REDACTED REPORT

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

NOV 12 2013

In Reply Refer To:

Ms. Catherine McMullen
Chief, Disclosure Unit
U.S. Office of Special Counsel
1730 M Street NW
Suite 300
Washington, D.C. 20036-4505

Re: OSC Files DI-12-3816 and DI-13-1713

Dear Ms. McMullen:

Please find enclosed an interim report on the status of the Department of Veterans Affairs' (VA) action plans for Case Nos. DI-12-3816 and DI-13-1713. By e-mail on October 23, 2013, your office requested information on two additional matters. VA's responses are discussed below.

With respect to OSC File DI-12-3816, your office asked for information regarding whether disciplinary action has been taken against those officials who contributed to, or directed violation of state and Federal laws and agency policies. The action plan, like the original report, does not identify any disciplinary action(s) that need to be taken. As noted in VA's report dated July 15, 2013, the non-compliant practices uniformly stem from the VA medical center's (VAMC) institutional failure to adhere to/or enforce current Federal laws and VA rules, regulations, and policies. The original complaint did not require VA to investigate the past/historical actions that may have led to such institutional failure. Since the leadership under which the institutional failure occurred have already left the facility and, in some cases are no longer employed by VA, a look-back into past/historical practices would not be feasible at this time. The facility's new leadership is taking corrective actions to remedy the past non-compliant practices and prevent them from recurring.

With respect to OSC File DI-13-1713, your office asked for information regarding (b)(6) read rate in relation to the number of hours he spent reading non-VA images, and for a determination on whether patient care was affected by the actions of the VAMC, the extent of the effect, and status of any necessary follow-up actions. As you are aware, (b)(6) left VA employment on (b)(6). As explained in the original report, outside films could not have been read on VA radiology equipment. If it were possible for (b)(6) to read outside films by accessing the university's web site from his VA laptop, the content would not be on the IT equipment, and there would be no way to confirm what activities he conducted when he was on the university's web site. Also, (b)(6) laptop would have been wiped clean by our IT office upon its

return to the Department. There is no possible way to investigate this allegation, thus explaining why the investigation team rejected anecdotal evidence and relied only on hard data stored in our radiology equipment systems.

Should you have any questions about the action plan for DI-12-3816, please contact Sharon Johnston at 202-461- 7658. For questions about the action plan for DI-13-1713, please contact Kathy Heaphy at 202-834-1869.

Sincerely yours,

Robert L. Jesse, MD, PhD

Enclosure

Office of the Medical Inspector Interim Report for the Under Secretary of Health G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi

November 8, 2013

Background:

At the direction of the Secretary, the Under Secretary for Health (USH) requested the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) send team of subject matter experts to investigate a complaint filed with the Office of Special Counsel (OSC) at the G.V. (Sonny) Montgomery Veterans Affairs (VA) Medical Center in Jackson, Mississippi (hereafter, the Medical Center), asserting that employees are or engaging or have engaged in misconduct that may constitute a violation of law, rule, or regulation, gross mismanagement, and abuse of authority that may create a substantial and specific danger to public health and safety at the Medical Center. The allegations were as follows:

Primary Care:

- The Medical Center did not have a sufficient number of physicians in Primary Care, resulting in failure to provide adequate care for patients and proper supervision of nurse practitioners (NP), who provide a majority of patient care services.

- Inadequate physician staffing levels have resulted in failure to properly supervise NPs which violates state licensure agreements, resulting in NPs practicing without proper certification.

- Inadequate physician staffing levels resulted in fraudulently completed Centers for Medicare and Medicaid Services home health certifications/forms for patients.

- Narcotics were improperly prescribed, e.g., physicians prescribed narcotics for patients they had not treated.

Radiology:

- A former radiologist, (b)(6) [redacted] at the Medical Center regularly marked patients' radiology images as "read" when, in fact, he failed to fully or properly review the images, and at times, failed to read them at all.

- The failure to properly read these images, or at times, to read them at all, led to numerous missed diagnoses of serious, and in some cases, fatal conditions including inoperable cancers, neck fractures, and enlarged lymph nodes.

- Medical records were falsified to cover-up the treatment and diagnostic errors.

- Management was aware of this malfeasance but never required that the images be re-reviewed or took steps to remedy this problem, and instead acted to protect the radiologist at fault.

- The agency failed to notify the large number of patients who were potentially affected by this lapse in clinical care.

An investigative team of subject matter experts conducted site visits at the Medical Center from April 15, 2013, through April 19, 2013, and May 7, 2013, through May 8, 2013, that resulted in a total of 23 recommendations, all endorsed by the USH. Two reports were issued to OSC in June 2013, DI-12-3816, and DI-13-1713. The facility's actions taken in response to the recommendations are included here.

