



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

May 15, 2015

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-14-4002

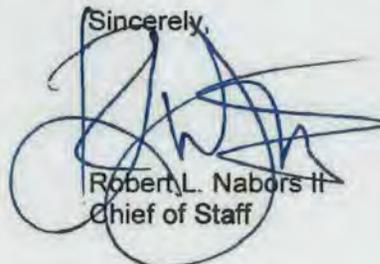
Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Carl Vinson Department of Veterans Affairs (VA) Medical Center (hereafter, the Medical Center), in Dublin, Georgia. The whistleblower alleged that advance practice registered nurses (APRN) lack state privileges to prescribe, yet write orders for medications, and that this practice constitutes a violation of state law, VA directives, and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary under 5 United States Code § 1213(d)(5).

When this referral was received, the Interim Under Secretary for Health was assigned to review this matter and prepare a report in compliance with the § 1213(d)(5) requirements. She, in turn, directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The report partially substantiates both allegations and makes seven recommendations to the Medical Center, two to the Veterans Integrated Service Network, one to the Veterans Health Administration, and one to VA. The report substantiates that Georgia state law on collaborative agreements and prescriptive authority was violated, but does not substantiate that these violations represent a substantial and specific danger to public health. The investigation found that all APRNs at the Medical Center who ordered/prescribed non-controlled substances did so in accordance with VA policy and their VA collaborative agreements (where required). APRNs from other states of licensure who ordered/prescribed medications at the Medical Center had state prescriptive authority. The investigation found no adverse incidents in patient care provided by the prescribing APRNs. Findings from the investigation are contained in the enclosed report, which I am submitting for your review. I have reviewed these findings and agree with the recommendations in the report. We will send your office follow-up information describing actions that have been taken by the Medical Center and other entities to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,



Robert L. Nabors II
Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel
OSC File Number DI-14-4002**

**Department of Veterans Affairs
Carl Vinson Veterans Affairs Medical Center
Dublin, Georgia**



Report Date: May 6, 2015

TRIM 2014-D-1262

Executive Summary

At the request of the Secretary, the Interim Under Secretary for Health (I/USH) directed the Office of the Medical Inspector (OMI) to assemble and lead a team to investigate allegations lodged with the Office of Special Counsel (OSC) by [REDACTED] (hereafter, the whistleblower), an advanced practice registered nurse (APRN) who consented to the release of her name. She alleged that APRNs employed at the Carl Vinson Department of Veterans Affairs (VA) Medical Center in Dublin, Georgia, (hereafter, the Medical Center) prescribe drugs without state licenses, and that this practice constitutes a violation of state law, VA directives, and a substantial and specific danger to public health. VA conducted a site visit to the Medical Center on December 2-4, 2014.

Specific Allegations of the Whistleblower

1. Ten APRNs in two departments at the Vinson VAMC lack state prescribing privileges, but routinely write orders for prescription medication; and
2. This deficiency potentially extends to all APRNs at the Vinson VAMC, and constitutes a violation of state law, VA Directives, and a substantial and specific danger to public health.

VA **substantiated** allegations when the facts and findings supported that the alleged events or actions took place and **did not substantiate** allegations when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate** allegations when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of the findings, VA makes the following conclusions and recommendations.

Conclusions for Allegation 1

- VA **substantiated** that 10 APRNs in two departments (the Mental Health and Primary Care clinics) at the Medical Center lack state authority to order/prescribe medications, but routinely write orders/prescriptions for non-controlled substances under their VA scope of practice. At the time of the site visit, none of the Georgia licensed certified nurse practitioners (NP) who prescribe medication had state-approved Nurse Protocol Agreements with a physician that permitted them to order/prescribe medications. NPs from other states of licensure met the requirements for prescriptive authority. The Medical Center authorized these 10 APRNs to practice under OCGA § 43-34-25, which requires Nurse Protocol Agreements. Nurse Protocol Agreements between APRNs and physicians are collaborative in nature and used by some states to define what activities an individual professional can undertake. Where required and not inconsistent with VA rules, regulations and policies, such agreements must be in compliance with

applicable state law and filed with the appropriate state agency. The State of Georgia requires the filing of Nurse Protocol Agreements with both the Board of Medicine (BOM) and State Board of Nursing (BON), ongoing collaboration between the NP and delegating physician, and that the physician complete chart reviews on at least 10 percent of the NP's charts. With the exception of state requirements for non-controlled substances prescribing authority, which VA regulates, VA nurses who are licensed in the State of Georgia must comply with applicable licensing regulation.

