



DEPARTMENT OF VETERANS AFFAIRS
Washington, DC 20420

July 15, 2013

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI- 12-3816

Dear Ms. Lerner:

I am responding on behalf of the Secretary to your letter regarding alleged violations at the G.V. (Sonny) Montgomery Department of Veterans Affairs (VA) Medical Center (VAMC) in Jackson Mississippi. These allegations were made by a Whistleblower, (b)(6), a primary care physician at the Jackson VAMC, who charged that the Jackson VAMC did not have a sufficient number of physicians in the Primary Care Unit (PCU), which resulted in failure to provide adequate care for patients and proper supervision of nurse practitioners, who provide the majority of patient care services. You asked VA to determine if the alleged misconduct constituted a violation of law, rule, or regulation, gross mismanagement, an abuse of authority, or a substantial and specific danger to public health and safety. The Secretary has delegated to me the authority to sign this report and take any actions deemed necessary under 5 United States Code (U.S.C.) § 1213(d)(5).

The Secretary asked the Under Secretary for Health to review this matter and to take any actions deemed necessary under 5 U.S.C. Section 1213(d). He, in turn, directed the Deputy Under Secretary for Health for Operations and Management to conduct an investigation. In its investigation, the fact-finding team determined that certain Federal laws and regulations, as well as state laws, may have been violated. Additionally, the team determined that due to mismanagement, both VA and Veterans Health Administration (VHA) policy may not have been followed, specifically related to credentialing and privileging and VHA outpatient scheduling processes and procedures. While no changes in agency rules, regulations, or practices should be made as a result of this investigation, the fact-finding team made a number of recommendations for the Jackson VAMC to adhere to or enforce current rules, regulations, practices, and policies, as noted in the report and summarized in the Executive Summary. There was no evidence of abuse of authority; however, the team found failure to follow VHA policies and procedures, specifically related to the PCU and physician oversight. Recommendations were made to ensure clinical reviews are conducted by Veterans Integrated Service Network (VISN) 16, which oversees the Jackson VAMC to ensure the service line complies with all applicable laws and VHA policies to maintain a high quality, safe health care environment for patient care.

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The Honorable Carolyn N. Lerner

Finally, VHA is in the process of developing a tabulated action plan (with applicable timeframes) and monitoring responsibilities for each of the recommended actions described in the Report. We will provide you with a copy of the action plan (in the form of a supplemental report) as soon as it becomes available.

I have reviewed the report and concur with the findings, conclusions, and recommendations. Thank you for the opportunity to respond to this issue.

Sincerely,



Jose D. Riojas
Interim Chief of Staff

Enclosure

THE VETERANS HEALTH ADMINISTRATION (VHA)

Report to the Office of Special Counsel (OSC)

OSC File Number DI-12-3816

G.V. (Sonny) Montgomery Department of Veterans Affairs (VA) Medical Center

Jackson, MS



Report Date: June 21, 2013

Any information in this report that is the subject of the Privacy Act of 1974 and/or the Health Insurance Portability and Accountability Act of 1996 may only be disclosed as authorized by those statutes. Any unauthorized disclosure of confidential information is subject to the criminal penalty provisions of those statutes.

Executive Summary

Summary of Allegations

At the direction of the Secretary, the Under Secretary for Health requested that the Office of the Deputy Under Secretary for Health for Operations and Management send a team of subject matter experts to investigate a complaint filed with the Office of Special Counsel (OSC) by (b)(6), a primary care physician and Whistleblower, at the G.V. (Sonny) Montgomery Department of Veterans Affairs (VA) Medical Center in Jackson, Mississippi (hereafter, the Medical Center). (b)(6) asserts that employees are, 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 Whistleblower alleged, in brief, that:

- The Medical Center did not have a sufficient number of physicians in the Primary Care Unit (PCU), resulting in failure to provide adequate care for patients and proper supervision of Nurse Practitioners (NP), who provide the majority of patient care services (Allegation #1);
- Inadequate physician staffing levels resulted in failure to properly supervise NPs, which violates state licensure agreements, resulting in NPs practicing without proper certification (Allegation #2);
- Inadequate physician staffing levels resulted in numerous fraudulently completed Centers for Medicare and Medicaid Services (CMS) home health certifications/forms for patients (Allegation #3); and
- Narcotics were improperly prescribed, e.g., physicians prescribe narcotics for patients they had not treated (Allegation #4).

The investigative review team conducted a site visit at the Medical Center from April 15, 2013, through April 19, 2013, and reviewed submitted documents; a second site visit was conducted by select team members on May 7 and May 8, 2013 to obtain and review additional staffing-related documents.

Conclusions for Allegations #1 and #2

Due to the complexities and interconnectedness of allegations #1 and #2, the team elected to investigate and dissect the two allegations concomitantly, including the findings and recommendations for both.

- The review team substantiates that the Medical Center does not have a sufficient number of physicians in the PCU and NPs have not had appropriate supervision/collaboration with Physician Collaborators.

The review team did not substantiate that inadequate care was provided (even with the noted scheduling problems). It is the professional expert opinion of the review team that there are enough problematic indicators present to suggest there may be quality of care issues that require further review. Although the review team found that all NPs have requisite certifications and licenses, NPs in the PCU were erroneously declared as Licensed Independent Practitioners (LIP), and the required monitoring of their practice did not consistently occur resulting in NPs practicing outside the scope of their licensure.

- The Medical Center's policy permitting NPs to practice as LIPs when that practice is not authorized by their individual state Practice Acts violates VHA policy. Only the two NPs licensed in Iowa are allowed to practice as LIPs.
- Granting NPs clinical privileges when they are not LIPs violates VHA policy. Only the two Primary Care NPs licensed in Iowa are allowed to be granted clinical privileges; all others must have a scope of practice.
- There is a lack of understanding among Medical Center leadership regarding NP practice and licensure requirements. This is evident by the fact that leadership erroneously declared NPs as LIPs and granted clinical privileges, yet they have also stipulated that NPs must have collaborative agreements per individual state licensing board requirements. This is further confounded by the fact that, despite requiring collaborative agreements (which is the correct approach), leadership has not implemented a process for ensuring all required collaborative agreements are in place, and the appropriate monitoring of NP practice by Physician Collaborators occurs.
- Ten of the 13 NPs currently practicing at the Medical Center and whose licenses require collaborative agreements have an approved collaborative agreement in place.
- Many, if not most, of the Primary Care NPs have not complied with state licensing board requirements for ensuring their practice is appropriately monitored by their Physician Collaborators, such as chart reviews and face-to-face meetings with the Physician Collaborator. In addition, the Medical Center has no process in place to ensure monitoring requirements are met.
- State requirements vary as to the appropriate ratio between NPs and a Physician Collaborator. Some states set no MD-to-NP ratio requirement. Others establish a ratio of 1:3, 1:4, or more. There should be a reasonable limit to the number of NPs per Physician Collaborator to ensure appropriate medical direction and supervision by the Physician Collaborator is provided, consistent with the terms

of the collaborative agreements. We are aware that in March 2013, the Mississippi Board of Medical Licensure amended Rule 1.3 of Chapter 1 of Part 2630 of the Mississippi Administrative Code to state, in relevant part: "Any one Physician should have no more than four collaborative agreements." [See Mississippi Administrative Code, Part 2630, Chapter 1, Rule 1.3], Requirements for collaborating physicians, which states: "Physicians are prohibited from entering into primary collaborative agreements with more than four Advanced Practice Registered Nurses at any one time unless a waiver is expressly granted by the Board for that particular collaborative agreement." According to a notice on the Board of Medical Licensure's Web site, implementation of the amendment is suspended until July 31, 2013. The consensus among team members is that the ratio should be limited to four or five NPs to one Physician Collaborator. Clearly, the one Medical Center Physician Collaborator, who has 14 current collaborative agreements, is in violation of this state requirement.

- All Medical Center PCU NPs currently have the required state NP licenses and national NP certifications.
- There was no evidence to indicate that the former Chief of Staff, (b)(6) (b)(6) had 160 collaborative agreements, as alleged by the Whistleblower. The review team found evidence that (b)(6) had only four collaborative agreements with Primary Care NPs during the review period of 2010 to present.
- The Medical Center PCU has an insufficient number of physicians.
- The NPs in the PCU have panel sizes that generally exceed VHA guidelines.
- Clinical quality data, available Ongoing Professional Practice Evaluation data, and the fact that only one provider has been reported to the National Practitioner Data Bank since October 1, 2010, for either a tort claim settlement or an adverse action against clinical privileges relating to the quality of care, are indicators that the Medical Center PCU staff is providing quality care. However, the following additional problematic indicators led the review team to conclude further review of the following needs to be conducted in order to explicitly declare that appropriate and adequate high quality care has been provided in the Medical Center PCU:
 - Insufficient physician staffing;
 - Sporadic tenure of Locum Tenens physicians;
 - NPs functioning as LIPs, when in fact they are not;
 - Failure to appropriately monitor the clinical practice of NPs;
 - Lack of timely response by providers to Computerized Patient Record System View Alerts;
 - Multiple patient appointment scheduling problems (e.g., double books, Vesting Clinic/Ghost Clinic); and

- Large volume of patient complaints regarding access to, and timeliness of, care
- The Medical Center NPs appear to be appropriately identifying themselves as NPs to their patients.

In summary, the team substantiates the Medical Center does not have a sufficient number of physicians, and NPs have not had appropriate supervision and collaboration with Physician Collaborators. The team did not substantiate that inadequate care was provided even with the noted scheduling problems. However, there are enough problematic indicators present to suggest there may be quality of care issues that require further review. Although the team found that all NPs currently have requisite NP certifications and licenses, NPs in the PCU have been erroneously declared as LIPs, and the required monitoring of their practice has not consistently occurred. NPs were potentially practicing outside the scope of their licensure and not appropriately monitored by Physician Collaborators.

Recommendations for Allegations #1 and #2

- The Medical Center leadership must immediately correct the erroneous declaration that all NPs will practice as LIPs.
- Medical staff bylaws must be amended to indicate that NPs are considered LIPs only when their state licensure permits or VA policy changes occur.
- The Medical Center leadership must immediately implement scopes of practice versus clinical privileges for NPs, who are not permitted to practice as LIPs.
- The 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.
- The Medical Center leadership should ensure the equitable distribution of collaborative agreements among physicians, and a reasonable limitation should be 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.
- The Medical Center leadership should eliminate use of Locum Tenens physicians in the PCU to the extent possible.

- Locum Tenens physicians should not be allowed to be Physician Collaborators because of their short tenure.
- 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.
- The Medical Center leadership must continue to aggressively work to hire permanent full-time physicians for the PCU to obtain an NP:MD ratio of 1:1. Once an adequate number of physicians is hired, the facility should reduce panel sizes for NPs to meet Veterans Health Administration (VHA) guidelines.
- The Medical Center leadership should consult the Office of Workforce Management and Consulting in VA Central Office to ensure they are utilizing all available resources to recruit primary care physicians.
- The Medical Center leadership should eliminate the use of Ghost Clinics. All clinics must have an assigned provider.
- The Medical Center leadership should eliminate the use of overbooked and double-booked appointments to the extent possible. The Medical Center leadership 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 so requested.
- The Medical Center must convert six-part credentialing and privileging folders to the electronic VetPro system, as required by VHA leadership.
- Veterans Integrated Service Network (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 were 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 the PCU from January 1, 2010, to present. The VISN should work with facility 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 facility should consider expanding the sample. Specific cases involving unresolved questions as to quality of care should be referred to the Office of the Medical Inspector for further investigation.
- 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).

- 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 Counsel as an important resource for the facilities as they review program compliance requirements.

Allegation #3: Inadequate Staffing Results in the Improper Completion of Medicare Home Health Certificates/Forms

Conclusion for Allegation #3

The team cannot substantiate the allegation that CMS home health certificates/forms are/were completed inappropriately and in violation of Federal law because the Medical Center's PCU staff has not followed statutory and regulatory requirements of the Medicare home health program. However, the team cannot rule out that the allegation may have some merit given the noted statements of interviewees and the team's substantiation of allegations related to the lack of supervision of NPs and the lack of necessary collaborative agreements between collaborating physicians and the NPs.

Recommendation for Allegation #3

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 VHA Under Secretary for Health, who will then need to consider if any follow-up action is necessitated. Additionally, facility leadership should consider development of a training and educational module for completion of these forms to ensure PCU and other staff are aware of Medicare compliance requirements.

Allegation #4: Facility Uses Improper Procedures for Issuing Narcotics Prescriptions

The team fully substantiates the allegation that past Medical Center management advised its NPs, most of whom are licensed in Mississippi, that they did not need to obtain individual (Drug Enforcement Administration (DEA) registration or file it with the Mississippi Board of Nursing (BON), since they could rely on the institutional registration

with a suffix. Further, the team found that the allegation that NPs in the PCU, including “grandfathered” NPs, were allowed to write narcotics prescriptions under the facility’s institutional DEA registration number, which is in violation of Federal and State law.

