

June 17, 2013

OSC File No. DI-12-4217

Ms. Pennington,

Attached are my comments to the June 3, 2013 VA response. In short, I disagree with most of the VA's responses and opine that the VA's conclusions are, 1) not supported by the facts, and thus, do not appear to be reasonable, 2) in most cases, the VA simply ignored the issues and did not address them at all, 3) in other cases, where the VA did mention (not address) the issue, their responses were non-responsive and finally, 4) the VA on the one hand claims Manila is unique and seems to imply that VA policy does not always apply in Manila, and then remarkably points out areas of non-compliance with VA policy in Manila with the implication that since no Manila unique policy exists...and Manila cannot always comply with VA policy...that any cases of non-compliance...virtually anything...in Manila are really not non-compliance, they have simply not yet been addressed and codified. This logic is ridiculous. VA Manila has been in the Philippines for almost 90 years and only now does the VA claim that Manila does not always have to apply with VA policy, but is silent on which policies? Ridiculous...until Manila unique policy is codified, Manila must comply with VA policy...period. Additionally, only when forced to do so by OSC, did the VA even interview me and that interview was an after-the-fact exercise; that while it may have met the technical requirement to conduct an interview did not come close to meeting the spirit and intent of the purpose of an interview...essentially the interview was only a sham to satisfy OSC's request for an interview. Most disturbing was the VA's contention that their actions were "putting Veterans first." Nothing could be further from the truth. The VA was putting "Veterans last." Further explanation follows.

Disagreement #1

The VA has presented no clinical or other evidence that no "substantial and specific danger to public health and safety" of the 25,000 Veterans seen at the VA Manila over the past 22 years did not occur and in-fact still exists. In-fact all the VA did was note that there were "no reports of adverse events", but then incredibly states that there "was no adverse drug event program in Manila to report adverse events to!" Essentially the VA is stating that since "nothing was reported, there must have been no problems." Ridiculous. The VA then states that to the best of their knowledge, there is no evidence that any of the 25 thousand affected veterans were ever notified that they were being dispensed Non-FDA approved drugs. The VA needs to immediately comply with its own policy, **VHA HANDBOOK 1004.08, DISCLOSURE OF ADVERSE EVENTS TO PATIENTS** (atch). This policy is the VA's method of clarifying the relationship between clinical, institutional, and large-scale disclosure to emphasize that disclosing an adverse event is a process that may require any or all types of disclosure. This action needs to be taken immediately, because to not do so is a clear and present danger to Veterans and substantial and specific danger to these veterans' health and safety. These veterans need this notification now, so they can seek medical treatment to mitigate any possible adverse impacts of being dispensed non-FDA approved drugs. The VA simply cannot keep the matter a secret and expect Veterans to figure things out for themselves...that they may have been harmed. **VA OIG Report # 13-01320-200** (attached) which dealt with Inappropriate Use of Insulin Pens at VA Western New York Healthcare System Buffalo, New York...this is an example of what "right" looks like in terms of notifying veterans. The VA noted a problem and immediately notified all potentially affected veterans. The VA did not wait for the veterans to figure things out for themselves

and decide to deal with any problems as veterans complained of contracting hepatitis...instead the VA notified all affected Veterans and had them report to the VA. Not surprisingly and unfortunately numerous veterans suffered adverse effects, however, if the VA had followed the same solution of secrecy in Buffalo as they appear willing to follow in Manila, then more than likely there would not have been any reports of adverse impacts in Buffalo as well!!...even the VA must recognize how ridiculous their position is.

Disagreement #2

“That there was no gross mismanagement, gross waste of funds.” Just the opposite is the case; even the VA admits that in FY 2012, the excess cost was \$655 thousand. Over eight years that McKesson has had the PPV contract, that amount is close to \$6 million. However, where a far greater gross waste of funds occurred was not in Manila, and not with Sierra Pacific Network 21, but instead with Steven A. Thomas, Director, National Contracting Service National Acquisition Center (NAC), U.S. Department of Veterans Affairs and Mr. German S. Arcibal, Senior Contract Specialist at NAC. These gentlemen either were intentionally or willfully blind...or worse...did not mandate that McKesson perform to the terms of the PPV contract. I have previously described this matter in great detail and provided substantial information to the VA, but the VA has chosen to simply ignore my information. The VA immediately needs to conduct a complete investigation into the hundreds of millions of dollars McKesson was paid in performance bonuses for a PPV contract that they did not meet the terms of. The VA needs to recoup these improper bonus payments and use the proceeds to “put Veterans first...not Contractors and Senior VA Officials “first” with huge performance bonuses.” Congress is currently investigating the McKesson PPV contract mismanagement, and that is perhaps why the VA simply choose to ignore my very specific facts on how badly...criminally is a better word...the McKesson PPV contract has been managed. Short response is that the VA simply ignored the McKesson issue and did not address it at all. Solving the McKesson PPV problem was an easy and simple problem to solve. Don’t be fooled by the VA’s and McKesson’s claims that it was a difficult problem to solve. In-fact, the VA Manila OPC is the only Federal Facility on the World who has not been in compliance with FDA rules for controlled drugs. All DoD facilities and US Embassies around the world are in compliance as it is an easy and simple program to manage.

