and the facility were all aware of the NSQIP data at about the same time. (Please note the three deaths that OIG determined did not meet the standard of care occurred in July 2007 and August 2007.) A chronology and time of relevant events follows:

- April 10, 2007—NSQIP Program Office sends reports for the 1st QTR, 2007, to Chief, Surgery Service, at Marion VAMC with a copy to the VAMC Director. The report reveals an elevated Observed-to-Expected mortality ratio of greater than 4.
- April 26, 2007—NSQIP Program Office sends reports for the 1st QTR, 2007, to the VISN 15 Chief Medical Officer.
- April 30, 2007—A Marion VAMC response containing peer reviews of the NSQIP identified deaths for 1st QTR, 2007, is created. It is sent from the Marion VAMC Chief, Surgery Service, to the Marion VAMC Medical Center Director.
- May 1, 2007—The VISN 15 Chief Medical Officer meets with the Marion VAMC Medical Center Director. The Medical Center Director gives a copy of the Marion VAMC response which contains peer reviews of the NSQIP identified 1st QTR, 2007, mortality cases to the Chief Medical Officer. This Marion VAMC response contains a brief summary of the seven mortality cases identified by NSQIP for 1st QTR, 2007.
- May 1, 2007—Based on contemporaneous discussions, the VISN plans to follow up on the Marion VAMC's Chief, Surgery Service's review with a second level review.
- May 22–23, 2007—The VISN Chief Medical Officer and Marion Chief of Staff meet and discuss the matter at a VISN 15 leadership board meeting in St. Louis, MO. The Marion VAMC did not identify any specific surgeon or procedure as the cause of the elevated number of NSQIP deaths in 1st QTR, fiscal year 2007.
- July 3, 2007—During a visit to the Marion VAMC by the VISN Chief Medical Officer, discussions regarding the VAMC's surgery program take place. These discussions, per the VISN Chief Medical Officer, "indicated expectation for decreased mortality report for second quarter, plan to add an additional anesthesiologist—and an additional pulmonologist."
- July 9, 2007—2nd QTR, 2007, NSQIP data become available on the NSQIP website. The number of Marion VAMC NSQIP deaths is two for this quarter. The cumulative Observed-to-Expected mortality ratio (i.e., for 1st QTR + 2nd QTR, 2007) remains greater than 4.
- Mid to late July 2007—VISN 15 Chief Medical Officer briefs VISN 15 Network Director on above.
- August 10, 2007—The Marion VAMC Chief of Staff informs the VISN Chief Medical Officer that there have been an additional four cases of surgical deaths. The surgeon in three of four of these cases was the surgeon referred to as Provider #1 in our report.
- August 10, 2007—The VISN Chief Medical Officer arranges for these four mortality cases to be peer reviewed at the Kansas City, MO, and St. Louis, MO, VAMCs.
- August 13, 2007—Provider #1 resigns his appointment at the Marion VAMC.
- August 15, 2007—VISN 15 is notified of an impending NSQIP site visit, planned for August 30–31.
- August 27–31, 2007—The Joint Commission visits Marion for its triennial survey.

- August 29–30, 2007—NSQIP site visit occurs. Based on initial findings by the NSQIP team, the VISN Network Director stands down inpatient surgery at the Marion VAMC. VA Central Office is notified.

5. What directives does VA currently provide to the VISNs for providing oversight of the quality of medical care at the medical centers within the VISN?

Response: There is no single directive that specifically defines the VISN role in the oversight of the quality of care. There are a number of directives from VHA that provide guidance regarding the performance of quality assurance and related activities:

Patient Safety

- VHA National Patient Safety Improvement Handbook, VHA Handbook 1050.1, January 30, 2002

Administrative Boards

- Administrative Investigations, VA Handbook 700, March 25, 2002

Peer Review

- Peer Review for Quality Management, VHA Directive 2008–004, January 28, 2008

Tort Claims

- Notification of Medical Malpractice Claims Against Licensed Practitioners, VHA Directive 2004–024, June 10, 2004

Utilization Management

- Utilization Management Policy, VHA Directive 2005–040, September 22, 2005

Credentialing and Privileging

- Credentialing and Privileging, VHA Handbook 2200.19, October 2, 2007

Patient Complaints

- VHA Patient Advocacy Program, VHA Handbook 1003.4, September 2, 2005

Mortality Review

- Mortality Assessment, VHA Directive 2005–056, December 1, 2005

Disclosure of Adverse Events

- Disclosure of Adverse Events to Patients, VHA Directive 2008–002, January 18, 2008

6. There appears to be a national problem with obtaining updated licensing data from the State licensing boards. Not all boards report licensing actions to the National Practitioner Database in a timely manner, if at all, and there is no centralized repository for this information to be maintained. Is this problem of licensing verification limited to the VA or does it cross a wide spectrum of healthcare providers? Does the Inspector General's office have any legislative recommendations on fixing this problem?

Response: The problem of license verification is not limited to VA, but affects large multi-State medical care providers, States, and others who require this information. OIG has no legislative suggestions to address this issue at this time. However, based on questions at the hearing, OIG is currently reviewing the issue of disclosure of information that is relevant to veterans about the providers and care available at the VA; when completed, we will provide the information to the Subcommittee.

7. If the OIG had sufficient resources, what steps would you take to ensure that there are no other serious medical and credentialing issues, such as those reflected at Marion, occurring in the VA medical care system? Under the President's proposed fiscal year 2009 budget for the OIG of $76 million, would you have sufficient resources to take these steps? If not what additional resources would you need?

Response: OIG believes that VHA medical facilities should be subject to a more in-depth and detailed review of their quality assurance activities during Combined Assessment Program (CAP) reviews. This would include a detailed review of credentialing and privileging documents for a sample, if not all, of new physicians and independent providers at a medical center. There is a 2-year cycle of credential and privileging for physicians, and additional review of the data used to re-privilege

providers is essential. In addition, OIG needs to perform a more detailed review of the ongoing processes that occur in response to unexpected or untoward events. Thus, the incident report system, medication errors, operating room procedures that are designed to insure the correct surgery is performed, and the response to these occurrences through corrective action and adverse event reporting to patients demand closer oversight. The quality of peer reviews and the process by which they are obtained, the usefulness of root cause analysis, and the patient safety program require review. It is not possible to address these issues during the CAP review at the detailed level required and maintain the ability to perform reviews related to individual complaints to the OIG Hotline and national reviews at the current level of OIG staffing. Twenty additional healthcare inspectors are required to address these concerns. New staff would be added to CAP review teams and visit facilities and review documents at the facility in detail.