Conclusions for Allegation #4

- Medical Center leadership was under the impression that all providers were allowed to use the institution’s generic DEA number, as long as the provider was working within the scope of a VA provider. In fact, as explained above, as a matter of Federal law and VA policy, where a practitioner’s state of licensure requires individual DEA certification in order to be authorized to prescribe controlled substances, the practitioner may not be granted prescriptive authority for controlled substances without such individual DEA certification. Thus, with respect to NPs whose state of licensure required individual DEA certification to prescribe controlled substances, we substantiated the Whistleblower’s allegations that the Medical Center’s practice violated Federal law and VA policy.
- As of the writing of this report, all NPs are licensed as an NP in a state and are certified nationally as an adult or family practice NP, including the two NPs still at the Medical Center, who were originally grandfathered in from the NP licensure requirement. Grandfathered in NPs are not exempt from meeting any additional requirements by their state of licensure for obtaining prescriptive authority for controlled substances.
- When management was made aware that not all NPs were authorized by their license to write prescriptions for controlled substances, they took immediate action to stop the practice and attempted to put the prescribing back in the hands of staff physicians. The team confirmed that some, but not all, staff physicians agreed to renew prescriptions based on a records review alone; thus, we substantiated the whistleblower’s allegations.
- When management learned that this practice was also improper because a face-to-face physician/patient encounter was required, they created the Locum Tenens clinic as a stop gap measure. Patients were physically seen by these physicians, and prescriptions written appropriately. These clinics continued until the NPs obtained their own DEA certificates. Current prescribing practices comply with Federal law and VHA policy.

Recommendations for Allegation #4

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

- The NP functional statement, qualification standards, and dimensions of practice of the facility must be revised to be consistent with national policy per VA Handbook 5005, Appendix G6.
- The facility 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 were actually prescribed controlled substances. A sample of at least 10 percent should be completed. If any clinical issues are identified, the review should be expanded.
- Facility 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.

Summary Conclusion

In conclusion, the team determined that certain Federal laws and regulations, as well as state laws, may have been violated. These are outlined in detail in the report. Additionally, the team determined that due to mismanagement, both VA and VHA policy may not have been followed, specifically credentialing and privileging and VHA outpatient scheduling processes and procedures. While no changes in agency rules, regulations, or practices should be taken as a result of this investigation, the fact-finding team made a number of recommendations for the Medical Center to adhere to/or enforce current rules, regulations, practices, and policies, as noted in the report and summarized in this Executive Summary. There was no evidence of abuse of authority; however, the team found potential liability from failure to follow VHA policies and procedures, specifically related to the PCU and physician oversight. Recommendations are made to ensure clinical reviews are conducted by VISN 16, which oversees the Medical Center to ensure the PCU complies with all applicable laws and VHA policies to maintain a high quality, safe health care environment for patient care.

I. Introduction

At the direction of the Secretary, the Under Secretary for Health requested that a team of subject matter experts investigate a complaint filed with the Office of Special Counsel by (b)(6), a primary care physician and Whistleblower, at the G.V. (Sonny) Montgomery VA Medical Center, in Jackson, Mississippi (hereafter, the Medical Center). (b)(6) alleged that employees are engaging in conduct that may constitute a violation of law, rule or regulation, gross mismanagement, and abuse of authority, and a substantial and specific danger to public health and safety at the Medical Center. The investigative review team conducted a site visit to the Medical Center from April 15, 2013, through April 19, 2013. Select members of the team, (b)(6) conducted a second site visit on May 7 and May 8, 2013 for the purpose of obtaining and reviewing additional staffing related documents.

II. Facility Profile

The Medical Center, part of VISN 16, consists of the main facility in Jackson and seven Community-Based Outpatient Clinics (CBOC). The main facility operates 128 inpatient beds for general medicine, surgery, neurology, and mental health services. The facility's Medical Intensive Care Unit has a 12-bed capacity and an average occupancy rate of 62 percent. The Surgical Intensive Care Unit has 8 beds, with an average occupancy rate of 47 percent. The Medical Center is affiliated with the University of Mississippi, training resident physicians in internal medicine and other specialty areas.

III. Summary of Allegations

- The Medical Center did not have a sufficient number of physicians in the PCU, resulting in failure to provide adequate care for patients and proper supervision of NPs, who provide the majority of patient care services (Allegation #1);
- Inadequate physician staffing levels resulted in failure to properly supervise NPs, which violates state licensure agreements, resulting in NPs practicing without proper certification (Allegation #2);
- Inadequate physician staffing levels resulted in numerous fraudulently completed Centers for Medicare and Medicaid Services (CMS) home health certifications/forms for patients (Allegation #3); and
- Narcotics were improperly prescribed, e.g., physicians prescribe narcotics for patients they had not treated (Allegation #4).

IV. Conduct of the Investigation

The investigation review team was chaired by (b)(6), Director, VA Capitol Health Care Network (VISN 5). Appointed team members included (b)(6), Quality Management Officer, VISN 5; (b)(6) Chief Medical Officer, VA Health Care Upstate New York (VISN 2); (b)(6), Human Resources (HR) Consultant, VHA Workforce Management and Consulting Office; and (b)(6) Chief Safety and Risk Awareness Officer, National Center for Patient Safety. Subject matter experts assisting the appointed members included (b)(6) RN, Program Manager, National Center for Patient Safety; (b)(6) M.D., Primary Care Officer, VISN 5; and (b)(6) HR Consultant, VHA Workforce Management and Consulting Office.

(b)(6) primarily focused on OSC Referral DI-12-3816 primary care issues. (b)(6) primarily focused on OSC Referral DI-13-1713 radiology issues. (b)(6) was unable to participate in the on-site review.

A review team representative contacted (b)(6) prior to the site visit to share the scope of the team's review and ensure the team understood the full scope of her concerns and had all of the documents she thought pertinent to the team's investigation.

Select review team members, (b)(6) conducted interviews and reviewed documents, policies, procedures, and reports relevant to the PCU allegations. A list of the documents reviewed by and relied upon by the review team is found in Attachment A. The review team also held an entrance and exit briefing with facility leadership (i.e. (b)(6), Medical Center Director; (b)(6) (b)(6), Acting Associate Director; (b)(6); Acting Chief of Staff; (b)(6) (b)(6) Acting; Associate Director for Patient Care Services; and (b)(6), Acting Assistant Director).

During the site visit, the following individuals were interviewed:

- (b)(6), Primary Care Physician and Whistleblower (who was told during her interview that she could provide additional information to the team during its site visit, if she had additional information that was not included in her previous communications, interview, or the OSC referral letter)
- (b)(6) VISN 16 Chief Medical Officer
- (b)(6), VISN 16 Deputy Chief Medical Officer and NP
- (b)(6), VISN 16 Quality Management Officer
- (b)(6), Medical Center Director at the Medical Center
- (b)(6), Former Chief of Staff and Staff Physician in Nephrology at the Medical Center
- (b)(6) Former Associate Chief of Staff for Primary Care and Chief of Occupational Health at the Medical Center

- (b)(6) Acting Chief of Staff and Chief of Medicine at the Medical Center
- (b)(6) Acting Associate Chief of Staff for Primary Care and Primary Care Physician at the Medical Center
- (b)(6), Primary Care Physician at the Medical Center
- (b)(6) Primary Care Physician at the Medical Center
- (b)(6) Former Primary Care Physician and Emergency Department Physician at the Medical Center
- (b)(6), Former Primary Care Physician and Staff Physician at the Medical Center
- (b)(6), Primary Care NP at the Medical Center
- (b)(6), Primary Care NP at the Medical Center
- (b)(6), Former Primary Care NP and Surgical Service NP at the Medical Center
- (b)(6), Women's Health/Primary Care NP at the Medical Center
- (b)(6), Primary Care NP and Primary Care NP Supervisor at the Medical Center
- (b)(6), Chief Steward (National Federation of Federal Employees) and Psychiatric NP at the Medical Center
- (b)(6) Primary Care Registered Nurse (RN) at the Medical Center
- (b)(6) Primary Care Scheduling Clerk at the Medical Center
- (b)(6), Primary Care Scheduling Clerk at the Medical Center
- (b)(6), Primary Care Administrative Officer at the Medical Center
- (b)(6), Acting Chief of Pharmacy at the Medical Center
- (b)(6), Chief Steward (American Federation of Government Employees) at the Medical Center
- (b)(6) Concerned Citizen

In addition, a second site visit, on May 7 and May 8, was conducted by review team members, (b)(6) to review NP credentialing and privileging files of 42 NPs employed at the Medical Center in primary care from January 1, 2010, to date. Review team members made numerous follow-up telephone and e-mail contacts with facility personnel to clarify and ensure accuracy of information gathered during the site visits and to obtain new information as deemed necessary by the review team.

Finally, review team members held a follow up conference call with (b)(6) to allow her the opportunity to provide additional information and clarification regarding her allegations.

The review team did substantiate allegations when the facts and findings supported that the alleged events or actions took place. The review team did not substantiate allegations when the facts showed the allegations were unfounded. The review team could not substantiate allegations when there was no conclusive evidence to either sustain or refute the allegations.

V. Findings, Conclusions and Recommendations

Because the issues included in these allegations are highly complex and many of them interconnected, we have characterized and addressed them in the following manner in an effort to provide a full and accurate context for the review team's findings and conclusions.

Allegations #1 and #2

(b)(6) alleged that:

- The Medical Center did not have a sufficient number of physicians in the PCU, resulting in failure to provide adequate care for patients and proper supervision of NPs, who provide the majority of patient care services (Allegation #1);
- Inadequate physician staffing levels resulted in failure to properly supervise NPs, which violates state licensure agreements, resulting in NPs practicing without proper certification (Allegation #2);

Findings

To address these two allegations, the review team focused on data from 2010 to the present (the time period referenced by the Whistleblower), including but not limited to:

- Primary Care NP supervision, licensure, and certification
- Primary Care staffing
- Quality of care
- Primary Care NP practices relative to identifying themselves to patients as NPs

A. Primary Care NP Supervision, Licensure, and Certification

A.1 Hospital Bylaws and VHA Policy

Hospital staffing is, in part, governed by the local facility bylaws which delineate the roles and responsibilities of staff. The Medical Center's bylaws are found in the document titled "Bylaws and Rules of the Medical Staff" and dated March 19, 2013. This document states, in relevant part, that NPs who practice at the Medical Center are LIPs. Article 8, Clinical Privileges, Section 8.01, Paragraph 3. As a result of the facility's decision to treat all NPs as LIPs, the Medical Center authorized its NPs to practice under clinical privileges.

VHA policy and procedures for the credentialing and privileging of LIPs is contained in VHA Handbook 1100.19, "Credentialing and Privileging." Paragraph 2a provides that "[a]ll VHA health care professionals who are permitted by law and the facility to provide patient care services independently must be credentialed and privileged as defined in this Handbook." The term "independent practitioner" is defined in paragraph 3h as:

[A]ny individual permitted by law (the statute which defines the terms and conditions of the practitioner's license) and the facility to provide patient care services independently; i.e., without supervision or direction, within the scope of the individual's license and in accordance with individually-granted clinical privileges. This is also referred to as a licensed independent practitioner (LIP). **NOTE: Only LIPs may be granted clinical privileges.**

The term "clinical privileging" is defined as "the process by which a practitioner, licensed for independent practice (i.e., without supervision, direction, required sponsor, preceptor, mandatory collaboration, etc.) is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure. Clinical privileges must be facility-specific and provider-specific." *Id.* at paragraph 3e.

Thus, under VHA Handbook 1100.19, NPs may not be considered LIPs unless their state of licensure permits. It is unclear when the Medical Center first made the decision to allow all NPs to practice as LIPs. However, based on the review team's review of credentialing and privileging folders, the decision reaches back as far as 2010.

Currently at the Medical Center PCU, there are only two NPs whose state licensure permits independent practice (Iowa).

Since 2010, a total of 42 NPs have worked in primary care. Currently, 16 NPs are employed in primary care, one of whom is the NP supervisor and does not have a panel of patients (explained below in more detail); 19 others are now working in another service at the Medical Center; and 7 are no longer employed at the Medical Center. These NPs have been licensed in various states, including 35 in Mississippi and one each in North Carolina, Tennessee, Florida, Ohio, Arkansas, and Iowa. One NP is dually licensed in Mississippi and Iowa. None of these states, except Iowa as noted above, allows independent practice for NPs.

Under VHA policy, NPs who are not LIPs per their state licensure are required to practice within a specialty area or primary care in collaboration with a qualified physician(s) and in accordance with a written scope of practice (SOP). State collaboration requirements vary by state. Some states may require a collaborative agreement for diagnosis, treatment and/or prescribing (both non-controlled and controlled substances). Other states may require a collaborative agreement for only some aspects of clinical practice. Required documentation of the collaborative arrangement also varies by state, with some states requiring a written agreement, while other states do not. States set the terms of the collaborative relationship (e.g., number of required document reviews by the physician supervisor, number of NPs per physician

supervisor, geographical distance between the physician supervisor and NP, etc.) In 1999, the Under Secretary for Health issued VHA Information Letter (IL) 10-99-003, which provided guidance (the IL is not policy) to the field regarding appropriate utilization of NPs and Clinical Nurse Specialists (CNS), consistent with then-existing policy contained in VHA Handbook 1100.19, Credentialing and Privileging, and VHA Manual M-1, Part I, Chapter 26, Hospital Accreditation. Appendix 26A of the Manual contained a model bylaws template to guide medical facility staff to develop local facility bylaws, rules, and regulations that are consistent with national policy. In paragraph 1 of the notes to bylaws template users, it states, “[n]othing in the VA medical facility Bylaws, Rules and Regulations can have any effect inconsistent with, or otherwise be inconsistent with, law or Department of Veterans Affairs (VA) regulations.” Further, the updated bylaws template,¹ at Article III, Sections 3.02.2.b and d states that Advanced Practice Registered Nurse (APRN) “may be privileged to practice independently *if in possession of State license/registration that permits independent practice,..*” while those who are not granted clinical privileges “will practice under a scope of practice.” (Emphasis supplied). Although VHA IL 10-99-003 itself has expired, its guidance remains consistent with the current VHA Handbook 1100.19, Credentialing and Privileging, and the updated bylaws template.