In September 2013, the USH requested the Office of the Medical Inspector (OMI) to oversee implementation of the action plans at the Medical Center.

OMI conducted a site visit to the Medical Center on October 22-23, 2013, to evaluate implementation of the recommended actions.

OMI reviewed and concurred with the Medical Center's action plan in response to report recommendations, and the status of actions is as described below. OMI and the DUSHOM will continue to monitor the progress and sustainability of recommendations.

A. PRIMARY CARE

Recommendations:

1. The Medical Center leadership must immediately correct the erroneous declaration that all nurse practitioners (NP) will practice as licensed independent practitioners (LIP).

Resolution: The Medical Center has identified and obtained licensure requirements for all of its NPs. Each NP has been provided with a written letter informing them of the declaration of LIP or non-LIP status based on their state of licensure. NPs licensed in a state that does not recognize them as an LIP will perform duties under a scope of practice as outlined in their state license. The Medical Center will continually update and maintain an in-depth spreadsheet to track NP-specific information including state of licensure, individual DEA certificate, certifications, LIP or non-LIP status, and physician collaborator as well as scope of practice information for non-LIPs.

2. Medical Staff Bylaws must be amended to indicate that NPs are considered LIPs only when their state licensure permits.

Resolution: The Medical Center has drafted proposed changes to the Medical Center Bylaws. The proposed changes were presented to the Executive Board of the

Governing Body for approval prior to presentation to the medical staff. The medical staff approved these changes to the Bylaws in late October 2013.

3. Medical Center leadership must immediately implement scopes of practice versus clinical privileges for NPs who are not permitted to practice as LIPs.

Resolution: The Medical Center has identified the licensure states of all NPs. Those NPs licensed in states, such as Mississippi, where they are not permitted to practice as LIPs, have been issued scopes of practice. The Chief Nurse Executive has reviewed and approved all scopes of practice. Each scope of practice will be catered to the NP's certification and designated area of assignment, to include acute care, adult care, family care, women's health, or surgical care. Several NPs have licensure in more than one state and have declared which license they are operating under to ensure transparency with the requirement for scopes of practice if not operating under an NP license that allows for LIP status.

4. Medical Center leadership must immediately ensure that all NPs who require collaborative agreements in fact have them, and that they are approved by the NP's respective state licensing board.

Resolution: All NPs who are required by their licenses to work under a scope of practice have a collaborative agreement with a physician at the Medical Center. The Arkansas State Board of Nursing has agreed to allow the establishment of a collaborative agreement with a physician at the Medical Center who is not licensed in the state of Arkansas in lieu of their restriction for same state licensure. The Medical Center maintains copies of all NP collaborative agreements. Upon renewal of their state license, the collaborating physician's information is entered into the NP's application for renewal. VA is not required to forward collaborative agreements to the state for approval.

5. The Medical Center leadership should ensure the equitable distribution of collaborative agreements among physicians, and a reasonable limitation placed on the number of collaborative agreements for any one physician. If a state's Nursing Practice Act establishes a limitation on the number of collaborative agreements that a collaborating supervising physician may have with an NP at any one time, then the Medical Center needs to comply with such requirements.

Resolution: The Medical Center has complied with the individual state requirements for collaborative agreement ratios. The Medical Center currently employs NPs licensed in the states of Arkansas, Iowa, and Mississippi; none of these states have set maximum NP-to-physician ratio guidelines. The current maximum ratio of assigned collaborative NPs-to-physicians at the Medical Center is 4:1.

6. The Medical Center leadership should eliminate use of locum tenens physicians in Primary Care to the extent possible.

Resolution: As patient care access needs dictate, the Medical Center will limit the use of locum tenens physicians when possible. At present, there are no locums tenens physicians assigned to Primary Care.

7. Locum tenens physicians should not be physician collaborators because of their short tenure.

Resolution: At present, there are no locums tenens physicians assigned to Primary Care. The Medical Center has made a commitment to avoid, if at all possible, using locum tenens as collaborative physicians if any are hired in the future.

8. The Medical Center leadership must immediately implement a process to ensure that appropriate monitoring of NP practice by physician collaborators occurs and is documented in accordance with state licensure requirements.

Resolution: The Medical Center provided physician collaborators with the appropriate monitoring guidelines required by the state in which each assigned NP is licensed. VHA Handbook 5005/27 Part II Appendix G6 (PII-G6-10 thru PII-G6-11) defines policy on collaborative relationships for Nurse II and Nurse III grades. The Medical Center's clinical service chiefs monitor physician collaborator requirements, and report compliance to leadership during the Quarterly Service Performance Dashboard Report.