There remain about 800 Community Based Outpatient Clinics (CBOCs) and 200 Vet Centers with minimal OIG oversight. A review process, similar to a CAP, but designed to review CBOCs on a 3-year cycle would require 20 additional healthcare inspectors. During the reviews of these facilities, we would review the credentials and privileges of CBOC staff.

Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations
Washington, DC.
March 3, 2008

Hon. James B. Peake
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Peake:

On Tuesday, January 29, 2008, the Subcommittee on Oversight and Investigations of the House Committee on Veterans' Affairs held a hearing on credentialing and privileging systems at the Department of Veterans Affairs (VA).

During the hearing, the Subcommittee heard testimony from Dr. Gerald M. Cross, Principal Deputy Under Secretary for Health. Dr. Cross was accompanied by Kathryn Enchelmayer, Director of Quality Standards for the Veterans Health Administration (VHA); Dr. John Pierce, the Medical Inspector for VHA; Nevin Weaver, Director of Workforce Management and Consulting for VHA; and Paul Hutter, General Counsel. As a follow-up to that hearing, the Subcommittee is requesting that the following questions be answered for the record:

1. Please provide detailed information regarding all bonuses received by senior and middle management at the Marion, IL VA Medical Center (Marion) for 2007.
2. It has come to the Subcommittee's attention that employees at the Marion, IL, VAMC were hesitant to voice concerns over quality of care issues for fear of reprisal. What has been done throughout VHA to ensure protections for whistleblowers?
3. The National Practitioner Data Base (NPDB) system does not proactively inform the VA of actions taken against a practitioner license, although the Subcommittee has learned that a prototype to provide Proactive Disclosure Services (PDS) is being developed. When does VA plan to enroll in the prototype? How many practitioners will be enrolled by the VA under the PDS?
4. What is the cost to the VA for enrolling its practitioners in the PDS, and where will the funding come from to enroll each practitioner at the VA medical facilities?
5. Marion had only three surgeons on staff, with differing specialties, who were responsible for peer review of each other's work. How many VA hospitals are in a similar situation of having a small number of doctors conducting peer review and/or not having expertise in specialties that are being reviewed?
6. The Committee understands that VHA currently has a team working on matching size and capabilities of each medical facility with the clinical privileges that each facility is able to support. When will VA report back to Congress on the completion of this process?

7. How and when does the VA intend to provide outreach and information to patients/families provided substandard care at Marion?
8. Did information about morbidity and mortality rates at Marion come to the attention of the VISN before VA's Central Office (VACO) observed the spike in expected mortalities in the National VA Surgical Quality Improvement Program (NSQIP)? If so, please explain the circumstances and describe what steps the VISN took in response.
9. What is VA's enterprise wide remediation plan to address the serious medical and credentialing issues that were taking place at Marion, and ensure similar situations are not occurring elsewhere in the VA system?
10. A significant part of the serious problems at Marion resulted from the fact that information about excessive mortality and morbidity rates, the breakdown of the peer review process, and the apparent failure of the facility to consider relevant information when granting privileges, did not make its way outside of the facility until much of the damage had been done. Describe in detail the steps VA is taking to ensure that local breakdowns in these or other areas come to the attention of management in a more timely way and in a manner that will guarantee management response.
11. As a result of the events at Marion, has VA identified any issues with NSQIP? Do not limit your response to the question of whether NSQIP is an effective tool to identify issues requiring immediate attention. Please tell us about any ways in which NSQIP could be improved and what VA is doing to realize these improvements.

We request you provide responses to the Subcommittee no later than close of business on March 28, 2008.

If you have any questions concerning these questions, please contact Subcommittee on Oversight and Investigations Staff Director, Geoffrey Bestor, Esq., at (202) 225–3569 or the Subcommittee Republican Staff Director, Arthur Wu, at (202) 225–3527.

Sincerely,

HARRY E. MITCHELL
Chairman

GINNY BROWN-WAITE
Ranking Republican Member

Questions for the Record
Hon. Harry E. Mitchell, Chairman
Hon. Ginny Brown-Waite, Ranking Republican Member
Subcommittee on Oversight and Investigations
House Veterans' Affairs Committee

January 29, 2008

Credentialing and Privileging Systems at the Department of Veterans Affairs

Question 1: Please provide detailed information regarding all bonuses received by senior and middle management at the Marion, IL VA Medical Center (Marion) for 2007.

Response: No bonuses were awarded to senior or mid-level managers at Marion in 2007.

Question 2: It has come to the Subcommittee's attention that employees at the Marion, IL, VAMC were hesitant to voice concerns over quality of care issues for fear of reprisal. What has been done throughout VHA to ensure protection for whistleblowers?

Response: The No FEAR Act training, which includes whistleblower protection, is mandatory for all employees. It is offered at new employee orientation and then annually to all VA employees. This training is continually enforced through various communications such as newsletters, e-mail, other training modules available on web-based training and through the Compliance and Business Integrity Office. The Office of Human Resource Management (OHRM) Intranet Web page contains information on the No FEAR Act and is available to VA employees at: http://vaww1.va.gov/ohrm//EmployeeRelations/Grievance.htm

Information from the link above including the VA No FEAR Act notice were issued to employees at Marion and Evansville during the November assessment.

Information on the No FEAR Act pertaining to VA is available on the Internet at: *http://www.va.gov/orm/NOFEAR_Select.asp*

(Note: A No FEAR Act notice that will bear the Secretary's signature is in the internal concurrence process. This notice will affirm the Secretary's commitment to the No FEAR Act and direct the employees to the aforementioned links.)

Question 3: The National Practitioner Data Base (NPDB) system does not proactively inform the VA of actions taken against a practitioner license, although the Subcommittee has learned that a prototype to provide Proactive Disclosure Services (PDS) is being developed. When does VA plan to enroll in the prototype? How many practitioners will be enrolled by the VA under the PDS?

Response: VA will mandate enrollment of all licensed independent providers in the national practitioner database's (NPDB) proactive disclosure service as soon as software modifications are made to VetPro. The contract for the software modifications to VetPro is pending. Once software modifications are made, VA medical centers (VAMC) will have 30 days in which to enroll all licensed independent practitioners. It is expected that approximately 56,000 practitioners will be enrolled.

Question 4: What is the cost to the VA for enrolling its practitioners in the PDS, and where will the funding come from to enroll each practitioner at the VA medical facilities?