Paragraph 2 of VHA IL 10-99-003 establishes guidance for APRNs² as follows:

2. APRNs are Masters degree-prepared RNs, who also possess advanced clinical certification. All newly employed APRNs are masters-prepared and nationally-certified. **NOTE:** *VHA continues to employ some NPs who were hired in the past who hold neither a Masters degree nor national certification; but these are in the minority. These nurses will function within a scope of practice commensurate with their training, demonstrated expertise, and licensure.*

a. Current VHA policy (VHA Manual M-1, Part I, Chapter 26, and VHA Handbook 1100.19) permits privileging of practitioners who are licensed and permitted by law and the facility to practice independently (i.e., no requisite for physician supervision or collaboration). This policy provides that facilities may grant privileges within the scope of the license held by the practitioner. These requirements are consistent with those of The Joint Commission on Accreditation of Healthcare Organizations.

b. The DEA permits prescription of controlled substances by practitioners authorized to prescribe controlled substances by the jurisdiction in which they are licensed to practice their profession (Title 21 Code of Federal Regulations (CFR) 1306.03).

¹ The Bylaws Template is a living document, which is updated at least annually and posted on VHA's Office of Quality, Safety and Value's Intranet site. The first update to the Bylaws Template that was contained in Appendix 26A was posted on April 15, 2010. The most recent update was posted in December 2012.

² The term Advanced Practice Registered Nurse includes NPs, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists. The term does not include Registered Nurses (RN).

c. For those APRNs whose license requires a collaborative agreement, the APRN will function within a specialty area or in primary care in collaboration with a qualified physician(s) and in accordance with a written scope of practice.

d. A written scope of practice statement should be developed between the APRN and the collaborating physician(s) and should include, at minimum:

- (1) Responsibility to the patients served;
- (2) Diagnosis and treatment authorities;
- (3) Patient record reviews with the collaborating physician;
- (4) Documentation of the APRN's prescriptive privileges for drugs, devices, immunizing agents, tests, and procedures;
- (5) Referral and consultation when indicated;
- (6) Patient coverage in cases of the absence of either a physician or APRN;
- (7) Resolution of disagreements between the APRN and physician; and
- (8) Other matters, as considered appropriate, by the collaborating parties.

e. Any limitation on the number of APRNs with whom a physician may have formal collaborative practice agreements should be determined locally.

To the extent that the Medical Center's bylaws permit all NPs to practice as independent practitioners without regard to the authority granted by their licensure, the bylaws are inconsistent with VHA policy as well as the national bylaws template (discussed above).

A.2. Collaboration Agreements

The investigative review team reviewed the credentialing and privileging folders of all 42 NPs who have worked in primary care since 2010. All of them were granted clinical privileges by the Medical Center. As explained above, clinical privileges may be granted only to LIPs. The review team found that none of the NPs should have been granted clinical privileges, with the exception of the two NPs after they received Iowa NP licenses in 2013.

More specifically, based on a review of all of their folders, the review team found:

- Forty-two NPs all had their required NP licenses and national certification, except for three who were grandfathered in as NPs and therefore, were not required to have an NP license, per VHA Handbook 5005/27, Staffing. Of the grandfathered

NPs, all three were licensed in Mississippi as an RN. One is no longer employed at the Medical Center; the other two NPs have acquired NP licensure since being grandfathered in. As described in greater detail below, in order to be grandfathered in from the requirement for NP licensure, they must have been hired before 2003. All three of the NPs were hired as NPs prior to 2003. (Policy information related to this grandfathering is addressed in section 3 below.)

- Of the 42 NPs employed since 2010 in primary care, there was evidence that 8 of them at some point during this period of time did not have a required collaborative agreement.
- Of the currently employed NPs in primary care, 13 of 15 are currently required to have collaborative agreements. Ten of the 13 have a signed and approved collaborative agreement in place. One of the remaining three NPs has a signed collaborative agreement as of April 29, 2013; however, the agreement has not been approved by the State of Ohio BON, and this was the NP's first ever collaborative agreement despite her having been employed at the Medical Center for a number of years. The two remaining NPs have collaborative agreements with a Locum Tenens Physician, who recently resigned employment at the Medical Center; the two NPs have not been assigned a new Physician Collaborator. A general analysis by state of licensure follows:
 - The State of Mississippi does not recognize NPs as LIPs and requires a collaborative agreement. Eight of the 10 NPs licensed in Mississippi have a signed collaborative agreement. The remaining two, while they had signed collaborative agreements, the agreements are with a Locum Tenens Physician, who is no longer employed at the Medical Center.
 - The State of North Carolina does not recognize NPs as LIPs and requires a collaborative agreement with a physician licensed in North Carolina. The NP licensed in North Carolina has a signed collaborative agreement in place with a North Carolina licensed physician, who is practicing in a VA facility in another state.
 - The State of Arkansas does not recognize NPs as LIPs and requires a collaborative agreement for prescriptive authority of controlled substances only. The NP licensed in Arkansas has been prescribing controlled substances for many years. However, the NP did not have a collaborative agreement until June 7, 2012, per information provided by the Medical Center.
 - The State of Ohio does not recognize NPs as LIPs and requires a collaborative agreement. The NP licensed in Ohio has a signed collaborative agreement as of April 29, 2013, but the collaborative agreement has not yet been approved by the Ohio BON. This NP did not

have a collaborative agreement prior to April 29, 2013, and has been employed at the Medical Center for a number of years.

- The State of Iowa recognizes APRN NPs as LIPs and does not require a collaborative agreement. To be recognized as an LIP, an NP must be registered with the Iowa BON at the advanced practice level (i.e., APRN), and nationally certified in a recognized nursing specialty. Two NPs are licensed in Iowa.
- The NP, who is only licensed as an APRN in Iowa, was hired prior to 2003. As such, the NP was grandfathered in under VHA policy and was not required to obtain an NP license. She has had national NP certification in Family Practice since 1994. The NP obtained an Iowa APRN license on April 10, 2013. The NP, therefore, is no longer grandfathered from the requirements to possess and maintain NP licensure and national specialty certification. Although the Medical Center policy permitted the grandfathered NP to practice independently prior to obtaining her APRN NP license, she was not recognized by Iowa as an LIP until 2013. Thus, during the time period covered by the allegations, the NP was required by national VA policy to practice under a collaborative agreement with a physician.
- The NP, who is licensed at the advanced practice level in both Mississippi and Iowa, required a collaborative agreement while working under the Mississippi APRN NP license, which the NP had. The NP obtained the Iowa APRN NP license on January 18, 2013, and therefore may now practice under his Iowa APRN NP license without a collaborative agreement.
- There are five physicians who serve as Physician Collaborators for the NPs who currently work in primary care.
 - One Physician Collaborator has collaborative agreements with five of the NPs.
 - One Physician Collaborator has collaborative agreements with five NPs currently practicing in primary care, plus additional collaborative agreements with nine NPs who work in other Departments at the Medical Center.
 - One Physician Collaborator, who was a Locum Tenens Physician, and is no longer employed at the Medical Center had collaborative agreements with four NPs. Three of the NPs whose formal collaborative agreements were with this Physician Collaborator have no other formal collaborative agreements. One of these NPs has a second Physician Collaborator

(namely the Physician Collaborator noted above who has 14 total collaborative agreements).

- Two Physician Collaborators have a collaborative agreement with one NP each. One of these two collaborators is licensed in North Carolina and collaborates with the NP who is also licensed in North Carolina. The North Carolina BON requires North Carolina-licensed NPs to collaborate only with physicians licensed in North Carolina. Because the Physician Collaborator is located in North Carolina, he does not have access to the Medical Center Computerized Medical Record System (i.e., CPRS) and thus is unable to conduct records reviews of the NPs' patient care.
 - Of the five Physician Collaborators, only three of them work in primary care at the Medical Center.
 - As already noted, one of the five Physician Collaborators is no longer employed at the Medical Center.
 - The Physician Collaborator noted above, who has a total of 14 collaborative agreements, is currently the Acting Chief of Staff, in addition to being the Chief of Medicine Service.
- (b)(6) alleged that (b)(6) former Chief of Staff, had at least 160 collaborative agreements. Of the 42 NPs employed at the Medical Center in primary care from January 1, 2010, to date, the investigative team found that (b)(6) was the collaborating physician for only 4. Two of these collaborative agreements are with NPs, who are still employed at Medical Center but in another department, and two were with NPs, who are no longer employed at the Medical Center.
 - States that utilize collaborative agreements have requirements for the Physician Collaborator to monitor the care provided by the NP. The monitoring requirements vary from state to state. At the Medical Center, there is no process in place to ensure that these monitoring requirements are met, and this has therefore led to lapses in meeting the state monitoring requirements.
 - Incidental to this review, the Medical Center has not yet transitioned from six-part paper credentialing and privileging folders to the electronic VetPro system as was required by VA Central Office by July 1, 2012.³

³ On March 2, 2011, VHA published a revision to the Records Control System 10-1, 10Q, Healthcare Provider Credentialing and Privileging Records, intended to eliminate the duplication between paper credentialing and privileging files and VetPro. Pursuant to a March 23, 2011, memorandum from the Deputy Under Secretary for Health for Operations and Management, VHA set a deadline of December 31, 2011, to retire the paper records. Because of difficulties encountered scanning the paper records, this deadline was extended to July 1, 2012, by a memorandum from the Senior Medical Officer, Office of Quality and Safety that was distributed by e-mail on October 3, 2011.

A.3. Grandfathering In NPs

The complaint alleged that up to 19 RNs at the Medical Center were “grandfathered in” to work as NPs without obtaining required state and national NP certification, in violation of the Nurse Qualification Standards in VA Handbook 5005, Part II, Appendix G6, including an NP in the Medical Center Women’s Health Department, who has practiced as an NP for 20 years without any state NP certification. The investigative review team determined that three NPs in the PCU had grandfathered status during the time period covered by the complaint.

VA is a national Federal health care system, with hospitals and clinics in every state. Under 38 United States Code (U.S.C.) § 7402(b) and implementing policy, VA physicians, dentists, nurses, podiatrists, pharmacists, psychologists, social workers, chiropractors, and certain other health care positions must be licensed or registered in “a” state to practice their profession and may practice at any VA facility, regardless of its location or the practitioner’s state of licensure. To enable the Secretary to direct, control and manage the Department, Congress authorized the Secretary to prescribe all rules and regulations, which are necessary and appropriate, to carry out all the laws administered by the Department. 38 U.S.C. § 501. The Secretary also has a specific statutory duty to establish the qualifications for its health care practitioners and otherwise regulate their professional conduct. 38 U.S.C. §§ 7401-7464. Unless otherwise specifically provided, the Under Secretary for Health has been delegated the authority to “prescribe all regulations necessary to the administration of the Veterans Health Administration,” subject to the Secretary’s approval. 38 U.S.C. §§ 7304(a) and (b); 38 CFR § 2.6(a).

As a matter of cooperation with the states, VA generally authorizes practice within the scope of a practitioner’s state license. However, in fulfilling its statutory duty to provide safe and appropriate medical care to the Nation’s Veterans, and per Article VI of the U.S. Constitution (Supremacy Clause), VA may establish clinical practice standards that are more expansive or otherwise inconsistent with state practice standards, with the exception of controlled substances prescribing which by Federal law, 21 U.S.C. § 823(f); 21 CFR §§ 1306.03(a)(1), requires adherence to state licensure requirements for such prescribing. State scope and practice standards do not apply to VA NPs to the extent they are inconsistent with those established by VA. VA has chosen to grandfather certain RNs to function as NPs for clinical nursing practice other than controlled substances prescribing.

VA Handbook 5005, Part II, Appendix G6, contains the qualification standards for VA nurses. Prior to 2003, NPs were qualified solely on the basis of the then existing nurse qualification standards, which did not contain additional requirements for NPs. When the nurse qualification standards were revised on January 12, 2003, specific provisions were added to require NPs to be licensed as an NP or otherwise recognized as an NP by a state and to have national NP certification. The revised qualification standards also grandfathered any NP on the rolls on January 12, 2003, from these requirements, provided they have no break in service. The revised standard also provided that any grandfathered NP, who subsequently obtains the qualifications will lose grandfathering status and must maintain the qualifications. The nurse qualification standards were

further revised on March 17, 2009, to add a requirement that the national certification as an NP must be in the specialty of assignment. Thus, an NP who was on the rolls on January 12, 2003, and has not had a break in service is grandfathered from the requirement for NP licensure and national certification in the specialty of assignment. NPs, who were hired between January 12, 2003, and March 17, 2009, are grandfathered only from the requirement that their national certification must be in the specialty of assignment. The 2009 revision also provided that a grandfathered NP, who has a break in service, or subsequently obtains the NP qualifications, is required to possess and maintain NP licensure and national certification in the specialty of assignment.

However, VA has no authority to grandfather NPs from Federal requirements for prescribing controlled substances. Through the Controlled Substances Act (CSA), 21 U.S.C. 802 et. seq., Congress has subjected health care practitioners to state licensure requirements for purposes of controlled substances prescribing. Under the CSA and implementing DEA regulations, a practitioner may prescribe controlled substances only if the practitioner is authorized to do so by his or her state license and is either registered or exempted from registration with DEA. 21 U.S.C. 823(f); 21 CFR 1306.03(a)(1)-(2). As a result, prescribing practitioners, including VA practitioners, are required to adhere to state licensing requirements for obtaining such authority. Thus, both the 2003 and 2009 revisions to the nurse qualification standards contain the following paragraph:

(c) Prescriptive Authority. This handbook does not address any additional requirements that NPs and clinical nurse specialists must meet before they are granted prescriptive authority.