9. Medical Center leadership must continue to aggressively work to hire permanent full time physicians for Primary Care, to obtain an NP-to-physician ratio of 1:1. Once an adequate number of physicians are hired, the Medical Center will ensure that NP panel sizes are reduced to meet VHA guidelines.

Resolution: The Medical Center has hired additional full time physicians. One new staff physician came on duty on October 6, 2013, and a second physician will begin on November 3, 2013. A third physician is in credentialing and privileging (C&P) process. As the total physician panel size capacity increases, NP panel sizes will decrease and come in line with established patient-aligned care team (PACT) model recommendations. The current staffing in Primary Care is 8 physicians and 14 NPs; the plan is to have 10 physicians and 14 NPs on staff before December 31, 2013.

10. Medical Center leadership should consult the Office of Workforce Management and Consulting in VA Central Office (VACO) to ensure they are utilizing all available resources to recruit primary care physicians.

Resolution: The Medical Center uses the VISN 16 physician recruiter along with advertisement on the VA Careers Web site, in several professional journals, and at universities and medical schools. The physician recruiter attends career fairs and

places advertisements nationally, to include Puerto Rico. There is currently a comprehensive recruitment action plan with Workforce Management as well.

11. Medical Center leadership should eliminate the use of ghost clinics. All clinics must have an assigned provider.

Resolution: The Medical Center has reviewed clinic names and provider profiles. All providers have been assigned to appropriate clinics. All clinics identified as no longer valid or required have been deleted and any assigned patients transferred to newly-hired health care providers.

12. Medical Center leadership should eliminate the use of overbooked and double-booked appointments to the extent possible. The Medical Center needs to implement the principles of open access scheduling, which means patients receive care when and where they want or need, including on the same day if requested.

Resolution: As the Medical Center recruits new physicians and establishes teams under the PACT model they anticipate the need for overbooked appointments will decline. The Medical Center reviewed appointment grids for all providers, and on May 1, 2013, began to transition to open access scheduling based on the needs of the Veteran. Letters were mailed out to patients informing them of the scheduling changes.

13. The Medical Center must convert 6-part C&P folders to the electronic VetPro system, as required by VHA leadership.

Resolution: All physicians and NPs are credentialed in VetPro. Leadership detailed a staff member into C&P from Primary Care to assist with document reconciliation and scanning of appropriate documentation into VetPro. Scanning was completed on October 15, 2013. OMI reviewed all primary care NP C&P folders in VetPro while on site on October 22, 2013, and found no deficiencies.

14. VISN 16 leadership should arrange for an external clinical quality review of all Primary Care at the Medical Center, particularly in light of the evidence that electronic View Alerts are often not being reviewed by physicians in a timely fashion and NPs were practicing outside the scope of their licensure. The Medical Center should conduct a clinical care review of a representative sample of the patient care records for all 42 NPs, as well as all physicians, who worked in Primary Care from January 1, 2010, to present. The VISN should work with Medical Center leadership to determine the sample size needed to ensure that the quality of care delivered by all of these providers was appropriate. If any clinical care issues are identified, the Medical Center should consider expanding the sample. Specific cases involving unresolved questions as to quality of care should be referred to OMI for further investigation.

Resolution: The VISN and Medical Center have established that 30 patient care records will be reviewed, along with ongoing professional practice evaluation (OPPE) data, for each physician and NP to ensure quality care was delivered. The VISN has identified the clinical reviewers to conduct the external clinical quality review. The VISN 16 Deputy Chief Medical Officer, in conjunction with OMI, created a review tool to be used. The review is estimated to take 1,050 hours of provider time to complete. If issues are identified during the review, a focused professional practice evaluation (FPPE) will be conducted for the provider and the case(s) will be referred to OMI.

15. The VISN 16 leadership should actively assist the Medical Center to implement these recommendations (and any others it deems necessary to ensure quality care is consistently rendered and available to PCU patients) through an approved action plan; and be responsible for submitting the action plan to the Under Secretary for Health along with periodic status reports (through to completion of all items).

Resolution: The VISN assigned a point of contact, the VISN 16 Accreditation Specialist, to assist in writing the action plan to address the recommendations, as well as ensuring actions are tracked until completed and closed out. The VISN and Medical Center have had two scheduled progress update meetings with OMI, and a face-to-face meeting to include additional interviews with Medical Center staff occurred October 22 - 23, 2013.

16. VHA should consider issuing an Information Letter (IL) to reinforce across the system the need for compliance with both NP state licensure requirements and with national policies on NP credentialing, privileging, and scopes of practice. Such guidance should identify Regional Counsels as an important resource for the facilities as they review program compliance requirements.

Resolution: The Office of Nursing Service's Advanced Practice Nursing Advisory Group will develop an IL that will detail the process to ensure compliance with advanced practice nursing requirements and issues of regulatory control.