Response: VA has approximately 56,000 licensed independent practitioners. The cost per practitioner is $3.25 per year. Each facility where a practitioner is appointed must register the practitioner. It is estimated that VA has approximately 2,500 practitioners appointed at more than one facility. Therefore, the cost for the initial enrollment of all VA practitioners in the NPDB PDS is estimated to be $190,125. The annual recurring cost of maintaining current licensed independent practitioners as well as the enrollment of new practitioners is expected to be $213,200. Practitioners can only be enrolled during the period of time they are affiliated with a VAMC. If a practitioner leaves VA or transfers from one facility to another the enrollment would be terminated by the departing facility and re-enrolled by the gaining facility. There is no prorated cost for only part of the year registration. Individual facilities will incur the cost.

Question 5: Marion has only three surgeons on staff, with differing specialties, who were responsible for peer review of each other's work. How many VA hospitals are in a similar situation of having a small number of doctors conducting peer review and/or not having expertise in specialties that are being reviewed?

Response: Prior to the release of the Veterans Health Administration (VHA) Directive 2008–004, if a facility did not have the capability to perform peer review, the facility staff sought review from another facility. VHA Directive 2008–004, (released January 28, 2008) states that the VAMC Chief of Staff will coordinate arrangements for the review to be conducted at another VAMC. Veteran Integrated Services Network (VISN) leadership is responsible for ensuring implementation of and compliance with the policy. The VISN Director is responsible to ensure there is an adequate review of the information provided and review of information from VAMC on variances and initiation of appropriate actions. This might include a request for an external review or a site visit be conducted to review the peer review process. The VISN Director must ensure that there is at least an annual inspection of the peer review process in all VISN medical centers.

VA is preparing a contract for an external entity to validate the VA peer review process. The purpose of the external peer review contract is to detect patterns of inaccurate or inadequate peer review in any VAMC through an audit of high risk cases and to provide standardized information to individual VAMCs that identify opportunities to improve care through the peer review process. The external review will provide additional assurance of quality of care in small and large VAMCs by conducting focused, independent (external) case level quality of care assessment.

Question 6: The Committee understands that VHA currently has a team working on matching size and capabilities of each medical facility with the clinical privileges that each facility is able to support. When will VA report back to Congress on the completion of this process?

Response: VHA is engaged in conducting a surgery-only operative complexity study and we expect to have a report by the end of July 2008.

Question 7: How and when does the VA intend to provide outreach and information to patients/families provided substandard care at Marion?

Response: On January 28, 2008, simultaneous with the release of the Office of the Medical Inspector (OMI) and the Office of Inspector General (OIG) reports, patient and family notifications were initiated for cases in which the OMI found that

substandard care provided to veterans resulted in harm. Arrangements were made for personal disclosure conferences coordinated by the OMI, Regional Counsel, VISN 15 Chief Medical Officer and VBA. Between January 30 and February 7, 2008, 24 of these meetings were completed and an additional two meetings were completed as of March 6, 2008. The meetings include a discussion of findings by an OMI physician, a discussion of legal and benefit options by Regional Counsel and VBA representatives, and the assignment of a local liaison (social worker or psychologist) for any further questions. Pastoral counseling is also offered at the conclusion of the meeting. Contacts were made by telephone and letter, and at this time we have confirmed receipt by all veterans or families identified by OMI. Some declined the offer of a meeting, others elected to have their attorneys meet directly with regional counsel, and others have requested to defer the scheduling of a meeting. We will continue this process until all of the identified veterans or family/families who desire a disclosure meeting have had this opportunity.

Question 8: Did information about morbidity and mortality rates at Marion come to the attention of the VISN before VA's Central Office (VACO) observed the spike in expected mortalities in the National Surgical Quality Improvement Program (NSQIP)? If so, please explain the circumstances and describe what steps the VISN took in response.

Response: In January 2007, the VISN Chief Medical Officer (CMO) received from National Surgical Quality Improvement Program (NSQIP) the fiscal year (FY) 2006 annual report concerning all facilities within the VISN. The surgical mortality data (observed/expected) for the Marion facility was 0.88 (less than the "expected" ratio of 1.0). In late April 2007, the VISN CMO received from NSQIP the first quarter FY 2007 data which reflected an increase in expected mortality at the Marion facility. The CMO met personally with the Marion VAMC Director at the VISN office in Kansas City on May 1, 2007, at which time the data, and a summary report of case reviews from the Marion Chief of Surgery were reviewed. A plan of action was discussed, including a plan for second level case review within the facility and additional support for surgical care, including the addition of a second anesthesiologist and organizational changes for the surgical program. The VISN Director was briefed by the CMO. Later in May 2007, the CMO met with the VAMC Director and Chief of Staff and discussed findings of the second reviews, which did not identify a specific procedure or individual surgeon as an etiology of the increase. In July 2007, the VISN CMO visited the Marion facility and met with the Chief of Staff. Second quarter NSQIP data reflected that the cumulative mortality rate for the year remained high but the number of deaths had decreased significantly in the second quarter. Additional actions at that time included recruitment of a third anesthesiologist and an additional pulmonary/critical care physician to the facility. On August 10, 2007, the VISN CMO was notified of additional surgical deaths, primarily involving a single surgeon, who resigned the following day. The VISN CMO arranged a case review of these cases to be performed by surgeons outside of the Marion facility. The plan for a NSQIP site visit was arranged on August 15, 2007.

Question 9: What is VA's enterprise wide remediation plan to address the serious medical and credentialing issues that were taking place at Marion, and ensure similar situations are not occurring elsewhere in the VA system?

Response: VA is preparing a contract for an entity external to VA to validate the VA peer review process. The purpose of the external peer review contract is to detect patterns of inaccurate or inadequate peer review in *any* VAMC through an audit of high risk cases and to provide standardized information to individual VAMCs that identify opportunities to improve care through the peer review process. The external review will provide additional assurance of good quality of care in small and large VAMCs by conducting focused, independent (external) case level quality of care assessment.

A meeting was held with senior leadership in The Office of Acquisition and Material Management. The contracting officer is identified as well as the contracting officer's technical representative. The core package for the solicitation is complete. Due to the size of this contract, estimated to be between $15 to $25 million over the 5 year span of the contract, a technical team is being assembled that will include not only staff from the Offices of Quality and Performance and Acquisition and Material Management, but also Office of Congressional and Legislative Affairs, Office of Public Affairs, and Office of General Counsel. This team will determine the type of contract to be competed; schedule a day for industry to gain information on the proposed contract prior to solicitation; and plan the solicitation. Industry must be given sufficient time to respond to the solicitation. It is anticipated that this contract will be awarded mid-to-late summer 2008.

VHA Directive 2008–008, requires that the VISN Director ensures there is an adequate review of the information provided and review of information from VAMCs on variance and initiation of appropriate actions. This might include a request that an external review or a site visit be conducted to review the peer review process. The VISN Director must also ensure that there is at least an annual inspection of the peer review process in all VISN medical centers.