All three grandfathered NPs were licensed in Mississippi as RNs. During the time period covered by the allegations, none of them met Mississippi's licensing requirements for controlled substances prescriptive authority.⁴ Nonetheless, the Medical Center directed all three grandfathered NPs to prescribe controlled substances under the institutional DEA registration, without regard to whether their licensure states had granted them such prescribing authority.

The two grandfathered NPs, who are still employed at the Medical Center, have since obtained an APRN NP license. (b)(6) obtained her Iowa APRN Family Practice NP license on April 10, 2013, and her personal DEA number on March 29, 2013. (b)(6) obtained her Mississippi NP license on September 1, 2012, but no longer works in PCU. Accordingly, the NPs are no longer grandfathered under VA policy and are required to maintain their APRN NP licensure. Currently, both NPs are appropriately licensed. (b)(6) is authorized to prescribe controlled substances at the Medical Center under her individual DEA registration.

⁴ Before prescribing controlled substances, a Mississippi-licensed NP must request such authority from the Mississippi BON, complete a board-approved educational program, complete 720 hours of monitored practice, register individually with DEA, receive a Uniform Controlled Substances Registration Certificate from DEA, and submit a \$100 fee to the BON. Miss. Admin. Code, Title 30, Part 2840, Chapter 2, Rules 2 2.1.B.9) and 2.4.C.2).

B. Inadequate NP and Physician Staffing Levels

B.1. VHA staffing policy

VHA Directive 2009-055, Staffing Plans (published November 2, 2009), assigns general responsibilities regarding staffing to various VHA officials. Under that policy each VISN Director is responsible for providing oversight to ensure the provision of necessary resources for facilities to implement appropriate staffing plans. *Id.* at para. 4.d. Additionally, each facility Director is responsible for ensuring, among other things, that staffing plans are incorporated into and maintained as part of facility strategic and operational plans, and ensuring staffing plans are reviewed, at least on an annual basis, evaluated, and revised when necessary to address emerging patient care needs. *Id.* at paragraph 4.(e)(3) and (4).

In primary care, provider staffing levels are based on, among other factors, patient panel sizes. Panel size is defined as the number of patients assigned to a specific primary care provider (PCP). Specific program requirements applicable to the operation of PCUs are set forth in VHA Handbook 1101.02, Primary Care Management Module (PCMM) (published April 21, 2009). In addressing staffing required in these units, this policy explains:

Many factors affect the appropriate number of patients that should be in a provider's panel. The amount of support staff, space, and administrative support can affect the number of patients that a given provider can follow. Therefore, the Department of Veterans Affairs (VA) does not set a national policy on the specific number of patients that must be provided for each provider full-time equivalent (FTE) employee. This is a local decision. Determination of the amount of provider resources, as measured by Primary Care Direct Patient Care (PCDPC), is only one factor that determines the appropriate panel size.

VHA Handbook 1101.02, Attachment A, page A-2, relates to the operation of primary care programs in CBOCs but this information is generally applicable across the VA system. The term "primary care panel" refers to the group of active Veteran patients assigned to a specific PCP or primary care team. *Id.* at paras. 4.d., 17. PCPs are defined as: "physicians, NPs, and physician assistants who provide ongoing and comprehensive primary care as defined by their privileges or scope of practice and licensure to a panel of assigned patients." *Id.* at para. 4.b. The term "Associate Providers" (AP) is defined as "residents, NPs, and physician assistants who provide ongoing and comprehensive primary care in collaboration with a physician provider as a member of a primary care team for a panel of assigned patients. They practice under the supervision of a precepting [PCP]." *Id.* at para. 4.c. Under VA policy, NPs and Physician Assistants (PA) can practice either as PCPs (if their scope of practice or

locally established privileges includes the skills and responsibilities required to provide primary care to the patients) or as AP. Id. at 16.d.

The size of a primary care panel is dependent on many factors. Panel sizes for undifferentiated primary care clinics (such as that which exists at the Medical Center) vary from site to site, depending upon patient characteristics of the primary care population and level of system support. Id. at para. 17.b. Undifferentiated primary care clinics are in contrast to clinics with specialized panels that care for specific categories of patients with specific, complex diseases (e.g., infectious disease panels, spinal cord panels).

VHA Handbook 1101.02 states that for sites with a patient population reflecting the norms for disease severity and reliance on VHA and who have current norms of 2.17 support staff per 1.0 FTE provider and 3.0 clinic rooms per 1.0 FTE provider, an expected panel would be 1,200 patients for a full-time, established primary care physician. Id.⁵ After adjustment for the factors identified, expected panels for VHA PCPs largely fall in the range of 1,000 to 1,400 patients. Id. The policy further indicates that a "1.0 FTE non-physician provider (NP or PA) is expected to carry a panel 75 percent the size of a 1.0 FTE MD. However, ratios of support staff and space should be the same for a 1.0 FTE non-physician provider as for a 1.0 FTE MD provider." Id. at para. 18.b.(2). Policy dictates that panel size should also be prorated to the time the PCP spends providing direct clinical care. Id. at para. 18.b.(3). Yet, how mid-level providers (MLP) are to be defined for purposes of these panels (e.g., as a PCP or an AP with a precepting physician) remains a facility determination. If the facility Director decides to have the mid-level as an AP and the medical doctor (MD) as the precepting physician, the patients would be included in the MD's panel as precepted patients with the mid-level provider as the AP. Id., Attachment A, pages A-1-A-2.

While the actual number of active patients assigned to a PCP remains a local specific determination based on the primary care needs of Veterans, who are registered for care at the facility, VHA policy does establish parameters (modeled expected panels) to help ensure there is adequate staffing (to meet the expected patient workload). As explained above, patient intensity scores, current levels of clinic room, and current levels of support staff for each site are taken into account in calculating any needed adjustments to panel size. A recognized factor that may reduce the productivity of individual PCPs is a facility's current level of support staff at the facility. Id. at para. 17.d. For purposes of the Handbook, the term support staff is defined as RNs, Licensed Practical Nurses (LPN), pharmacists including Doctor of Pharmacology (PharmD), medical assistants, health technicians, and medical clerks in the clinic. Id. Ultimately, it is the responsibility of the local facility Chief of Staff to determine, among other things, the time allocation for each PCP dedicated to patient care and maximum panel expectations. Id. at para. 7.a. Such official is also charged with reviewing PCMM data related to efficiency, workload,

⁵ We underscore that these norms were based on 2009 data. Current national VHA data from VSSC Primary Care reflect the norms are now 3: 1 support staff and 2.4 rooms per 1.0 FTE provider (physician and non-physician). The expected panel size remains the same at 1200 for a Primary Care Physician and 900 for a NP or PA, despite the increase in support staff and slight decrease in number of exam rooms.

and staffing, although VA policy permits the facility Chief of Staff to delegate this responsibility to a primary care clinical leader or designee. Id. at para. 7.b.

B.2. Nursing Practitioners and Physician Staffing Levels at the Medical Center

Based on information obtained from the Nurse Locality Pay System Annual Report on Staffing (beginning July 1st and ending June 30th for 2010, 2011, and 2012) for the first four bulleted items and based on current records for the last item, the highest number of NPs employed at the Medical Center throughout 2012-2013 was 90. The specific breakdown is as follows:

	<u>7/1/09- 6/30/10</u>	<u>7/1/10- 6/30/11</u>	<u>7/1/11- 6/30/12</u>	<u>7/1/12 - current</u>
Beginning On-board	75 NPs	79	90	86
Ending On-board	79 NPs	90	86	84

With respect to physicians, as of the date of this review, the Medical Center had:

- Three full-time physicians (MDs), one of whom is the Acting Associate Chief of Staff for Primary Care (current recruitment efforts and pending hires are expected to soon raise this figure);
- Two Locum Tenens physicians (these two Locum Tenens physicians provide clinical services within the facility pursuant to contractual arrangements);
- Fifteen primary care NPs; and
- One NP Supervisor who does not see patients.

Seventy-five percent of the total PCU staff (MDs and NPs) at the Medical Center is comprised of NPs, while the VHA national average for NPs in primary care is 25 percent according to VA Central Office, Office of Primary Care Operations. The current ratio of NPs to MDs in primary care at the Medical Center is approximately 3 NPs to 1 MD (including the Locum Tenens physicians). The team confirmed that no national or local policy exists which establishes a requisite ratio of NPs to MDs in a PCU. We reasonably assume the lack of policy is not an oversight but rather a necessity to lend sufficient flexibility to the facility, as explained in the section on policies related to staffing above. Based on anecdotal evidence, however, the team understands that facilities that are comparable to the Medical Center typically have the inverse situation, that is, 3 MDs to 1 NP.

In addition to looking at the staffing ratio of NPs to MDs, the review team also reviewed the ratio of “patient panel size” to adjusted capacity. As explained above, this ratio defines the number of patients assigned to a PCP in relation to that provider’s capacity to see patients based on the provider’s time in clinic, number of exam rooms, and support staff available. This ratio does not include new patients and walk-in patients. Based on current VHA guidelines, found in VHA Handbook 1101.02, the ratio of patient panel size to adjusted capacity for MD and NP is between 90 percent and 105 percent. At the Medical Center, as of April 2013, the ratio of patient panel size to adjusted capacity for MDs ranged between 84 percent and 98 percent; for NPs, it ranged between 100 percent and 110 percent. As of September 2012, the ratio of patient panel size to adjusted capacity for MDs ranged between 80 percent and 96 percent; for NPs it ranged between 102 percent and 120 percent, with one outlier at 85 percent. In summary, these data indicate that at the Medical Center, MDs are generally paneled appropriately per the guidelines set forth in VHA Handbook 1101.02; however, NPs are generally over-paneled. This indicates a need for additional providers, and given the high ratio of NPs to MDs as discussed above, these additional providers should be physicians.

It is unclear from the record whether the facility’s disproportionate NP staffing levels/ratios in the PCU resulted from the fact that the facility had, in error, privileged all their NPs as LIPs and, as a result considered the PCU panels/staffing levels to be adequate with no need of physician-supervision of the NPs; or the shortage of PCU physicians resulted in a misplaced dependence on NPs to meet workload demands.

Despite the current existence of appropriately-sized panels for MDs, several interviewees (i.e., former and current practicing primary care MDs, the former Associate Chief of Staff for Primary Care, the former Chief of Staff, and two currently employed Scheduling Clerks) believe that the PCU is understaffed, especially in terms of physicians. They reported physicians frequently worked late hours and often late into the night to see overbooked new patients and walk-in patients, who are not reflected in panel sizes.

Of particular concern to the review team was that many interviewees indicated that PCU physicians, due to their workloads, are often unable to review and address “View Alerts” for up to 2 or 3 weeks. View Alerts are electronic notifications sent to providers daily, including lab, imaging and pathology results; consult recommendations; and other medical notes for co-signature. Some of these alerts can be serious and require immediate attention. Critical alerts are notated as such on the actual electronic alert. Further, to absolutely ensure providers are informed of critical (potentially life threatening) lab and radiology results, per facility policies, these results must be verbally communicated to the appropriate provider. There was no evidence of patient harm; however, the review team was unable to thoroughly assess this issue, which exceeded the scope of the immediate investigation. As stated below, the review team recommends this issue be the subject of further investigation.

When asked about efforts to recruit more physicians for the PCU, the review team was informed that since 2010, Medical Center leadership has employed multiple primary care physician recruitment actions, (e.g., open/continuous announcements, recruitment and relocation incentives, and use of the Education Debt Reduction Program benefits authorized by 38 U.S.C. §§7681-7683. In 2012 and 2013, the facility began advertisements in the local newspaper. Currently, the facility expects to complete the hiring process for several physicians who will be on-board in the upcoming months. Of note, the Medical Center Director, the former Associate Chief of Staff for Primary Care, and the Acting Chief of Staff each expressed the facility's current goal of achieving a 1:1 ratio of NPs to MDs.

C. Failure of PCU NPs to Identify themselves as NPs to Patients or to Wear Proper Identification Badges

The Whistleblower alleges that NPs were failing to identify themselves as such to their patients or to wear proper identification, and as a result, some patients consequently believed their NPs were physicians. VA security rules, generally enforced by VA guards, address identification requirements for persons entering the facility, including employees. VA Directive 0735, (published February 17, 2011) implements Homeland Security Presidential Directive 12 (HSPD-12), which resulted in the standardization of identification procedures and requirements for Federal employees and contractors. In short, these Governmentwide identification requirements obligate VA employees (and others requiring routine access to VA facilities or information systems) to wear their Personal Identity Verification (PIV) badges while on the premises or when using VA computer equipment or information technology systems.

Consistent with these policies, the Standards of The Joint Commission, namely Standard EC.02.01.01, #1 and #7 require, respectively, that a hospital identify safety and security risks associated with the environment of care that could affect patients, staff, and other people coming to the hospital's facilities and identify individuals entering its facilities (noting that it is the responsibility of the hospital for determining which of those individuals require identification and how to do so).

PIV badges do not identify the individual's position or title. Further, VHA does not require its employees to wear a separate name tag that specifically identifies their position title. However, VHA practitioners are required to appropriately identify themselves to patients. The Joint Commission Standard RI.01.04.01, #1 and #2 require, respectively, that a hospital respect the patient's right to receive information about the individual(s) responsible, as well as those providing, his or her care, treatment, and services and inform the patient of the name of the physician(s), clinical psychologist, or other practitioner(s) who will provide his or her care, treatment, and services.

In a similar vein, VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, paragraphs 13.a.(8) and (9) require, as part of the informed consent process, that the practitioner:

- Identify by name and profession the practitioner who has primary responsibility for the relevant aspect of the patient's care. Also identify by name and profession any other individuals responsible for authorizing or performing the treatment or procedure under consideration.
- Advise the patient if another practitioner will need to be substituted for any of those named. If the need for a substitution is known prior to initiating a treatment or procedure that requires signature consent, the patient must be informed of the change and this discussion and the patient's assent must be documented in the patient's electronic health record.