Disagreement #3

While even the VA tacitly acknowledges the benign neglect that Manila has received over the years, the most disturbing and troubling aspect with the issue of non-FDA approved drugs, and with failure to notify Veterans of potentially adverse impacts and gross waste of funds, is the VA’s perverse and offensive manner of using the statement “putting Veterans first” as a sort of “get out of jail free card” to justify their failure. I would opine that in some cases breaking certain minor bureaucratic rules to help out a veteran would be acceptable and even commendable, but for the VA to justify every major and critical mistake they ever make under the guise of “putting Veterans first” is a practice that needs to stop immediately...it is a symptom of the VA’s troubled culture. However, this is simply my (and Congress) opinion. The fact is that in Manila these issues put the “Veterans last.” In addition to placing their health and safety in danger, Sierra Pacific Network 21 punished VA Manila by only providing an Annual Operating Budget in amounts that assumed Controlled drugs were being properly purchased from McKesson PPV. Over the years, this action chronically caused VA Manila to run a budget deficit of close to \$655 thousand. However, instead of properly supplementing VA Manila’s Budget, VISN 21 instead, forced VA Manila to reduce services to Veterans and also was willfully blind to severe staffing

shortages caused by the budget deficit. VA Manila employees...the most dedicated and loyal VA employees in the world....no one else is even close...were forced to work huge hours of unpaid overtime just to keep up with the demands required by the number of Veterans in Manila. My second week on the job, I had to deal with a letter from VISN 21 (attached, letter dated June 7, 2011). This letter demanded that we develop an action plan to make up for the additional increased costs caused by McKesson not complying with the PPV contract and also suggested ways we reduce staffing and services to veterans. Amazing, the budget deficit was almost exactly the annual savings (\$655 thousand) the VA will realize, now that OSC has essentially forced McKesson to comply with the terms of the PPV. Reducing services to veterans and placing them at harm by prescribing non-FDA approved drugs is not putting "veterans first" it is putting them "last."

Disagreement #4

The VA never interviewed me. What is most egregious is that the all of the very most senior members of VISN 21 were in Manila the first week of April 2013 and not only did they not interview me, they aggressively ignored me. These same senior VISN 21 members are 1) the same people responsible for Manila not having FDA approved drugs for 22 years, 2) for not developing policy unique to Manila, 3) chronically underfunding VA Manila because we were not able to obtain controlled drugs from McKesson PPV and finally and most appalling, 4) the very same senior VISN 21 people who visit Manila every year for a compliance inspection and presumably were either willfully blind or incompetent and allowed and even blessed the VA Manila operation...because they surely did not identify any of the findings I had to point out to them...after working at the VA for only 6 months! Again, these were VISN 21's most senior people, not novices, who inspected VA Manila each and every year for the past 22 years! The adverse events area is one of the mandatory areas that medical inspection and review teams are supposed to look at during annual visits. If there are no such records, then it is supposed to be an item for immediate resolution, with a corrective action plan, and follow-up reporting's. What happened? The VA is silent on this matter. I am assuming that this was not addressed in prior inspection team visits. I am sure that each and every one of these Senior Executives most likely has received substantial performance bonuses each and every year...but with VA merit does not seem to be the defining factor in receiving performance bonuses, so by VA standards, these executives were properly rewarded. Amazing, but fortunately Congress is now dealing with unwarranted bonuses by senior VA executives. Absent any logical answer to this question, then the only solution is incompetence...and sever disciplinary action...to include removal or reassignment; against senior VISN 21 leaders needs to be taken. While the VA did eventually interview me...only after being forced to by OSC ...while it may have met the technical requirement to conduct an interview...it did not come close to meeting the spirit and intent of the purpose of an interview...essentially the interview was only a 30 minute sham to satisfy OSC's request for an interview. I saw no evidence that of the issues I raised verbally during the short interview were addressed by the VA. I even went so far after the interview to send them additional information (which they suggested they did not want to see). In particular I sent detailed information about how criminally negligent the McKesson PPV was being managed and the VA simply never once even used the word "McKesson" in their response.