17. To determine whether Medicare home health certification forms are/were being appropriately completed by the PCU providers, VHA should task the appropriate VHA offices, e.g., the VHA Office of Compliance and Business Integrity and the Office of Patient Care Services, Home Health Program, to work together to conduct a random check of Medical Center PCU patient charts to determine if any Medicare forms are present, and if so, whether they were completed appropriately. Such findings need to be reported to the USH, who will then need to consider if any follow-up action is necessary. Additionally, Medical Center leadership should consider development a training and educational module for completion of these forms to ensure Primary Care and other staff are aware of Medicare compliance requirements.

Resolution: OMI interviewed physicians and NPs during the site visit, and the Home Health Program coordinators via telephone the following week. The Medicare home health certification forms are not part of the electronic health record (EHR) and are not scanned for placement therein. OMI was told all home health certification forms completed by NPs are submitted to a collaborating physician for signature. The Home Health Program coordinators assured OMI that any improperly completed forms are returned to the appropriate physician for signature. The Medical Center leadership has reviewed the process for Medicare form completion with all clinical staff in Primary Care.

18. The three NPs who have not yet received their individual DEA certificates should be encouraged to obtain these as soon as possible. Until that time, they are not writing prescriptions for controlled substances, and are relying on the collaborating physicians to write these prescriptions as necessary.

Resolution: The Medical Center encouraged all NPs to obtain individual DEA certificates. At the time of the original investigation, there were three NPs without their own DEA certificates. Since then, two NPs applied for and have received individual DEA certificates, and one NP has retired. The Medical Center completed and will continually review the spreadsheet containing all information about NP licensure to ensure compliance. On October 22, 2013, the Medical Center's Pharmacy Service reviewed all prescriptions for the preceding 3 months requiring DEA certification and did not find any unauthorized controlled substance prescriptions.

19. The NP functional statement, qualification standards, and dimensions of practice of the Medical Center must be revised to be consistent with national policy per VA Handbook 5005 appendix G6.

Resolution: The NP functional statements, qualification standards, and dimensions of practice have been updated for the Medical Center, consistent with national policy per VA Handbook 5005 appendix G6 and approved by the Chief Nurse Executive. The Medical Center's clinical service chiefs will ensure service-level specific NP functional statements are completed and filed in each individual NP's competency folder.

20. The Medical Center must complete a clinical care review of a random sample of the patient care records for the NPs who were prescribing controlled substances, outside of the authority granted by their license. This review should focus on patients who actually were prescribed controlled substances. If any clinical issues are identified the review should be expanded.

Resolution: Within the 30 patient care records per provider to be reviewed to address item 14, the Medical Center will review NP prescriptions of controlled substances to ensure that their prescribing was clinically appropriate. If issues are identified during the review, a focused professional practice evaluation (FPPE) will be conducted for the provider and the case(s) will be referred to OMI.

21. Medical Center policies and bylaws concerning the practice of NPs should be updated to reflect VA national policies and the licensure and DEA requirements for this profession. Functional statements should be updated to reflect all current regulations.

Resolution: The Medical Center has drafted proposed changes to the Medical Center Bylaws. The proposed changes were presented to the Executive Board of the Governing Body for approval prior to presentation to the medical staff. The medical staff approved these changes to the Bylaws in late October 2013.

B. Radiology

22. The Medical Center should review all eight cases identified by Lumetra as having moderate to high assessed impact including all relevant medical records and appropriate subspecialty consultation to determine the degree of harm, if any, and to conduct appropriate disclosures to patients and/or their families in accordance with VHA policy concerning institutional disclosure.

Resolution: The VISN has appointed a staff physician from a different facility within VISN 16 to review the eight cases in question alongside the Lumetra data. Following completion of the review, the Medical Center will conduct the appropriate disclosures to patients and families if warranted and will forward their findings to the VISN and OMI.

23. (b)(6) VHA Chief Consultant, Diagnostic Services, should identify an appropriate number of (b)(6) studies drawn from the period (b) 2003 – (b)(6) 2007, so that an external peer review can be conducted. The Medical Center, in consultation with (b)(6) should determine any further action if the discrepancy rate is outside the expected baseline.

Resolution: (b)(6) has thoughtfully determined that no further cases need to be reviewed. Several reviews have already been completed to assure quality care was provided and the cases have met the standard of care. A review to establish competency by the radiologist, to include a study of 300 of his cases, was completed several years ago, and is a large enough sample to identify an incompetent radiologist. To review this radiologist again, especially if he is the only radiologist reviewed, would appear malevolent. To do such a review properly would require reviewing very large numbers of cases from each of the radiologists that worked at the Medical Center to show that he performed at a lower standard. Furthermore, administrative action is not an option for a former employee, and so many years have passed that VHA could not take legal action.