NPs with whom the review team interviewed were asked how they identify themselves to patients; they uniformly responded that they identify themselves as NPs to their patients. One noted that despite her proper introduction, some of her patients still insist on referring to her as "doctor." Respecting patient privacy, the review team could not independently conduct unannounced spot checks to observe staff behavior in treatment settings, but the review team verified that all NPs wore/displayed their VA (PIV) identification badges.

D. Quality of Care Adversely Affected by Use of Unsupervised NPs and Inadequate Number of Physicians

To ensure the quality of care by VHA health care practitioners, their clinical performance must be scrutinized. For NPs who are LIPs, this is done through the credentialing and privileging processes. For all other NPs, including those whom VA has grandfathered, it is done through the process required in a collaborative scope of practice. As explained above, the facility violated VA policy by granting privileges to all NPs and considering them to be LIPs, regardless of the authority granted by their state of licensure. Furthermore, the facility did not have a process in place to ensure that the clinical care provided by NPs was appropriately monitored by Physician Collaborators, as required by their collaboration agreements. The PCU also has a subpar staffing ratio of MDs to NPs, excessive patient panels for NPs, and a shortage of physicians that contributed to the physicians' inability to view electronic alerts (View Alerts) in a timely manner, each of which has the potential to jeopardize patient health and safety. To investigate whether quality of care was adversely affected by this (clinical) work environment, the review team evaluated the PCU's performance using the following indicators of quality: staffing levels; clinical quality data; and patient perception of care as reflected by the filing of tort claims and patient complaints. Additionally, the team investigated, whether the appointment scheduling problems alleged by the Whistleblower may have adversely affected quality of care.

A review of key clinical quality data from fiscal years (FY) 2011, 2012, and 2013 reflected that the Medical Center consistently met or exceeded, with few exceptions, the national benchmarks for Diabetes Care, Heart Disease Prevention, Cancer Screening, Immunizations, and Tobacco Cessation. The facility reports that, since October 1, 2010, there has been only one physician provider reported to the National Practitioner

Data Bank (NPDB) and state licensure board for a tort claim payment, and no provider has been reported for an adverse action against clinical privileges relating to the quality of their patient care. A review of the 42 NP credentialing and privileging folders corroborated that there have been no NPs reported to the NPDB.⁶ A review of the Patient Advocate Tracking System (PATS), a Web-based system used to document, track, and report patient-related issues, shows that from FY 2011 to date, 28.5 percent of reported issues related to primary care were about issues of Access to and Timeliness of Care (565 reports/1,985 total reports).⁷ The available data indicates a high quality of care, with no identified problems. However, the investigative review team did not identify a specific policy or process that had been in effect at the Medical Center to ensure that the clinical performance of NPs was regularly monitored. The team found that the clinical care of NPs was sporadically monitored by Physician Collaborators, the Quality Management Office, and by annual performance reviews. To confirm quality of care and to ensure patient safety, the Medical Center has recently instituted regular Ongoing Professional Practice Evaluations (OPPE) of the clinical care provided by its NPs.

With respect to the scheduling of appointments in the PCU, the Whistleblower alleges that patients frequently are scheduled to "Ghost Clinics," that is, fictional clinics created in the VAMC's scheduling system to which no provider is assigned. It is also alleged that some patients are checked in but never seen by a provider on that same day. In other cases, it is alleged that patients are checked in and wait to be seen as space and time allow, or else that appointments are canceled with no notice and sometimes are not rescheduled for a year or more.

VA's policy and procedures for outpatient scheduling is found in VHA Directive 2010-027, VHA Outpatient Scheduling Processes and Procedures (published June 9, 2010). While facilities are generally required to schedule appointments in a manner that meets patients' needs without undue waits or delays, VA's scheduling policy reflects the regulatory requirement to give priority, when scheduling appointments, to Veterans with a service connected (SC) disability rated 50 percent or greater based on one or more disabilities or unemployability; and to Veterans needing outpatient care for a SC disability. 38 CFR 17.49; VHA Directive 2010-027, para. 2. Priority scheduling of any SC Veteran must not however impact the medical care of any other previously scheduled Veteran, and Veterans with SC disabilities are not to be prioritized over other Veterans with more acute health care needs. *Id.* Emergent or urgent care is to be provided on an expedient basis and takes precedence over a scheduling priority based on SC. *Id.*

⁶ VA reports two types of actions to NPDB: malpractice payments made on behalf of a physician, dentist, or other licensed health care practitioner; and adverse actions against the clinical privileges of physicians and dentists. 38 CFR Part 46; VHA Handbook 1100.17, National Practitioner Data Bank Reports. While some NPs may have an adverse action taken against their clinical privileges, the adverse action would not be reported to the NPDB. However, NPs could be reported the NPDB for any malpractice payments made on their behalf.

⁷ The remaining reports related to primary care concerned coordination of care, requests for information, medical records issues, Medical Center regulations issues, decisions/preferences, staff courtesy, eligibility issues, compliments, physical comfort, and patient education.

In brief, VHA Directive 2010-027 requires that the facility Director, among other things, ensure standardized systems are in place to balance supply and demand for outpatient services, including continuous forecasting and contingency planning. Also, the Director must define “standard work” for clinic teams, which are aimed at ensuring efficient operation of the clinic. Such standard work includes ensuring clinic flow occurs in a standardized manner including patient check-in with scheduling staff, nurse interview, provider visit, and check-out. *Id.* at para.4.c.(3)(a). In addition, such standard work must ensure that a check-out process as described in the policy occurs following each clinic visit. *Id.* at para. 4.c.(3)(c).

The policy describes other “business rules” for standardizing work that apply to clinics and their schedulers. Of note, the business rules include practices that synchronize internal provider leave notification practices with clinic slot availability to minimize patient appointment cancellations. *Id.* at para. 4.c.(3).(e).1-4. VHA policy further requires that clinic cancellations be avoided whenever possible. If a clinic must be canceled, or a patient fails to appear for a scheduled appointment, the medical records need to be reviewed to ensure that urgent medical problems are addressed in a timely fashion; provisions are made for necessary medication renewals; and patients are rescheduled as soon as possible, if clinically appropriate. *Id.* at paragraph 4.c.(19)(j). Finally, the Directive also requires facility leadership to be vigilant in the identification and avoidance of inappropriate scheduling activities. *Id.* at para. 4.c.19.(l).

VA policy does not set scheduling requirements for walk-in patients because those patients are by definition unscheduled. The policy does require, however, that applicable profiles be designed in Veterans Health Information Systems and Technology Architecture (otherwise known as VistA) software program to ensure sufficient capacity at VA medical centers to accommodate unscheduled walk-in patients. In all cases, patients with emergent or urgent medical needs must be provided care or be scheduled to receive care, as soon as practicable, independent of SC status and whether care is purchased or provided directly by VA. *Id.* at 4.c.19.(a). VA policy also establishes generally that patients who cannot be scheduled in targeted timeframes must be put on electronic waiting lists. *Id.* at 4.c.19.(b).

The Medical Center has an established practice whereby all patients who present to the PCU as a walk-in are seen the day they present. Walk-in patients, unless they present with urgent/emergent medical needs, are often double-booked into a single appointment slot of one provider. These patients often have to wait for hours to be seen. In addition, this double booking into a single appointment slot causes a delay in the time the regularly scheduled patients are seen by their providers. Approximately 10 percent of the total patient appointments in primary care between 2010 and 2013 were either unscheduled or overbooked. Interview statements from scheduling clerks, NPs, and physicians confirmed this practice.

Interviewees (scheduling clerks, NPs, and physicians) also indicated that the Medical Center permits patients to be scheduled in clinics that do not have an assigned provider (this might be considered to be the Ghost Clinics referenced by (b)(6)). One

example of this type of clinic is the Vesting Clinic, which the facility established for new patients' initial appointment in primary care. In what appears to be a unique practice by the PCU, the Vesting Clinic was established without an assigned, dedicated provider. As a result, when a patient checks in for his or her scheduled Vesting Clinic appointment, the patient is added to another provider's schedule as an overbooked (or double-booked) appointment, resulting in two patients (an established and a new) being booked into a single 30-minute appointment slot.

According to the Whistleblower, in the event that a provider vacates his or her position, that provider's future clinic appointments are not cancelled, and the patients are not reassigned to another provider; further when these patients present for the appointment, they are checked-in in the normal fashion and triaged by nursing staff but not seen by a provider. The Whistleblower alleges this process is maintained to provide workload credit for the PCU. Statements by NPs and physicians corroborate the Whistleblower's allegation that these appointments are not cancelled, but contrary to the allegation, they indicated that the patients are, in fact, seen by a provider because they are double booked into another provider's schedule for that day.

Conclusions for Allegations #1 and #2

- The Medical Center's policy permitting NPs to practice as LIPs when that practice is not authorized by their individual state practice acts violates VHA policy. Only the two NPs licensed in Iowa are allowed to practice as LIPs.
- Granting NPs clinical privileges when they are not LIPs violates VHA policy. Only the two primary care NPs, licensed in Iowa, are allowed to be granted clinical privileges; all others must have a scope of practice.
- There is a lack of understanding among the Medical Center leadership regarding NP practice and licensure requirements. This is evident by the fact that, as already stated, leadership has erroneously declared NPs as LIPs and granted clinical privileges, yet they have also stipulated that NPs must have collaborative agreements per individual state licensing board requirements. This is further confounded by the fact that, despite requiring collaborative agreements (which is the correct approach), leadership has not implemented a process for ensuring all required collaborative agreements are in place and the appropriate monitoring of NP practice by Physician Collaborators occurs.
- Ten of the 13 NPs currently practicing at the Medical Center and whose licenses require collaborative agreements have an approved collaborative agreement in place.
- Many, if not most, of the primary care NPs have not complied with state licensing board requirements for ensuring their practice is appropriately monitored by their Physician Collaborators, such as chart reviews and face-to-face meetings with

the Physician Collaborator. In addition, the Medical Center has no process in place to ensure monitoring requirements are met.

- State requirements vary as to the appropriate ratio between NPs and a Physician Collaborator. Some states set no MD-to-NP ratio requirement. Others establish a ratio of 1:3, 1:4, or more. There should be a reasonable limit to the number of NPs per Physician Collaborator, to ensure appropriate medical direction and supervision by the Physician Collaborator, consistent with the terms of the collaborative agreements. (We are aware that in March 2013, the Mississippi Board of Medical Licensure amended Rule 1.3 of Chapter 1 of Part 2630 of the Mississippi Administrative Code to state, in relevant part: "Any one Physician should have no more than four collaborative agreements." See Mississippi Administrative Code, Part 2630, Chapter 1, Rule 1.3, Requirements for Collaborating Physicians, states: "Physicians are prohibited from entering into primary collaborative agreements with more than four APRNs at any one time unless a waiver is expressly granted by the Board for that particular collaborative agreement." According to a notice on the Board of Medical Licensure's Web site, implementation of the amendment is suspended until July 31, 2013.) The consensus among review team members is that the ratio should be limited to four or five NPs to one Physician Collaborator. Clearly, the one Medical Center Physician Collaborator, who has 14 current collaborative agreements has more than should be allowed.
- All Medical Center PCU NPs currently have the required state NP licenses and national NP certifications.
- There was no evidence to indicate that the former Chief of Staff, (b)(6) had 160 collaborative agreements as alleged by the Whistleblower. The review team found evidence that (b)(6) had only four collaborative agreements with primary care NPs during the review period of 2010 to present.
- The Medical Center PCU has an insufficient number of physicians.
- The NPs in the PCU have panel sizes that generally exceed VHA guidelines.
- Clinical quality data, available OPPE data, and the fact that only one provider has been reported to the NPDB since October 1, 2010, for either a tort claim settlement or an adverse action against clinical privileges relating to quality of care, are indicators that the Medical Center primary care staff is providing quality care. However, the following additional problematic indicators have led the review team to conclude further review needs to be conducted in order to explicitly declare that adequate/high quality of care has been provided in the Medical Center PCU:
 - Insufficient physician staffing;

- Sporadic tenure of Locum Tenens physicians;
 - NPs functioning as LIPs when in fact they are not;
 - Failure to appropriately monitor the clinical practice of NPs;
 - Lack of timely response by providers to CPRS View Alerts;
 - Multiple patient appointment scheduling problems, e.g., double booking, Vesting Clinic/Ghost Clinic;and
 - Large volume of patient complaints regarding access to and timeliness of care.
- The Medical Center NPs appear to be appropriately identifying themselves as NPs to their patients.
 - In summary, the team substantiates that the Medical Center does not have a sufficient number of physicians, and NPs have not had appropriate supervision/collaboration with Physician Collaborators. The review team did not substantiate that inadequate care was provided (even with the noted scheduling problems). However, there are enough problematic indicators present to suggest there may be quality of care issues that require further review. Although the review team found that all NPs currently have requisite NP certifications and licenses, NPs in the PCU have been erroneously declared as LIPs, and the required monitoring of their practice has not consistently occurred. NPs were potentially practicing outside the scope of their licensure and were not appropriately monitored by Physician Collaborators.

Recommendations for Allegations #1 and #2

- Medical Center leadership must immediately correct the erroneous declaration that all NPs will practice as LIPs.
- Medical staff bylaws must be amended to indicate that NPs are considered LIPs only when their state licensure permits.
- Medical Center leadership must immediately implement scopes of practice versus clinical privileges for NPs, who are not permitted to practice as LIPs.
- Medical Center leadership must immediately ensure that all NPs who require collaborative agreements in fact have them, and they are approved by the NP's respective state licensing board.
- Medical Center leadership should ensure the equitable distribution of collaborative agreements among physicians, and a reasonable limitation should be 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.