The major medical issues that have become apparent through our analysis of the Marion situation are fundamentally attributable to systems and complexity management. Specifically, the ability to deliver safe and high quality surgical and procedural care is dependent not only on the skills of a given surgeon or operator, but also on the team supporting them as well as the institutional capabilities, including response times for key services. Thus, remediation requires not only ensuring the capability of the primary operators through the credentialing process, but also on better understanding and ensuring that the proper support is in place across all levels.

A task force has been working to analyze, report, and make recommendations for an enterprise wide approach to managing surgical complexity. That process has developed methodology for ranking the complexity of all surgical procedures and for assigning facilities a complexity ranking based on a broad range of capabilities including space, equipment, staff, consultative support for both pre- and post-operative care, and response times. In addition, there are patient characteristics that also being factored into this equation. These are being assembled into a 'matrix' that will ensure procedures are only performed in the appropriate environments, by the appropriate operators, with appropriate support at all levels. This process will be presented at a VHA-wide quality conference next week, (April 1–4, 2008).

A charge has been developed to assemble a similar task force to review all non-surgical procedures, such as cardiac interventions, to ensure that the same level of assurance is available for where and by whom medical procedures are being performed.

VHA has initiated a broad review of its clinical tracking programs, including NSQIP. The validity of our statistical methodologies will be subjected to external review as will the methodologies for data management and the entire structure for data reporting being evaluated internally. The goal is to strengthen both the robustness of the program and its ability to enhance facility performance. A national quality monitoring program is also under development for the non-surgical procedures, beginning with the cardiac catheterization lab procedures. This group is charged with developing processes for national monitoring of quality and outcomes for cardiac interventions, as well as processes for remediation when problems are identified.

As patient complexity increases, so does the need for higher levels of support. Toward this end there are ongoing systematic reviews and enhancements of both intensive care units (ICU) and emergency departments throughout VHA. A system-wide methodology for monitoring key outcomes measures in ICU patients (IPEC) is being extended to include all medical-surgical beds; a program to expand the availability of intensivists and hospitals, especially for lower complexity facilities, is being developed. Emergency departments are being standardized across VHA to ensure early management of acutely ill patients is optimized and appropriately meets the needs of the facilities. A pilot for providing higher lever intensivist support to smaller facilities and to improve house-staff supervision for facilities with residency programs is being developed using a "virtual ICU" monitoring system.

The overall goal for all of these initiatives is to ensure that all health care delivery across VHA is performed in the environment and at the time most suited for the complexity of the patients and procedures.

Question 10: A significant part of the serious problems at Marion resulted from the fact that information about excessive mortality and morbidity rates, the breakdown of the peer review process, and the apparent failure of the facility to consider relevant information when granting privileges, did not make its way outside of the facility until much of the damage had been done. Describe in detail the steps VA is taking to ensure that local breakdowns in these or other areas come to the attention of management in a more timely way and in a manner that will guarantee management response.

Response: A new Acting Director and Acting Chief of Staff are in place and recruitment for permanent positions is underway. The facility has been working with the National Center for Organizational Development (NCOD) on an ongoing basis to assist with improving employee communication and satisfaction.

Additional staff was added for quality management in order to provide additional focus, tracking and management of the peer review program. A national practitioner

data bank (NPDB) query was obtained for all staff physicians in October as a proactive process to identify potential issues. Clinical privileges for all procedures have been reviewed and adjusted as appropriate to both provider and organizational factors.

Joint Commission has conducted a full survey (late August) and three follow-up unannounced surveys, and the facility remains fully accredited.

The facility is moving forward with other clinical programs, including the recent opening of an expanded mental health clinical space, with plans in progress for a clinical annex for the Marion facility and expanded space for the Mt. Vernon and Effingham Community Based Outpatient Clinics (CBOC).

VA published VHA Directive 2008–004, Peer Review for Quality Management, January 28, 2008, clearly defines the roles and responsibilities of not only medical center leadership but also VISN and VHA headquarters leadership in the oversight of the peer review process and ensures that the review of facility information occurs at least quarterly with an annual inspection. Additionally, VA is preparing to complete a contract for an entity external to VA to validate the VA peer review process. The purpose of the external peer review contract is to detect patterns of inaccurate or inadequate peer review in any VAMC through an audit of high risk cases and to provide standardized information to individual VAMCs that identify opportunities to improve care through the peer review process. The external review will provide additional assurance of good quality of care in small and large VAMCs by conducting focused, independent (external) case level quality of care assessment.

VA required training of all medical staff leaders on the importance of the credentialing and privileging process using three Web based training modules. This training included identifying the roles and responsibilities of medical staff leaders in the credentialing and privileging process as well as requirements for effective implementation of ongoing monitoring of practitioner competency and continuous professional practice evaluations. The required training was completed January 31, 2008; and over 3,200 medical staff leaders took each of the three training modules.

In October 2007, VA implemented VISN-level review of practitioners prior to appointment by a medical center if the practitioner meets one of three medical malpractice criteria. These criteria are:

1. Three or more medical malpractice payments in payment history;
2. Two medical malpractice payments totaling $1,000,000 or more; or
3. A single medical malpractice payment of $550,000 or more.

During this second level review, VISN leadership has an opportunity to review and provide oversight to the credentialing and privileging process at the medical center level and determine if any additional follow-up is required.

In addition to statistical data measures, VHA also has an internal quality review team. The System-wide Ongoing Assessment Review Strategy (SOARS) mission is to provide assessment and educational consultation to VHA facilities using a systematic method for on-going self-improvement. SOARS also provide continuous readiness to reduce survey preparation anxiety and chaos, and help prevent and reduce repeat or high risk recommendations from external reviews and proactively identify areas of potential risk.

Question 11: As a result of the events at Marion, has VA identified any issues with NSQIP? Do not limit your response to the question of whether NSQIP is an effective tool to identify issues requiring immediate attention. Please tell us any ways in which NSQIP could be improved and what VA is doing to realize these improvements.

Response: In 1991, the National Surgical Quality Improvement Program (NSQIP) was established as a Special Purpose Workgroup (SPW) under the Office of Patient Care Services. It was developed to provide data to Veterans Health Administration (VHA) operations and field entities for enhanced monitoring of specific surgical outcomes. NSQIP also responded to quality issues raised by the VHA field or Central Office entities. Public Law (PL 99–166 December 3, 1985, Subchapter V Quality Assurance) stated that VHA compare its mortality and morbidity "from prevailing national mortality and morbidity standards for similar procedures."