- While we found a violation of state law on collaborative agreements and prescribing authority, we did not find any substantial risk to public health and safety. Under the Medical Center's Collaborative Agreements, APRNs work with supervisory physicians. Further, the APRNs at the Medical Center who order/prescribe non-controlled substances do so in compliance with VHA Directive 2008-049 and their VA Collaborative Agreements (where required). None of the NPs were permitted to directly prescribe controlled substances medications without co-signature from a physician. In addition, none of the NPs had been given the electronic key required to e-prescribe controlled substances. VA reviewed peer reviews, quality reviews by supervising physicians, and patient safety records and found no adverse incidents in patient care provided by the NPs.
- Medical Center Leadership became aware of the requirement for Nurse Protocol Agreements with the State of Georgia this past June, prepared a corrective plan, but did not execute it.

Recommendations to the Medical Center:

1. The Credentialing and Privileging (C&P) department must verify that all APRNs, including contract and fee-based providers, are adhering to applicable state law.
2. Ensure that APRNs are knowledgeable about their state's licensure laws and requirements, including continuing education requirements.
3. Make sure that all NPs who require collaborative agreements with their supervising physicians have them, that they are approved by each NP's state licensing board (as applicable), and are updated according to applicable state law.
4. Immediately implement a process to ensure that appropriate monitoring of NPs by physician collaborators occurs in accordance with applicable state licensure requirements and is documented.
5. Make sure that leadership (Medical Staff and Credentialing Professionals; Clinical Service and Product Line Chiefs, Credentials Committee Members (Professional Standards Boards), Executive Committee of the Medical Staff members; Chief of Staff (CoS) and medical facility Directors, Risk Managers (RM), and Quality and Performance Improvement professionals) are educated and have a working knowledge of state licensure requirements for professional clinical staff.

Recommendations to Veterans Integrated Service Network (VISN) 7:

6. The Quality Management Officer (QMO) must verify that all C&P officers within the VISN have received proper education and annual training and/or certification appropriate to their positions.
7. The QMO must verify that VA medical centers within the VISN are following applicable state and VA guidelines for APRN practice, in accordance with each APRN's state of license and VA policies on APRN credentialing, privileging and prescribing.

Recommendation to the Veterans Health Administration (VHA):

8. Issue an Instructional Letter to all medical centers reinforcing the requirement for compliance with VA national policies on APRN credentialing, privileging and prescribing, and applicable state licensure requirements for APRNs.

Conclusions for Allegation 2

- VA **substantiated** that all APRNs at the Medical Center licensed in the State of Georgia lack state-approved Nurse Protocol Agreements, which constitutes a violation of state law; however, we **did not substantiate** that these violations represent a substantial and/or specific danger to public health because the Medical Center had internal Collaborative Agreements in place between the APRNs and physicians. Under the Medical Center's Collaborative Agreements, APRNs work under the supervision of physicians. VA reviewed peer reviews, quality reviews by supervising physicians, and patient safety records and found no adverse incidents in patient care provided by the NPs. Although they lacked state authority to order/prescribe medications, the APRNs at the Medical Center were authorized to order and prescribe non-controlled substances in accordance with VHA Directive 2008-049 and their VA Collaborative Agreements (where required).
- VA concludes that the 17 APRNs at the Medical Center who order/prescribe medications met VA's requirements for medication ordering and prescribing. The remaining five APRNs do not order/prescribe medications as a part of their VA duties.
- VA concludes that Medical Center leadership failed to ensure that APRNs met applicable state requirements for Nurse Protocol Agreements, where required and not inconsistent with VA rules, regulations and policies. However, state requirements for the ordering/prescribing of non-controlled medications do not apply to APRNs at the Medical Center. The ordering/prescribing of non-controlled medications by APRNs is in accordance with VA rules, regulations and policies.

Recommendations to the Medical Center:

9. Make sure that all APRN licenses are verified and that each APRN declares under which state license he or she is operating (if more than one license).
10. C&P must develop a tracking system that identifies when the licenses of APRNs are about to expire, must notify the individual, and must monitor whether continuing education and training requirements have been satisfied, and what remedial actions are necessary.