- Medical Center leadership should eliminate use of Locum Tenens physicians in the PCU to the extent possible.
- Locum Tenens physicians should not be Physician Collaborators because of their short tenure.
- 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.
- Medical Center leadership must continue to aggressively work to hire permanent full-time physicians for the PCU, to obtain an NP:MD ratio of 1:1. Once an adequate number of physicians is hired, the facility should reduce panel sizes for NPs to meet VHA guidelines.
- Medical Center leadership should consult the Office of Workforce Management and Consulting in VA Central Office to ensure they are utilizing all available resources to recruit primary care physicians.
- Medical Center leadership should eliminate the use of Ghost Clinics. All clinics must have an assigned provider.
- 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.
- The Medical Center must convert six-part credentialing and privileging folders to the electronic VetPro system, as required by VHA leadership.
- 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 were often not being reviewed by physicians in a timely manner, 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 the PCU from January 1, 2010, to present. The VISN should work with facility 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 facility should consider expanding the sample. Specific cases involving unresolved questions as to quality of care should be referred to the Office of the Medical Inspector for further investigation.

- 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).
- VHA should consider issuing an 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 Counsel as an important resource for facilities as they review program compliance requirements.

Allegation #3: Inadequate Staffing Results in the Improper Completion of Medicare Home Health Certificates/Forms

It is alleged that Medicare home health certificates/forms are/were completed inappropriately and in violation of Federal law because the Medical Center's PCU staff have not followed statutory and regulatory requirements of the Medicare home health program. Specifically, it is alleged that the forms, which are used by non-VA providers to bill Medicare for these services, were not, in fact, based on the requisite face-to-face evaluations with physicians and/or not properly certified, as required by law. The Whistleblower acknowledged that NPs may participate in the requisite face-to-face patient evaluations. It is alleged that because the PCU NPs are not working under requisite collaborative agreements and because 85 percent of the patients are not under the care of a physician, these forms are being signed by VA employees in violation of Department of Health and Human Services (HHS)/CMS law. For instance, it is alleged that (b)(6) are not qualified to complete these forms because they do not provide direct patient care and serve only in an administrative capacity.

When medically necessary and appropriate, home health services, which are included in VA's medical benefits package, are to be made available to enrolled Veterans. 38 CFR 17.38(a)(1)(ix). Where available in the VA system, these services are provided by VA through contractual arrangements but not provided directly by VA. As with other aspects of their care, Veterans have the option to use either their VA benefits or other health care benefits when seeking health care services. In many cases, Veterans elect to use their Medicare benefits instead of their VA benefits to obtain home health services because, for instance, doing so provides them with a greater selection of providers in their area from which to choose, placement is often easier, or there is no copayment required.⁸ Historically, about 80 percent of Veterans using VA for their

⁸ VHA Handbook 1140.6, Purchased Home Health Care Services Procedures (2006), includes the following:

A Veteran who is dually eligible for both VA care and Medicare may elect to have home care services paid for under the Medicare benefit. Veterans who choose Medicare retain their eligibility for VA care and benefits. Veterans should be notified that VA has no authority to pay for any balances or co-payments that may be due after Medicare or any other non-VA source makes payment for care.

health care choose to use their Medicare home care health care benefits. In such cases, the participating Medicare providers who furnish the home health services submit the claims and are reimbursed or paid for their services by CMS. As a condition of payment, CMS requires written and signed certification by a physician of the need for the home health services, consistent with applicable law and regulation. Such certification is typically memorialized through use of an approved, standard, pre-printed form that is completed by the patient's treating physician.

As part of the VA medical benefits package and pursuant to VHA policy, VA health care professionals must honor all requests by patients for completion of non-VA medical forms (with the exception of the completion of examination forms if a third party customarily pays health care practitioners for examination but does not pay VA). See 38 CFR 17.38(a)(1)(xv) and VHA Directive 2008-071, Provision of Medical Statements and Completion of Forms by VA Health Care Providers. Examples of these non-VA forms include but are not limited to Family Medical Leave Act forms, life insurance applications, non-VA disability retirement forms, state workers' compensation forms, state driver's license or handicap parking forms, and Social Security Administration examination forms. Because VA providers are often (but not necessarily) the sole health care provider for the requesting Veteran patient, patients seeking home health services through a Medicare home health provider may still need their VA PCP to complete part of the CMS form as a means of documenting that the patient is in need of home health services.

The chief CMS form at issue here captures information required by 42 CFR § 424.22 [Requirements for home health services] and is titled Home Health Certification and Plan of Care, Form CMS-485 (C-3) (02-94) (Formerly HCFA-485) (Form Approved OMB No. 0938-0357). By its terms, a physician must describe the home health care services that are needed and certify that the patient is confined to his/her home and needs intermittent skilled nursing care, physical therapy and/or speech therapy or continues to need occupational therapy. The certifying/recertifying physician also certifies that the patient is under his/her care, and that he/she has authorized the services on that plan of care and that he/she will periodically review the treatment plan. The form has places for the certifying and attending physician to sign. In short, the certification may only be completed by a physician.

Certification of the need for home health services must be based on a face-to-face patient encounter (during which the clinical documentation is obtained). While ultimate interpretation of CMS rules is the exclusive domain of HHS, section 424.22 expressly requires, "that a physician, who is responsible for performing the initial certification must document a face-to-face encounter with the patient and such encounter must occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter." 42 CFR § 424.22(a)(1)(v). This regulation further provides that the physician who conducts the patient encounter may be, among others, the certifying physician himself or herself; a physician, with privileges, who cared for the patient in an acute or post-

acute care facility from which the patient was directly admitted to home health; or an NP or a clinical nurse specialist who is working in accordance with state law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

42 CFR §§ 424.22(a)(1)(v)(A)(1)-(3). The regulations also address recertification requirements. 42 CFR § 424.22(b).

As HHS explained when promulgating its final payment rules for home health care, “[t]he face-to-face encounter provision in the Affordable Care Act was designed as an anti-fraud provision, and CMS is committed to ensuring that Medicare reimbursement is available only to patients actually in need of home health services.” 77 FR 67068, 67108. While HHS explained that the certification must, by statute, be done by a physician, the Department did create flexibility as to who could conduct the face-to-face patient encounter in response to comments received on the proposed rule. HHS stated that “[a]fter carefully considering all of the comments received, we are finalizing the additional flexibility as proposed. We will modify the regulations at § 424.22(a)(1)(v) to allow [a non-physician practitioner] in an acute or post-acute facility to perform the face-to-face encounter in collaboration with or under the supervision of the physician who has privileges and cared for the patient in the acute or post-acute facility, and allow such physician to inform the certifying physician of the patient's homebound status and need for skilled services.” *Id.*

The review team was informed by program officials that, at the request of the home health agencies, acting on behalf of the patients or the patients themselves, VA physicians are asked to complete part of CMS Form 485, following the clinical determination by the home health agency that skilled home care is required. Specifics of the care plan follow an assessment made by the home health agency which completes the form. The form is sent to VA only because of the need for a physician signature based on a face-to-face encounter with the CMS beneficiary within 30 days of the start of the home health care order and physician signature. While these forms are scanned into the patients' VA records, they are used only by the Medicare-participating home health agencies, which independently submit these claims for CMS payment for, or reimbursement of, their services.

The review team finds that VA physicians completing these forms at the request of their patients need to adhere to the specific CMS certification and patient encounter requirements. NPs should not certify these forms, although they may properly conduct the face-to-face patient encounter if they are/were, in fact, working in accordance with state law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician with privileges, who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

Confusion exists among Medical Center staff about how these forms should be completed and by whom. One PCP stated during her interview that she received stacks of forms to sign, and another indicated she stopped signing the forms because she had

no collaborative agreement with the NP who conducted the face-to-face patient encounter. While the NPs on service uniformly understand that they cannot sign as the certifying provider, there is confusion as to which physicians may properly complete these forms and perform the certifications.

Despite requests, neither the Whistleblower nor the interviewees identified any specific cases in connection with this allegation. A chart review was not feasible, given the scope of the program and time constraints of this investigation. We underscore that investigation of this allegation is not a direct exercise or direct data pull, because these services are not provided by VA but rather by a provider in the private sector. As explained above, VA PCU providers are not completing these forms for purposes of VA billing CMS; rather, they are completing these forms at the request of their primary care patients who elect to get these services in the private sector using their CMS benefits or at the request of those private sector providers acting on behalf of these patients. Thus, this type of data is not captured through existing reporting metrics.

Conclusions for Allegation #3

We cannot substantiate this allegation. Yet, the team cannot rule out that the allegation may have some merit given the noted statements of interviewees and the review team's substantiation of allegations related to the lack of supervision of NPs and the lack of necessary collaborative agreements between collaborating physicians and NPs.

Recommendation for Allegation #3

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 PCU patient charts to determine if any CMS forms are present, and if so, whether they were completed appropriately. Such findings need to be reported to the Under Secretary for Health, who will then need to consider if any follow-up action is necessary. Additionally, facility leadership should consider development of a training and educational module for completion of these forms to ensure PCU and other staff are aware of CMS compliance requirements.

Allegation #4 - Facility Uses Improper Procedures for Issuing Narcotics Prescriptions

A. Use of the institutional DEA registration number

The complaint alleged that past Medical Center leadership advised its NPs, most of whom are licensed in Mississippi, that they did not need to obtain individual DEA registration or file it with the Mississippi BON, since they could rely on the institutional

registration with a suffix. The complaint further alleged that NPs in the PCU unit, including grandfathered NPs, were allowed to write narcotics prescriptions under the facility's institutional DEA registration number, in violation of Federal and state law. Such practice had allegedly been ongoing during the Whistleblower's 4-year tenure as a PCU physician.

Federal law

States generally regulate the practice of medicine within their borders to ensure the health and well-being of their residents. The Controlled Substances Act (CSA), 21 U.S.C. §§ 801 et seq., and implementing regulations issued by DEA in 21 CFR Part 1300, regulate medical practice involving the use of controlled substances. Each state also enacts controlled substances laws that are designed to be in harmony with Federal law. However, the CSA will preempt state-controlled substances laws where "there is a positive conflict between that provision of this subchapter and that state law so that the two cannot consistently stand together." 21 U.S.C. § 903.

Under the CSA and DEA's regulations, an individual practitioner may prescribe controlled substances only if the practitioner is authorized to do so by his or her state license and is either registered or exempt from registration with DEA. 21 U.S.C. § 823(f); 21 CFR §§ 1306.03(a)(1)-(2). Under 21 CFR § 1301.12, a separate DEA registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed. However, DEA allows individual practitioners, who are agents or employees of a hospital or clinic, to prescribe under the institutional DEA registration with unique individual suffix provided they meet certain conditions, including licensure in the state of practice. 21 CFR §§ 1301.22(c)(1)-(2). In 1993, DEA established a separate category of practitioner registration for MLPs and permitted MLPs on the staff of a hospital or clinic to use the institutional registration as well, in lieu of being registered individually, provided they met the conditions in 21 CFR §§ 1301.22(c)(1)-(2). See 58 FR 31171 (June 1, 1993), Definition and Registration of Mid-Level Providers.

Under 38 U.S.C. § 7402(b) and implementing regulations, VA physicians, dentists, nurses, podiatrists, pharmacists, psychologists, social workers, chiropractors, and certain other health care positions must be licensed or registered in "a" state to practice their profession, and may practice at any VA facility, regardless of its location or the practitioner's state of licensure. Thus, a licensed VA prescribing practitioner may be practicing at a VA facility in a state where he or she is not licensed. DEA has long permitted VA practitioners to prescribe controlled substances within VA using the institutional DEA registration with unique suffix, provided they are authorized by their license to prescribe such substances, even when they are employed in a VA facility in a state other than where they are licensed. The permissibility of this practice was confirmed by DEA in a June 7, 2006, letter to the Under Secretary for Health from the Deputy Assistant Administrator, Office of Diversion Control. Further, on July 31, 2012, DEA issued a revised policy memorandum to its Special Agents in Charge, Assistant

Special Agents in Charge, Diversion Program Managers, and Diversion Group Supervisors to clarify DEA policy regarding the Federal Government Practitioners Program (FEDDOC). This policy memorandum states, in part:

DEA has a longstanding policy regarding FEDDOC practitioners that permits a DEA registration be issued to the practitioner in one state as long as that person maintains a valid professional license in any state.

The Memorandum is included as Attachment C. In addition, a Federal practitioner who is required to obtain individual Federal DEA registration in order to carry out his or her Federal duties is exempted from payment of registration fees. 21 CFR § 1301.21(a)(2). Such an individual, fee-exempt DEA registration may be used only for Federal practice.

VA policy

VA's long-standing policy on use of the facility's institutional DEA registration is contained in the Secretary's regulations in VA Handbook 5005, Part II, Chapter 3, Section B, paragraph 8a, which states, "[c]ertification by DEA is not required for VA employment, since employees may use the facility's institutional DEA certificate." VHA's regulation in VHA Handbook 1100.19, paragraph 5h (1), similarly provides that "[i]ndividual certification by DEA is not required for VA practice, since practitioners may use the facility's institutional DEA certificate with a suffix." However, the statement is qualified by a note to paragraph 5h, which states, "[w]here a practitioner's state of licensure requires individual DEA certification in order to be authorized to prescribe controlled substances, the practitioner may not be granted prescriptive authority for controlled substances without such individual DEA certification."⁹ To the extent that the Medical Center policy and practice was to permit NPs to prescribe controlled substances using the institutional DEA certification even when their state of licensure required an individual certification, that policy was inconsistent with Federal law and VA policy.