NSQIP analysis was initially based on two key hypotheses:

1. Surgical morbidity and mortality rates are determined by patient-related risk factors such as primary disease, extent of disease, comorbid conditions, and sociodemographics and by a range of processes related to health care providers, the facilities, and institutional policies.

2. After adjustment for patient specific preoperative (risk) factors, operative mortality and morbidity indicate the quality of processes and structures of surgical care at a particular institution.

Aggregate reports of observed to expected (O/E) ratios of morbidity and mortality for each facility have proven to be important instruments for monitoring and improving the quality of care, originally based on facility action and later based upon widespread sharing with Veteran Integrated Services Networks (VISNs) and VA Central Office (VACO) entities. Risk-adjusted aggregated data calculations are based upon logistic modeling of all procedures for a given fiscal year.

Although the accuracy of data collected was verified by the VA Office of the Medical Inspector (OMI), over time it became clear that quality programs need to be more nimble, timely, and detailed with their reporting in order to provide a true oversight function. The assumption that providing annual risk-adjusted data to field and VACO entities would, in itself, improve results in specific facilities was not validated, although overall aggregate results improved over the decade the program had existed.

Starting in 2005, a number of changes were initiated with the intent to make NSQIP an improved oversight tool. NSQIP expanded its activities to include quarterly reports to VA operations, to focus upon results of specific operations including colectomy, bariatric procedures aneurysm repair, pancreatectomy, and transplant procedures. Actual mortality figures in addition to risk adjusted ratios are now calculated and compared to national averages.

In 2007, NSQIP initiated a web-based, color coded, quarterly website dashboard reporting system. This provided statistical evaluation of outliers based on a probability of 0.10 for both O/E ratios and actual mortality. Out of necessity, the ongoing web-based calculations were based upon hierarchical modeling of the performances of the previous year for comparison.

In addition, NSQIP can now tabulate quarterly aggregate patient safety issues, including correct site surgery and prevention of retained surgical item in response to VHA Directives 2004–028 and 2006–030.

In the case of Marion, these proactive, programmatic enhancements enabled the Office of Patient Care Services to detect serious performance concerns that had recently arisen. In order to further improve its capabilities NSQIP has added a senior nurse Validation Manager and is in the process of adding more enhancements which include additional statistical personnel, Bayesian Statistics for small number detection of outliers, and ongoing real-time comparisons of actual and expected mortality. An operating room supervisors' national conference stressing quality and safety along with a general educational meeting are scheduled for April 2008.

Two work groups were appointed by the Under Secretary for Health to further evaluate NSQIP procedures and surgical complexity at all facilities. The Surgical Quality Work Group will include in their review the capture of critical or sentinel events for urgent review and the use of rolling six-month NSQIP averages to provide greater sensitivity to changes that occur between fiscal year comparisons. The Operative Complexity Work Group will provide a template of surgical complexity of all procedures to assure that a procedure and the facility complexity and its support structures are in alignment.

To further ensure that medical center and VISN leadership comprehend and effectively utilize NSQIP, a conference on Quality Enhancement is planned for April 2008. All VAMC Chief of Staff and Nurse Executives, in addition to VISN CMO and QMO are expected to attend. There are two required sessions specifically, discussing NSQIP at this conference.

U.S. Department of Veterans Affairs,
Washington, DC.
May 14, 2008

Hon. Bob Filner
Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This letter transmits the views of the Department of Veterans Affairs (VA) on H.R. 4463, the "Veterans Health Care Quality Improvement Act." The bill contains numerous provisions that are excessively prescriptive and would impede the operations and structure of the Veterans Health Administration (VHA). We have enclosed a sectional analysis, which addresses each section in depth. A copy of this letter is also being sent to Congressman Miller, who requested these views at a recent hearing held on January 29, 2008, before the Subcommittee on Oversight and Investigations.

The Department strongly opposes two provisions of H.R. 4463. The first would require that within one year of appointment, each physician practicing at a VA facility (whether through appointment or privileging) be licensed to practice medicine in the State where the facility is located. VHA is a nationwide health care system. By current statute, VA practitioners may be licensed in any State.

If this requirement were enacted, it would impede the provision of health care across State borders and reduce VA's flexibility to hire, assign and transfer physicians. VA makes extensive use of telemedicine. This requirement also would significantly undermine VA's capacity and flexibility to provide telemedicine across State borders. In addition, VA's ability to participate in partnership with our other Federal health care providers would be adversely impacted in times such as the aftermath of Hurricanes Katrina and Rita, where we are required to mobilize members of our medical staff in order to meet regional crises.

Currently, physicians who provide medical care elsewhere in the Federal sector (including the Army, Navy, Air Force, U.S. Public Health Service Commissioned Corps, U.S. Coast Guard, Federal Bureau of Prisons and Indian Health Service) need not be licensed where they actually practice, so long as they hold a valid State license. Requiring VA practitioners to be licensed in the State of practice would make VA's licensure requirements inconsistent with these other Federal health care providers and negatively impact VA's recruitment ability. In addition, many VA physicians work in both hospitals and community-based outpatient clinics. Many of our physicians routinely provide care in both a hospital located in one State and a clinic located in another State. A requirement for multiple State licenses would place VA at a competitive disadvantage in recruitment of physicians relative to other health care providers.

Although the provision would allow physicians one year to obtain licensure in the State of practice, many States have licensing requirements that are cumbersome and require more than one year to meet. Such a requirement could disrupt the provision of patient care services while VA physicians try to obtain licensure in the State where they practice or transfer to VA facilities in States where they are licensed.

Further, we are not aware of any evidence of a link between differences in State licensing practices and quality of patient care. In 1999, the Government Accountability Office (GAO) reviewed the effect on VA's health care system that a requirement for licensure in the State of practice would have. The GAO report concluded, in part, that the potential costs to VA of requiring physicians to be licensed in the State where they practice would likely exceed any benefit, and that quality of care and differences in State licensing practices are not directly linked. See GAO/HEHS–99–106, "Veterans' Affairs: Potential Costs of Changes in Licensing Requirement Outweigh Benefit" (May 1999).

The other objectionable provision in H.R. 4463 would require that the Under Secretary for Health be a board-certified physician. Public Law 108–422, section 503, removed the requirement that the Under Secretary for Health be a doctor of medicine. Section 3(b) would undo this recent amendment, which affords the President greater flexibility in appointing, and the Senate in confirming, the best-qualified individual. The current statute appropriately requires the Under Secretary for Health to be appointed solely on the basis of demonstrated ability in the medical profession, in health care administration and policy formulation, or in health care fiscal man-

agement, and on the basis of substantial experience in connection with VHA programs or programs of similar content and scope.