I closing the VA is simply playing a shell game with the VA Manila issues. The shell game the VA has employed can best be described as not admitting responsibility, but then pointing out that a different portion of the VA was responsible for the problem...but it was not really a problem and if it was it was not a problem because no program or policy existed to manage that area, and if it did, then VA Manila was most likely not required to comply with that policy. Nothing is mentioned of the numerous VISN

21 compliance inspections done the past 22 years that best can be described as being done in a willfully blind or ignorant manner. Not once has the VA admitted they were ever at fault, at times the VA even claimed they were being "proactive" in the management of VA Manila. My actions upon reporting for duty in Manila in May 2011 were to immediately deal with the VISN 21 letter to address the budget deficit. I choose to correct the cause and not the symptom and decided forcing McKesson to comply with PPV was the solution. It took some time, but eventually with OSC's help we have fixed the non-FDA approved drug problem and the savings that were created now will allow us to have adequate staffing and look for ways to improve service to Veterans...not reduce...as VISN 21 wanted us to do in June 2011. However, now that we have fixed the most pressing problem, the VA needs to take immediate steps to notify any of the 25 thousand Veterans who may have suffered adverse health incidents cause by the non-FDA approved drugs, and the VA needs to immediately have their OIG investigate all the performance bonuses that we illegally paid to McKesson the past 8 years. I respectfully note that I call this "putting Veterans first."

I would like to thank VISN 21 for at least one thing they did good IRT VA Manila. They hired me a career DoD employee who had never worked for the VA to come to Manila and be a change agent. As a result of that decision, I have been able to effect great change in VA Manila. I don't think anyone, to include me, ever thought it would take a partnership with OSC to effect that change...but it-is-what-it-is, and I am proud of my actions and can look any VA senior official in the eye and state the facts...that is why the VA senior officials refused to interview me, because they can't "stand" the facts. Instead, the VA simply pulls rank and even resorts to whistle blower reprisals...which is why this matter is at OSC.

Sincerely,



Robert R. Crawford

Attachments

Documents Referenced

http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2800

<http://www.va.gov/oig/pubs/VAOIG-13-01320-200.pdf>

VISN 21, June 7, 2011, Budget Deficit Action Plan

Department of
Veterans Affairs

Memorandum

Date: June 7, 2011

To: Director, VA Sierra Pacific Network

Subject: Budget Deficit FY11-Action Plan

From: Director, VBA Regional Office, Manila
Clinic Manager, Manila OPC

1. When the VISN team was at the Manila Clinic earlier this year, we initiated discussions about the pharmacy budget. We are aware that, by working with Diana Higgins, some economies have been realized but not sufficient to eliminate the pharmacy budget deficit this fiscal year. This deficit is \$553,000. In addition, your overall budget, excluding pharmacy, has a projected \$50,000 deficit for this fiscal year, for a total \$600,000 deficit for FY 11.
2. Dr Petzel has indicated that Manila is not exempt from MCCF Billing and co-pay requirements. Collecting additional fees may assist in your budget in the future but it will require time to set up systems in order to meet this mandate. In addition, I have requested that VHA CPO re-evaluate Manila's funding allocation to more accurately reflect your future funding needs. This will not assist you this year, if changes are even made, but may help in the future.
3. I am asking you to prepare a written, detailed report describing what actions you will take to manage the budget deficit this year and prepare for next year. Issues that were discussed previously have included: not providing over the counter medications, reducing fee costs, reducing FTE (e.g., housekeeping staff) when services can be provided in another way, not providing Epogen when dialysis is being done in the community for a nonservice-connected condition, and focusing on your key missions of compensation and pension and treatment of service-connected conditions. I am also asking you to provide data on the number of patients being sent out on fee for service-connected conditions when the care needed could be provided in the clinic. Please indicate the types of fee services provided, the rationale for using fee and the costs related to those services. Also, I would like verification that only patients with service-connected End Stage Renal Disease (ESRD) are being placed on Fee Dialysis.
4. Please provide an action plan to me, Roxanna Hargrove, Mary Anne Johnson, Terry Sanders and Judy Daley by June 20th. We will use your action plan for monitoring your progress in reducing your deficit. We will restart our VISN calls, with the next call being June 22nd by v-let. During this call, we will discuss your action plan and then determine the frequency of future calls.
5. Thank you for attention to addressing this budget issue. I look forward to reviewing your plans.



Sheila M. Cullen