State law

By way of example, before prescribing controlled substances, a Mississippi-licensed NP must request controlled substances prescriptive authority from the Mississippi BON, complete a board-approved educational program, complete 720 hours of monitored practice, register individually with DEA, receive a Uniform Controlled Substances Registration Certificate from DEA, and submit a \$100 fee to the BON. Mississippi Administrative Code, Title 30, Part 2840, Chapter 2, Rules 2.2.1.B.9 and 2.4.C.2. Thus, Mississippi requires a practitioner to have individual DEA registration, not institutional DEA registration with suffix and accepts the Federal DEA registration in lieu of a separate state DEA registration or CDS certificate. *Id.*, at Rule 2.4.

B. Prescribing without a face-to-face examination of the patient

⁹ A similar provision for dependent health care practitioners is contained in VHA Directive 2012-030 at Attachment A, paragraph 6b and Note.

The complaint alleged that physicians at the Medical Center were pressured to prescribe controlled substances prescriptions for patients of NPs without the opportunity to see these patients, in violation of legal requirements for a face-to-face examination of the patient. The complaint further alleged that the Medical Center hired Locum Tenens physicians to run a Controlled Substances Clinic in the PCU, catering to patients who required narcotics prescriptions, including patients of NPs. This practice allegedly lacks continuity of care or proper coordination of a patient's extensive medical needs, which results in a danger to patients.

Federal law

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. 21 CFR § 1306.04; 21 U.S.C. § 829(e)(2)(A). DEA has not defined the parameters of what constitutes "legitimate medical purpose" or "in the usual course of professional practice," but notes courts have construed the phrase to mean "in accordance with a standard of medical practice generally recognized and accepted in the United States." DEA Notice of Proposed Rulemaking on Dispensing Controlled Substances for the Treatment of Pain, 71 FR at 52717 (September 6, 2006) (quoting *United States v. Moore*, 423 U.S. 122, 139 (1975)). DEA notes that the Supreme Court in *Gonzales v. Oregon*, 126 S.Ct. 904, 925 (2006), "continued to cite *Moore* with approval and for the proposition that legitimate medical purpose requirement in the CSA 'ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'"

States regulate the general practice of medicine and determine what constitutes a bona-fide patient-provider relationship. This relationship generally is established when a patient presents with a medical complaint, and the practitioner obtains a medical history, conducts at least one in-person examination of the patient, and records the results. Whether drug therapy is warranted for a particular patient would be determined by the circumstances of that patient's medical situation. Permissible exceptions to the in-person medical examination requirement may include a prescription by a "covering practitioner."

By way of example, Mississippi defines a "valid prescription" as a "prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient, or a covering practitioner." Miss. Code Ann. 41-29-137(f)(1). A "practitioner" is defined as "A physician, dentist, veterinarian, scientific investigator, optometrist certified to prescribe and use therapeutic pharmaceutical agents under Sections 73-19-153 through 73-19-165, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state." Miss. Code Ann. 41-29-105(y)(1). A "covering practitioner" is a practitioner "who conducts a medical evaluation other than an in-person medical evaluation at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous 24 months, and who

is temporarily unavailable to conduct the evaluation of the patient.” Miss. Code Ann. 41-29-137(f)(2)(B). Mississippi’s Administrative Code provides that, “[n]o physician shall prescribe, administer or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication therefore.” Mississippi Administrative Code, Title 30, Part 2640, Chapter 1, Rule 1.4.

The past practice of Medical Center management was to authorize its APRNs, most of whom are licensed in Mississippi, to prescribe controlled substances under the hospital’s DEA registration with a suffix unique to the individual. After conducting a review, (b)(6); Chief of Staff, recommended the suspension of this practice pending further review and advisement from Regional Counsel, DEA and VA Central Office. (b)(6) requested a plan from the Chief, Medicine Service, and Acting Chief of Staff/Primary Care to ensure that no Veteran went without needed medications; accordingly, NPs were instructed to ask physicians to sign the prescriptions.

In July 2012, (b)(6) reviewed the DEA Web site and Mississippi statutes and regulations governing prescription renewals. He also requested assistance and guidance from the VISN and Mississippi BON. Based on this review, there appeared to be no prohibition on allowing “covering physicians” to renew controlled substance prescriptions (after reviewing medical record to determine continuing need for the prescription) without a face-to-face visit. Based on the above, the Chief, Medicine Service and Acting Chief of Staff/Primary Care requested staff physicians in primary care to work with the NPs to review Veterans’ charts requiring prescriptions, decide if the review justified continued prescriptions, and if so, renew the prescriptions accordingly. Some of the physicians agreed to do so, and some refused.

In August 2012, a DEA officer came unannounced to the facility Emergency Department and informed several physicians that the above practice was not allowed and physicians could be prosecuted. When alerted by the physicians about the DEA officer’s opinion, the Chief of Staff immediately suspended the plan. With the assistance of the VISN and VA Central Office, the facility Director, Chief of Staff, and Acting Chief of Staff/Primary Care developed a Controlled Substance Clinic in each primary care clinic using a VHA Locum Tenens physician. As noted previously, Locum Tenens physicians are temporary and usually work for an agency that supplies temporary doctors. They are licensed and credentialed by the facility before they come to work. On August 18, 2012, the first Veteran was seen in the Controlled Substance Clinic, which was staffed by a Locum Tenens physician. On November 30, 2012, the Controlled Substance Clinic ended as many of the NPs had obtained individual Federal DEA certifications, as allowed by Mississippi and other states. At this time, all prescriptions are written by either the primary care physician or an NP with his/her own DEA certification.

Since the end of the Controlled Substances Clinic, controlled substances prescriptions have been provided by NPs with individual Federal DEA numbers and physicians assigned to primary care clinics. At the time of the team’s site visit, all but three NPs had obtained individual DEA certificates. All NPs were licensed as NPs in at least one state. These states include Mississippi, Arkansas, North Carolina, Iowa, and Ohio. All

NPs were certified by at least one national certifying agency, in either family medicine or adult medicine. The NPs who do not yet have DEA certificates are working with their collaborating physicians to obtain prescriptions as necessary.

Conclusions for Allegation #4

- Medical Center leadership was under the erroneous impression that all providers were allowed to use the institution's generic DEA number, as long as the provider was working within the scope of a VA provider. In fact, as explained above, as a matter of Federal law and VA policy, where a practitioner's state of licensure requires individual DEA certification in order to be authorized to prescribe controlled substances, the practitioner may not be granted prescriptive authority for controlled substances without such individual DEA certification. Thus, with respect to NPs whose state of licensure required individual DEA certification to prescribe controlled substances, we substantiated the Whistleblower's allegations that the Medical Center's practice violated Federal law and VA policy.
- As of the writing of this report, all NPs are licensed as an NP in a state and are certified nationally as an adult or family practice NP, including the two NPs still at the Medical Center, who were originally grandfathered in from the NP licensure requirement. Grandfathered NPs are not exempt from meeting any additional requirements by their state of licensure for obtaining controlled substances prescriptive authority.
- When Medical Center leadership was made aware that not all NPs were authorized by their license to write prescriptions for controlled substances, they took immediate action to stop the practice and attempted to put the prescribing back in the hands of staff physicians. The team confirmed that some, but not all, staff physicians agreed to renew prescriptions based on a records review alone; thus, we substantiated the Whistleblower's allegations.
- When Medical Center leadership learned that this practice was also improper because a face-to-face physician-patient encounter was required, they created the Locum Tenens clinic as a stop gap measure. Patients were physically seen by these physicians, and prescriptions written appropriately. These clinics continued until the NPs obtained their own DEA certificates. Current prescribing practices comply with Federal law and VHA policy.

Recommendations for Allegation #4

- The three NPs, who have not yet received their individual DEA certificates, should be encouraged to obtain them as soon as possible. Until that time, they will not be writing for controlled substances and will rely on Physician Collaborators to write prescriptions, as necessary.

- The NP functional statement, qualification standards, and dimensions of practice of the facility must be revised to be consistent with national policy per VA Handbook 5005 appendix G6.
- The Medical Center must complete a clinical care review of a random sample of 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 were actually prescribed controlled substances. If any clinical issues are identified, the review should be expanded.

Facility 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.

VI. A listing of any violation or apparent violation of any law, rule, or regulation

The team substantiated that former Medical Center leadership directed NPs to practice under clinical privileges as LIPs, without regard to VHA policy or whether they were licensed as independent practitioners; did not ensure that the clinical practice of NPs was appropriately monitored by either their Physician Collaborators or through credentialing and privileging processes; and directed NPs to prescribe controlled substances using the institutional DEA registration with suffix, without regard to whether they were granted such prescriptive authority by their licenses or were required by their licensing board to prescribe under individual Federal DEA registration. The team also substantiated that Medical Center leadership requested PCP physicians to write controlled substances prescriptions for patients of the NPs based on a records review alone, without first conducting a face-to-face patient examination, under the belief that they were “covering physicians,” and that some PCP physicians did so. These facility policies and practices violated the following Federal laws, rules, regulations and VA policies, as well as state licensing rules and regulations for collaborative agreements and controlled substances prescribing:

- The Controlled Substances Act, 21 U.S.C. § 823(f) (DEA registration requirements);
- DEA regulations, 21 CFR § 1306.03(a)(1)-(2) (Persons entitled to issue prescriptions);
- VA Handbook 5005, Part II, Appendix G6/27 (March 17, 2009), Nurse Qualification Standard VHA Handbook 1100.19, Credentialing and Privileging;
- VHA Directive 2008-049, Establishing Medication Prescribing Authority for Advanced Practice Nurses (August 22, 2008);
- VHA Directive 2012-030, Credentialing of Health Care Professionals;

- VHA Directive 2010-027, VHA Outpatient Scheduling Processes and Procedures (2010);
- VHA Updated Bylaws Template; and
- State licensing laws relating to collaborative agreements and controlled substances prescribing authority.

VII. Description of Any Actions to be Taken as a Result of the Investigation

No changes in national agency rules, regulations, or practices will be taken as a result of this investigation. Substantiation of the Whistleblower's allegations uniformly stem from the Medical Center's institutional failure to adhere to/or enforce current Federal laws and VA rules, regulations, and policies, as noted throughout the report. However, the team found that the facility's new leadership had taken some corrective measures to remedy past practices and prevent them from recurring. Leadership, under whom the noted non-compliant practices occurred, had already left the facility, and in some cases, the Department. VHA will be responsible for ensuring the facility completes the following recommended actions:

- Medical Center leadership must immediately correct the erroneous declaration that all NPs will practice as LIPs.
- Medical staff bylaws must be amended to indicate that NPs are considered LIPs only when their state licensure permits.
- Medical Center leadership must immediately implement scopes of practice versus clinical privileges for NPs, who are not permitted to practice as LIPs.
- 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.
- Medical Center leadership should ensure the equitable distribution of collaborative agreements among physicians, and a reasonable limitation should be 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.
- Medical Center leadership should eliminate use of Locum Tenens physicians in the PCU to the extent possible.

- Locum Tenens physicians should not be Physician Collaborators because of their short tenure.
- 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.
- Medical Center leadership must continue to aggressively work to hire permanent full-time physicians for the PCU, to obtain an NP:MD ratio of 1:1. Once an adequate number of physicians are hired, the Medical Center should reduce panel sizes for NPs to meet VHA guidelines.
- Medical Center leadership should consult the Office of Workforce Management and Consulting in VA Central Office to ensure they are utilizing all available resources to recruit primary care physicians.
- Medical Center leadership should eliminate the use of Ghost Clinics. All clinics must have an assigned provider.
- 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 it, including on the same day, if requested.
- The Medical Center must convert six-part credentialing and privileging folders to the electronic VetPro system, as required by VHA leadership.
- VISN 16 leadership should arrange for an external clinical quality review of all primary care delivered 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 the PCU 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 these providers was appropriate. If any clinical care issues are identified, the facility should consider expanding the sample. Specific cases involving unresolved questions as to quality of care should be referred to the Office of the Medical Inspector for further investigation.
- 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).

- VHA should consider issuing an 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.
- 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 Business Compliance and Integrity and the Office of Patient Care Services, Home Health Program, to work together to conduct a random check of 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 Under Secretary for Health, who will then need to consider if any follow-up action is necessitated. Additionally, facility leadership should consider development of a training and educational module for completion of these forms to ensure PCU and other staff are aware of CMS compliance requirements.
- 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 for controlled substances, and are relying on the collaborating physicians to write for prescriptions as necessary.
- The NP functional statement, qualification standards and dimensions of practice of the facility must be revised to be consistent with national policy per VA Handbook 5005 appendix G6.
- The facility 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.
- Facility 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.