The Office of Management and Budget advises that there is no objection to the submission of this report from the standpoint of the Administration's programs.

We appreciate the opportunity to comment on this bill. Copies of this bill report are being transmitted to Senators Akaka and Durbin (who also requested the Department's views).

Sincerely yours,

James B. Peake, M.D.
Secretary

SECTION BY SECTION

Section 2. Standards for Appointment and Practice of Physicians in Department of Veterans Affairs Medical Facilities.

Section 2(a)(1) of the bill would amend Subchapter I of chapter 74 of title 38, United States Code, to add a new section 7402A, Appointment and practice of physicians: standards.

New section 7402A(a) would require the Secretary, through the Under Secretary for Health, to prescribe standards for appointment and practice as a VA physician that incorporate the requirements of Section 2 of the bill. New section 7402A(b) would require physicians, as a condition of appointment to VA, to provide a full and complete explanation to VA of each lawsuit, civil action, or other claim (whether open or closed) against them for medical malpractice or negligence (except those closed without judgment against or payment by them or on their behalf); each payment made by or on their behalf to settle any such lawsuit, action or claim; and each investigation of disciplinary action taken against them relating to their performance as a physician.

These provisions are unnecessary. Qualification requirements for appointment as a VA physician are set forth in 38 U.S.C. § 7402. To be eligible for appointment in VHA, a physician must hold the degree of doctor of medicine or doctor of osteopathy from a college or university approved by the Secretary, have completed an internship satisfactory to the Secretary, and be licensed to practice medicine, surgery, or osteopathy in a State. Except as provided in 38 U.S.C. § 7407(a), a physician also must be a U.S. citizen and possess basic proficiency in spoken and written English. Furthermore, physicians who have or have had multiple licenses, registrations, or State certifications are subject to the employment restrictions in 38 U.S.C. § 7402(f) for any license terminations or surrenders for cause (i.e., for reasons of substandard care, professional misconduct or professional incompetence). By policy, all physicians must undergo a rigorous credentialing process. VA already requires all applicants and employed physicians to disclose the following: any involvement in administrative, professional or judicial proceedings, including Federal tort claims proceedings, in which malpractice is, or was, alleged; anything that would adversely affect or limit their clinical privileges, including previous adverse privileging actions; and anything that has or would adversely affect or limit their professional credentials, including licensure, registration, certification, individual DEA certification, and/or other relevant credentials.

Failure to provide this information on an application is considered falsification and may be sufficient grounds for denial of appointment or termination from employment. In addition, at a minimum of every two years, VA physicians are required to resubmit their applications for clinical privileges. A physician who fails to disclose the requested information at the time of this reappraisal may be terminated.

VA has no objection to requiring physicians seeking appointment to authorize their State licensing board(s) to disclose information to VA concerning lawsuits, claims, investigations, payments, etc. However, legislation is not required. The Under Secretary for Health issued policy that took effect on January 1, 2008, that would require all applicants to sign a written request to State licensing board(s) authorizing the release of this information to VA.

New section 7402A(c) would require physicians, as a condition of continuing service under the appointment, to agree to disclose within 30 days of occurrence each medical malpractice or negligence judgment against them; payments made by or on their behalf to settle any lawsuit, action, or claim for medical malpractice or negligence; and any disposition of or material change in such matters. It also would require physicians to biennially submit the written request and authorization to the State licensing board(s) described in section 7402A(b) as part of the biennial review of their performance as a physician.

This provision is also unnecessary. By policy, VA physicians already are required to disclose anything that would adversely affect or otherwise limit their appointment and/or clinical privileges, including any changes in the status of their credentials; any involvement in administrative, professional or judicial proceedings, including Federal tort claims proceedings, in which malpractice is, or was, alleged; and any previous adverse privileging actions. Failure to do so may result in administrative or disciplinary action.

New section 7402A(d) would require the Regional Director of the relevant Veteran Integrated Services Network (VISN) to perform and fully document a comprehensive investigation of each matter disclosed concerning the physician seeking appointment or continued employment in that VISN. New section 7402A(e) would require the Regional Director of the relevant VISN to approve the appointment of the physician, and provide written certification that each disclosed matter had been investigated, and written justification why any matters raised in the course of investigation would not disqualify the individual from appointment.

These provisions too are unnecessary. The Deputy Under Secretary for Health for Operations and Management issued guidance on October 10, 2007, that instituted system-wide changes to help ensure that the credentialing and privileging system is optimized throughout VHA Changes include a requirement that the Service Chiefs personally document their own review of all licensed health care practitioners. Where the physician has a record flagging, VHA must obtain primary source verification and documentation of the flagging issues. The Service Chief's comments on the appraisal documents must reflect an analysis of the issue and recommendations.

Where the response to the National Practitioner Data Bank-Health Integrity and Protection Data Bank query displays any of the criteria listed below, the credentialing staff will refer the credentials file to the VISN Chief Medical Officer (CMO), prior to presentation to the Executive Committee of the Medical staff for review and recommendation whether to continue the appointment and privileging process. These criteria are:

1. Three or more medical malpractice payments in payment history,
2. A single medical malpractice payment of $550,000 or more, or
3. Two medical malpractice payments totaling $1,000,000 or more.

The VISN CMO will review all circumstances, including the individual's explanation of the specific circumstances in each case and the primary source verification of the bases for medical malpractice payments, to determine whether the appointment is appropriate. If a query about a license results in a report of surrender or revocation, primary source documentation of the action will be obtained from the licensing board. The credentials file will be reviewed with Regional Counsel, or designee, to determine if the practitioner meets appointment requirements. In all circumstances where information from the primary source indicates there is an ongoing investigation, follow-up with the licensing board must occur at least monthly and be documented in VetPro. In addition, the Office of Quality and Performance (OQP) will forward any alerts received from the Federation of State Medical Boards (FSMB) Disciplinary Alert Service to the appropriate medical center staff within 24 hours. Once the licensing board takes final action, the service chief and the Executive Committee of the Medical Staff must review the practitioner's privileges and appointment to determine if any action is necessary. The credentialer must document this review, and any necessary action, in the practitioner's credentialing and privileging record.

In July 2007, VA launched training modules specific to the roles and responsibilities of medical staff leadership in the credentialing and privileging process. This is mandatory training for all medical center Directors, Chiefs of Staff, Chiefs of Quality Management, Chiefs of Services with credentialed staff, VISN CMO, and VISN Quality Management Officer. This was accomplished by January 31, 2008.

New section 7402A(f) would provide that a physician may not be appointed to VA unless board certified in the specialties of practice. However, this requirement may be waived (not to exceed one year) by the Regional Director for individuals who complete a residency program within the prior two year period and provide satisfactory evidence of an intent to become board certified.

VA opposes this provision. Current statute does not require board certification as a basic eligibility qualification for employment as a VA physician. VA policy currently provides that board certification is only one means of demonstrating recognized professional attainment in clinical, administrative or research areas, for purposes of advancement. However, facility directors and Chiefs of Staff must ensure that any non-board certified physician, or physician not eligible for board certification, must be otherwise, well qualified and fully capable of providing high-quality

care for veteran patients. VA is entitled to considerable deference regarding the standards of professional competence that it requires of its medical staff, including whether the requirement for specialty certification is reasonable and not applied arbitrarily and capriciously. Were this measure enacted, the requirements could potentially induce a chilling effect, impeding our ability to recruit the most qualified physicians and provide the best care possible to veterans. At this point in time, VA has physician standards that are in keeping with those of the local medical communities.

New section 7402A(g) would require that within one year of appointment each physician practicing at a VA facility (whether through appointment or privileging) be licensed to practice medicine in the State where the facility is located.

VA strongly objects to enactment of section 7402A(g). VHA is a nationwide health care system. By current statute, VA practitioners may be licensed in any State. If this requirement were enacted, it would impede the provision of health care across State borders and reduce VA's flexibility to hire, assign and transfer physicians. VA makes extensive use of telemedicine. This requirement also would significantly undermine VA's capacity and flexibility to provide telemedicine across State borders. In addition, VA's ability to participate in partnership with our other Federal health care providers would be adversely impacted in times such as the aftermath of Hurricanes Katrina and Rita, where we are required to mobilize members of our medical staff in order to meet regional crises.

Currently, physicians who provide medical care elsewhere in the Federal sector (including the Army, Navy, Air Force, U.S. Public Health Service Commissioned Corps, U.S. Coast Guard, Federal Bureau of Prisons and Indian Health Service) need not be licensed where they actually practice, so long as they hold a valid State license. Requiring VA practitioners to be licensed in the State of practice would make VA's licensure requirements inconsistent with these other Federal health care providers and negatively impact VA's recruitment ability. In addition, many VA physicians work in both hospitals and community-based outpatient clinics. Many of our physicians routinely provide care in both a hospital located in one State and a clinic located in another State. A requirement for multiple State licenses would place VA at a competitive disadvantage in recruitment of physicians relative to other health care providers.

Although the provision would allow physicians one year to obtain licensure in the State of practice, many States have licensing requirements that are cumbersome and require more than one year to meet. Such a requirement could disrupt the provision of patient care services while VA physicians try to obtain licensure in the State where they practice or transfer to VA facilities in States where they are licensed. The potential costs of this disruption are unknown at this time.

Further, we are not aware of any evidence of a link between differences in State licensing practices and quality of patient care. In 1999, the Government Accountability Office reviewed the effect on VA's health care system that a requirement for licensure in the State of practice would have. The GAO report concluded, in part, that the potential costs to VA of requiring physicians to be licensed in the State where they practice would likely exceed any benefit, and that quality of care and differences in State licensing practices are not directly linked. See GAO/HEHS-99–106, "Veterans' Affairs Potential Costs of Changes in Licensing Requirement Outweigh Benefit" (May 1999).

New section 7402A(h) would require each VA medical facility to enroll each privileged physician in the National Practitioners Data Base Proactive Disclosure Service.

This provision is unnecessary. The Under Secretary for Health has directed his staff to work with the National Practitioner Data Bank (NPDB)'s Branch of the Department of Health and Human Services to enroll VA's licensed independent practitioners in the Proactive Disclosure Service. We are currently in the process of establishing a system to ensure that all licensed independent practitioners are enrolled in that Service.

Section 2(b) of the bill would provide that the board certification and in-State licensure requirements would take effect one year after the date of the Act's enactment for physicians on VA rolls on the date of enactment. Section 2(b) also would provide that the requirement for enrollment in the NPDB Proactive Disclosure Service would take effect 60 days after the Act's enactment.

The requirements for board certification and licensure in the State of practice could temporarily disrupt VA's operations if physicians are unable to obtain board certification and in-State licensure within one year, or are unable to transfer to a State where they are licensed.

Section 3. Enhancement of Quality Assurance by the Veterans Health Administration.

Section 3(a) would amend subchapter II of chapter 73 of title 38, United States Code, to add a new section 7311A, Quality assurance officers. It would require the Under Secretary of Health to designate a National Quality Assurance Officer to be responsible for establishing and enforcing VA's quality-assurance program, including a system through which employees, on a confidential basis, may submit reports on matters relating to quality of care problems, peer review of physician actions, and accountability of the facility director and chief medical officer for the actions of facility physicians. It also would require the designation of a Network Quality Assurance Officer (who is a board certified physician) for each VISN, and a Quality Assurance Officer (who is a practicing physician at the facility) for each medical facility. In addition, it would set up an organizational reporting structure regarding the discharge of the responsibilities and duties of the quality assurance officers.

VA already has an organizational structure that includes a national Quality and Performance Office, headed by the Chief Quality and Performance Officer, who is required to be a physician. Each of VA's 21 VISNs has a Quality Management Officer, and each of VA's 153 hospitals has a Quality Manager. These employees are not required to be physicians because VA believes it is more important that they fully understand how to manage reviews of quality of care processes at the facilities to which they are assigned. Very few physicians have the specific knowledge needed to accomplish this task. The industry standard for hiring qualifications of a Quality Manager is a graduate level nurse with advance training in Quality Management. Quality Managers are tasked to oversee the quality of care processes at their facilities, and refer issues that need to be reviewed to the appropriate individual, Committee, or facility leader for appropriate action. As noted below in analysis of section 3(c), VA already has a confidential process for reporting problems with the quality of care furnished by VHA.

Section3(b) would amend section 305(a)(2) of title 38, United States Code, to require that the Under Secretary for Health be a board-certified physician.

VA opposes this provision. Public Law 108–422, section 503, removed the requirement that the Under Secretary for Health be a doctor of medicine. Section 3(b) would undo this recent amendment which affords the President greater flexibility in appointing, and the Senate in confirming, the best-qualified individual. The current statute appropriately requires the Under Secretary for Health to be appointed solely on the basis of demonstrated ability in the medical profession, in health-care administration and policy formulation, or in health-care fiscal management, and on the basis of substantial experience in connection with VHA programs or programs of similar content and scope.