ATTACHMENT A: List of Documents and References

1. VHA Handbook 1100.19, Credentialing and Privileging (November 14, 2008)
2. VHA Handbook 1101.02, Primary Care Management Module (PCMM) (April 21, 2009)
3. VA Handbook 5005/27, Staffing Plans (March 17, 2009) (this includes 2003 version with 2009 changes)
4. VHA Directive 2008-049, Establishing Medication Prescribing Authority for Advanced Practice Nurses (August 22, 2008)
5. VHA Directive 2008-071, Provision of Medical Statements and Completion of Forms by VA Health Care Providers
6. VHA Directive 2009-055, Staffing (November 2, 2009)
7. VHA Directive 2010-027, VHA Outpatient Scheduling Processes and Procedures (2010)
8. VA Directive 0735, Homeland Security Presidential Directive 12 (HSPD-12) Program (2011)
9. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures (2009)
10. VHA Manual M-1, Part I, Chapter 26, Hospital Accreditation
11. VHA IL 10-99-003, Under Secretary for Health Information Letter - Utilization of Nurse Practitioners and Clinical Nurse Specialists (February 1999)
12. Memorandum from the Deputy Under Secretary for Health for Operations and Management, Health Care Provider Credentialing and Privileging Records (March 23, 2011)
13. Memorandum from Senior Medical Officer, Office of Quality and Safety, Health Care Provider Credentialing Records (distributed by e-mail on October 3, 2011)
14. Letter to the Under Secretary for Health from the Deputy Assistant Administrator, Office of Diversion Control (June 7, 2006)
15. DEA Policy Memorandum to Special Agents in Charge, Assistant Special Agents in Charge, Diversion Program Managers, and Diversion Group Supervisors to clarify DEA policy regarding the Federal Government Practitioners Program (FEDDOC) (July 31, 2012)
16. Joint Commission Standards EC.02.01.01, #1 and #7
17. HHS Form CMS-485 (C-3)(02-94)
18. Controlled Substance Act, 21 U.S.C. 823(f); 21 CFR 1306.03(a)(1)-(2).
19. Bylaws and Rules of the Medical Staff of VHA G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi (March 19, 2013)
20. Medical Center Policy F-113-36, Critical Values and Other Mandatory Notifications (June 13, 2013)
21. Medical Center Policy F-114-26, Notification and Follow-Up of Abnormal Radiology Findings (April 5, 2010)
22. Jackson VAMC HEDIS (Outpatient Clinical Quality) Dashboard
23. Nurse Practice Acts for the States of Mississippi, North Carolina, Ohio, Arkansas, Iowa
24. Credentialing and Privileging folders of 42 NPs at the Jackson VAMC
25. PCMM data for PCPs at Jackson VAMC
26. Scheduling grids for Primary Care Clinics at Jackson VAMC

27. Workload data for PCPs at Jackson VAMC
28. VHA Handbook 1140.6, Purchased Home Health Care Services Procedures, (2006)

NP Name	Employment Status C=Current employee at JVAMC in PC CJ= Current employee at JVAMC not in PC NC= No longer employed at JVAMC	State of Licensure	NP License Original Date	NP Type Certification/ Date	CA Required Y or N	CA in Place Y or N	CA Date Current	CA Date Original	Collaborating MD/ work location	Individual DEA and issue date	NPDB Y or N
(b)(6)	CJ	MS	11/30/94	ANCC Family 12/1/94	Y	Y	10/11/12	12/00/10	(b)(6) Jackson VAMC	6/26/12	N
(b)(6)	C	NC	1/24/98	ANCC Family 9/1/96	Y	Y	12/31/12	12/00/10	(b)(6) Fayetteville NC VAMC	N	N
(b)(6)	CJ	MS	2/12/96	ANCC Adult/Ger 9/1/95	Y	Y	12/18/12	12/9/10	(b)(6) Jackson VAMC	7/19/12	N
(b)(6)	CJ	MS	4/27/99	ANCC Family 12/1/98	Y	Y	12/15/12	12/7/10	(b)(6) Jackson VAMC	5/3/11	N
(b)(6)	C	MS	1/9/95	ANCC Family 12/1/94	Y	Y	3/22/13	12/21/10	(b)(6) Jackson VAMC	1/9/13	N
(b)(6)	CJ	MS	12/2/02	ANCC Acute Care 12/1/01	Y	Y	12/12/12	12/30/10	(b)(6) Jackson VAMC	N	N
(b)(6)	CJ	MS	4/13/10	ANCC Family 3/15/10	Y	Y	12/5/12	9/7/11	(b)(6) (b)(6) Jackson VAMC	8/10/12	N
(b)(6)	C	MS	7/26/06	AANP Family 7/1/06	Y	Y	12/14/12	12/14/10	(b)(6) Jackson VAMC	12/28/12	N

(b)(6)	NC	TN	8/13/04	ANCC Family 2/1/08	Y for Rx authority	N	N/A	N/A	N/A		12/7/06	N
(b)(6)	C	MS	12/16/93	ANCC Family 12/1/93	Y	Y	3/17/13	12/9/10	(b)(6) Jackson VAMC		5/4/12	N
(b)(6)	C	MS	12/9/11	AANP Family 11/1/11	Y	Y	10/30/12	2/7/12	(b)(6) Jackson VAMC		1/16/13	N
(b)(6)	NC	FL	3/5/03	ANCC Family 4/1/98	Y	Y - expired last 8 months of employ ment	Left Jackson 1/31/13- CA had expired 5/31/12	6/1/11	(b)(6) Milton, FL			N
(b)(6)	CJ	MS	4/8/09	ANCC Family 3/16/09	Y	Y	10/22/12	12/7/10	(b)(6) Jackson VAMC			N
(b)(6)	C	MS	6/18/04	AANP Family 6/1/04	Y	Y	12/27/12	12/14/10	(b)(6) Jackson VAMC		7/11/11	N
(b)(6)	CJ	MS	12/6/95	ANCC Family 12/1/95	Y	Y	11/6/12	12/9/10	(b)(6) and Pamela Graham - Jackson VAMC		6/27/12	N
(b)(6)	CJ	MS	6/1/11	ANCC Family 9/1/07	Y	Y	3/22/13	7/19/12	(b)(6) r Jackson VAMC			N
(b)(6)	C	MS	6/28/05	ANCC Family 7/13/05	Y	Y	12/14/12	12/13/10	(b)(6) (Locums) no longer employed at Jackson VAMC		4/27/13	N

(b)(6)	NC	MS	2/24/97	ANCC Family 4/1/97	Y	Y	Left Jackson 8/25/12- CA still in effect	12/7/10	(b)(6) Jackson VAMC	8/27/12	N
(b)(6)	C	MS	9/11/07	ANCC Family 9/11/07	Y	Y	11/13/12	12/16/10	(b)(6) Jackson VAMC	8/2/11	N
(b)(6)	NC	MS	6/3/11	ANCC Family 10/1/01	Y	Y	Left Jackson 8/11/12- CA still in effect	7/19/12	(b)(6) Jackson VAMC	N	N
(b)(6)	C	IA	4/10/13	ANCC Family 12/1/94	Y ¹	N	N/A	N/A	N/A	3/29/13	N
(b)(6)	CJ	MS	9/1/04	ANCC Family 9/1/04	Y	Y	3/20/13	12/13/12	(b)(6) Jackson VAMC	N	N
(b)(6)	C	MS IA	12/24/08 1/18/13	ANCC Family 4/28/08	Y ²	N ³	12/14/12	12/13/10	(b)(6) (Locums) no longer employed at Jackson VAMC	4/1/13	N
(b)(6)	CJ	MS	8/22/97	ANCC Family 9/1/97	Y	Y	12/6/12	12/9/10	(b)(6) Jackson VAMC	N	N
(b)(6)	CJ	MS	11/28/95	ANCC Family 12/1/95	Y	Y	12/19/12	12/8/10	(b)(6) Jackson VAMC	12/22/10	N
(b)(6)	C	MS	9/9/04	ANCC Family 8/1/04	Y	N ³	2/26/13	12/8/10	(b)(6) (Locums) no longer employed at Jackson VAMC	1/9/13	N

(b)(6)	NC	MS	12/21/94	ANCC Adult 12/1/94	Y	Y	Left Jackson 6/23/12- CA still in effect	12/7/10	(b)(6) Jackson VAMC	N	N
(b)(6)	CJ	MS	12/18/97	ANCC Family 9/1/97	Y	Y	3/26/13	12/17/10	(b)(6) VAMC	N	N
(b)(6)	CJ	MS	9/1/12	ANCC Family 9/1/97	Y ⁴	Y	3/22/13	3/22/13	(b)(6) Jackson VAMC		N
(b)(6)	NC	MS	Grandfather	AANP Family 12/1/99	Y for Rx authority	Y	12/9/10	12/9/10	(b)(6) Jackson VAMC	N	N
(b)(6)	C	OH	3/24/05	ANCC Family 4/1/04	Y	N ⁵	4/29/13	4/29/13	(b)(6) Jackson VAMC	N	N
(b)(6)	C	MS	4/10/09	ANCC Family 1/26/09	Y	Y	10/30/12	12/7/10	(b)(6) Jackson VAMC	2/27/13	N
(b)(6)	CJ	MS	12/17/98	ANCC Family 12/1/98	Y	Y	11/18/12	12/13/10	(b)(6) Jackson VAMC	3/21/12	N
(b)(6)	CJ	MS	8/19/05	ANCC Family 7/8/05	Y	Y	10/22/12	12/8/10	(b)(6) Jackson VAMC	N	N
(b)(6)	CJ	MS	3/14/97	ANCC Family 12/1/96	Y	Y	4/19/13	12/8/10	(b)(6) Charlotte Scott-Bennett Jackson VAMC	3/14/12	N
(b)(6)	NC	MS	9/26/11	ANCC Family 7/14/11	Y	Y	Left Jackson 6/23/12- CA still in effect	2/7/12	(b)(6) Jackson VAMC	N	N

(b)(6)	C	AR	2/27/96	ANCC Adult 4/1/89	Y for Rx authority ^b	Y	6/7/12	6/7/12	(b)(6) (Spencer) Jackson VAMC	2/22/11	N
(b)(6)	C	MS	11/27/95	ANCC Family 12/1/97 and Adult 12/1/95	Y	Y	3/22/13	12/7/10	(b)(6) (b)(6) (Locums) no longer employed Jackson VAMC	6/26/12	N
(b)(6)	CJ	MS	12/4/98	ANCC Family 12/1/96	Y	Y	11/8/12	12/7/10	(b)(6) Jackson VAMC	2/27/13	N
(b)(6)	C	MS	9/21/04	ANCC Family 9/1/04	Y	Y	11/26/12	12/17/10	(b)(6) Jackson VAMC	4/9/13	N
(b)(6)	CJ	MS	2/22/00	ANCC Family 8/1/99	y	y	11/6/12/	12/7/10	(b)(6) Jackson VAMC	4/15/11	N
(b)(6)	CJ	MS	11/28/94	ANCC Adult 1/11/92	Y	Y	3/17/13	12/9/10	(b)(6) Jackson VAMC	10/21/00	N
1 (b)(6) NP was grandfathered prior to obtaining IA license on 4/10/13. Per VHA Directive NP would have required a CA for prescriptive authority under her grandfathered status. Once she obtained IA license she no longer required a CA.											
2 (b)(6) : NP required CA under MS license, which NP had. CA no longer required since 1/18/13 under IA license.											
3 (b)(6) and (b)(6) : Physician Collaborator was a Locum Tenens and is no longer employed at the Jackson VAMC. Collaborative Agreement is thus not in effect.											
4 (b)(6) : NP was grandfathered. Per VHA Directive would have required a CA for prescriptive authority under her grandfather status. However, NP did not have CA prior to 3/22/13.											

Memorandum



Subject Revised Policy Regarding the Federal Government Practitioners Program (FEDDOC) (DFN: 601-04)	Date JUL 31 2012
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To
 Special Agents in Charge
 Assistant Special Agents in Charge
 Diversion Program Managers
 Diversion Group Supervisors

From *Joseph T. Rannazzisi*
 Joseph T. Rannazzisi
 Deputy Assistant Administrator
 Office of Diversion Control

The purpose of this memorandum is to clarify the Office of Diversion Control's (OD) policy regarding the Drug Enforcement Administration (DEA) Federal Government Practitioners Program (FEDDOC). FEDDOC practitioners are individuals who are direct hire employees of a Federal government agency (not contract practitioners) and are eligible for a fee exemption as set forth in 21 Code of Federal Regulations (C.F.R.) § 1301.21(a)(2). DEA has a longstanding policy regarding FEDDOC practitioners that permits a DEA registration be issued to the practitioner in one state as long as that person maintains a valid professional license in any state. This memorandum reaffirms the FEDDOC policy providing the following criteria are met:

- The FEDDOC practitioner's registered business address must be the official place of business.
- A FEDDOC registration can only be used for official duties on behalf of the Federal agency.
- Whenever a FEDDOC practitioner changes his or her official place of business, he or she must request a modification of registration pursuant to 21 C.F.R. § 1301.51, to reflect the location at which he or she is currently practicing.
- A FEDDOC practitioner must maintain a valid and current professional license. If the practitioner holds a professional license in a state that requires two licenses, then the practitioner must keep both licenses active and current only if the registered address is in the same state as the licenses, in order to be in compliance with that state.

The following Federal agencies are current participants in DEA's FEDDOC Program:

- BOP - Bureau of Prisons
- CDC - Centers for Disease Control and Prevention

DHS - Department of Homeland Security
DOJ - Department of Justice
FAA - Federal Aviation Administration
FDA - Food and Drug Administration
HHS - Health and Human Services
IHS - Indian Health Services
NASA - National Aeronautics and Space Administration
NCI - National Cancer Institute
NIH - National Institutes of Health
NIMH - National Institute of Mental Health
NOAA - National Oceanic and Atmospheric Administration
PHS - Public Health Services
USDA - United States Department of Agriculture
USPS - United States Postal Service
VA - Department of Veterans Affairs
U.S. Capitol Physician's Office
White House

If a FEDDOC practitioner wants to maintain a separate DEA registration for a private practice, which would include prescribing for private patients, he or she must be fully licensed to handle controlled substances by the state in which he or she is located pursuant to 21 C.F.R. § 1306.03(a). Under these circumstances, a FEDDOC practitioner is not eligible for the fee exemption under 21 C.F.R. § 1301.21(a)(2), to conduct his or her private practice and must pay DEA's registration fee.

Any questions regarding the FEDDOC Program may be addressed to the Registration and Program Support Section at (202) 307-7994.