Section 3(c) would require the Under Secretary for Health to establish a confidential reporting system through which VA employees may report quality of care matters to facility and network quality assurance officers.

This provision is not necessary. VA already has in place a confidential process for employees to report problems. Every hospital is required to advertise this process throughout the facility. Employees may also use a variety of other external or internal methods to report their concerns. Internally, one may call the Office of the Inspector General's Hotline. Outside of VA, methods include: reporting a problem under the provisions of the Federal Whistleblower Protection Act; and providing information to the Joint Commission (previously the Joint Commission on Accreditation of Health Care Organizations). Internally, VA employees can provide confidential information to the Office of the Medical Inspector; the National Patient Safety Office, and to the Office of Compliance and Business Integrity.

Section 3(d) would require VA to conduct a one-time comprehensive review of all current VA policies and protocols for maintaining health care quality and patient safety. This would include a review of the National Surgical Quality Improvement Program (NSQIP), including an assessment of the efficacy of its quality indicators, data collection methods, and the frequency of its regular data analyses, and the adequacy of allocated resources. Section 3(d) also would require VA to submit a report to Congress concerning its findings and recommendations within 60 days of the Act's enactment. VA supports this provision.

Section 4. Incentives to Encourage High-Quality Physicians to Serve in the Veterans Health Administration.

Section 4(a) would amend title 38, United States Code, by adding new section 7431A(a) to require the Secretary to carry out a loan repayment program for physicians who serve in hard-to-fill positions. Under new section 7431A, the Secretary would repay loans covered under the section in exchange for not less than three years of service by the participating physician in a hard-to-fill position at a VA facil-

ity. Loans covered by this provision would include any loan described in 10 U.S.C. § 16302(a)(1)–(4) and any other loans designated by the Secretary for which the proceeds were used by the physician to finance the education leading to the physician's medical degree.

Under the program, physicians would have to enter into a written agreement with the Secretary under which they agree to perform satisfactory service for a specified number of years in a physician position at a VA facility specified in the agreement. Physicians participating in the program would also have to agree to possess and retain such professional qualifications needed to fulfill their service obligation. Repayment of loans would be made on the basis of completed years of service, but in no case could the amount of repayment exceed $30,000 for any one year of service.

New section 7431A(b) would require the Secretary to conduct a tuition reimbursement program for medical students who agree to serve for a specified number of years as a VA physician in a hard-to-fill position. Specifically, individuals enrolled in a course of education leading to board certification would be eligible for this benefit. Individuals receiving tuition reimbursement under this program would also receive a stipend in the amount of $5,000 for each academic year after having entered into an agreement with the Secretary under this section.

In signing the written agreement, a participant would also be required to agree to satisfactorily complete the course of education leading to board certification as a physician; to become board certified as a physician; and upon completion of their education program, to perform satisfactorily in the specified physician position and to possess and retain the requisite professional qualifications throughout their service obligation period. The amount of reimbursement payable for one year could not exceed $30,000. Any individual who breaches his or her obligations under an agreement would be required to repay the funds they received, pursuant to requirements established by the Secretary.

New section 7431A(c) would extend participation in the Federal Employees Health Benefits Program (FEHBP) to individuals not otherwise eligible for health insurance under chapter 89 of title 5 if they agree to serve as a physician in a VA facility in a hard-to-fill position for not less than five days per month (of which two days must occur in each 14-day period). Participating physicians would be able to enroll in one of the FEHBP plans on a self or family basis. In carrying out this provision, the Secretary would be required to consult with the Director of the Office of Personnel Management.

All of these incentives would be in addition to any other recruitment or retention benefits these individuals are eligible for or entitled to under the law.

Section 4(b) of the bill would require the Secretary, to the extent practicable, to compel each VA medical facility to seek to establish an affiliation with a medical school within reasonable proximity of the facility.

VA does not support section 4 insofar as it would establish a new student loan repayment program for VA physicians. Such authority is not necessary. VA's Education Debt Reduction Program (EDRP) (authorized by 38 U.S.C. §§ 7681–7683) is sufficient to reimburse recently appointed VA physicians for amounts paid on their medical education loans. Currently, the Department has authority to award those physicians up to $50,824 (tax free) over a period of 5 years to reimburse them for amounts paid on their medical school educational loans. (The maximum allowed by statute is $44,000, but this is automatically increased each calendar year by the amount of the general pay increase for Federal employees pursuant to 38 U.S.C. § 7631.) Data reflect that the current authority is a highly effective recruitment and retention tool. For instance, a study done of EDRP award recipients from the first year of program implementation showed that 75% of physicians receiving awards in 2002 remained with VHA for the duration of their award eligibility, which ended in 2007. In addition, we note that the bill would require the Secretary to provide this loan repayment benefit rather than making it available as a discretionary recruitment and retention tool. Thus, we support continued funding of the EDRP but do not believe authority to establish a similar loan repayment program is needed.

VA does not support the provisions of section 4 that would establish the tuition reimbursement program for medical students. The Administration is currently evaluating the recruitment and retention incentives aimed at ensuring the Veterans Health Administration has the health professionals needed to deliver high-quality health care to our Nation's veterans. Once we have completed our review we will be in a better position to evaluate the need for a tuition reimbursement program for individuals who are not currently employed by the Department.

We are mindful, however, that VA would not immediately reap recruitment benefits under the tuition reimbursement program, After graduation, these students must still complete internship and residency requirements, and most do not perform their training at the same institutions where they obtain their medical degrees.

Many students additionally pursue fellowships after their residency requirements are completed. All in all, these training requirements can extend up to seven years post-graduation for some specialties. This does not account for the fact that many students change their area of specialty during these training periods, thereby extending their overall period of training. Thus, there would be a significant lag between the time VA makes payments on behalf of particular students and the time those students could actually be appointed as physicians to VHA. It is because of the difficulty and costs involved in tracking each student during his or her training periods that we do not support imposition of an annual stipend. Awarding stipends under these circumstances would simply not be feasible,

VA does not support the terms of section 4 that would extend participation in the FEHBP to individuals covered by that section. While we are greatly interested is in attracting physicians in "hard-to-fill" positions the legislation would provide more favorable treatment to this class of physicians than other similarly situated employees not only at the Department, but in the Federal Government as a whole.

Section 5. Reports to Congress.

Section 5(a) would require VA to submit annual reports, from 2009 to 2012, to Congressional veterans affairs committees on the implementation and amendments of this Act during the previous fiscal year, and VA's recommendations for legislative or administrative action to improve the authorities and requirements of the Act, the quality of health care, and the quality of VA physicians.

VA does not support section 5. This section is unnecessary, because most provisions of the bill are already being implemented.