Recommendation to VA:

11. Take appropriate administrative action against individuals who had knowledge of applicable state requirements for Nurse Protocol Agreements, but failed to act promptly to ensure that APRNs had state-approved Collaborative Agreements, where required.

Summary Statement

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center employees have engaged in conduct that may constitute a violation of law, rule, or regulation, and a substantial and specific danger to public health. In particular, the Office of General Counsel (OGC) has provided a legal review, and the Office of Accountability Review (OAR) has examined the issues from a Human Resources (HR) perspective to establish accountability, when appropriate, for improper personnel practices. VA found violations of state law and VA directives, but did not find a substantial and specific danger to public health and safety. The ordering/prescribing of non-controlled substances by NPs at the Medical Center was done in accordance with VHA Directive 2008-049. VA reviewed peer reviews, quality reviews by supervising physicians, and patient safety records and found no adverse incidents in patient care provided by the NPs.

Table of Contents

Executive Summary.....	ii
I. Introduction.....	1
II. Facility and VISN Profile.....	1
III. Specific Allegations of the Whistleblower.....	1
IV. Conduct of Investigation.....	1
V. Findings, Conclusions, and Recommendations.....	2
VI. Summary Statement.....	15
Attachment A.....	16
Attachment B.....	18

I. Introduction

At the request of the Secretary, the I/USH directed OMI to assemble and lead a VA team to investigate allegations lodged with OSC by the whistleblower, an APRN at the Medical Center, who alleged that APRNs there prescribed drugs without state licenses, that this practice potentially extended to all APRNs, and that it constituted a violation of state law, VA directives, and was a substantial and specific danger to public health. VA conducted a site visit to the Medical Center on December 2–4, 2014.

II. Facility Profile

The Medical Center is a complexity level 3 facility offering patient care for multiple services including acute care, mental health, ambulatory and primary care, optometry, women's health, extended care, as well as specialized programs such as cardiology, pulmonology, general surgery, podiatry, audiology, urology, and physical therapy.¹ With 34 inpatient beds, 145 domiciliary beds, and 161 community living center (CLC) beds, the Medical Center provided health care services for over 39,000 Veterans in fiscal year (FY) 2013, including nearly 300,000 outpatient visits.

The Medical Center is part of the VA Southeast Network, VISN 7, which includes facilities in Alabama, Georgia, and South Carolina. It operates four community-based outpatient clinics (CBOC) in Albany, Brunswick, Macon, and Milledgeville, and one Outreach Center in Perry, Georgia. The Medical Center maintains active affiliate agreements with 27 college and university programs across 17 disciplines. Its academic affiliations include Midwestern University College of Health Sciences, South University, Georgia Southern University, and Mercer University.

III. Specific Allegations of the Whistleblower

1. Ten APRNs in two departments at Vinson VAMC lack state prescribing privileges, but routinely write orders for prescription medication; and
2. This deficiency potentially extends to all APRNs at Vinson VAMC, and constitutes a violation of state law, VA Directives, and a substantial and specific danger to public health.

IV. Conduct of Investigation

The VA team visiting the Medical Center consisted of [REDACTED], MD, Medical Investigator; (b) (6), Family Nurse Practitioner (FNP), OMI Clinical Program Manager; (b) (6), Doctor of Nursing Practice (DNP), FNP, Liaison for

¹ Complexity level 3: complexity levels are determined by patient population (volume and complexity of care), complexity of clinical services offered, and education and research (number of residents, affiliated teaching programs, and research dollars). Complexity level 1 is the most complex and level 3 is the least complex; complexity for level 2 facilities is considered moderate. (Veterans Health Administration (VHA) Executive Decision Memo (EDM), 2011 Facility Complexity Level Model).

National APRN Policy; and [REDACTED], HR specialist. VA reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured the women's health clinic, the outpatient mental health clinic, and the primary care clinic. We also held entrance and exit briefings with Medical Center leadership.

VA interviewed the whistleblower via teleconference on November 20, 2014, and conducted a face-to-face interview with her on December 2, 2014.

We also interviewed the following Medical Center employees:

- (b) (6), Acting Medical Center Director
- (b) (6), DNP, Associate Director for Patient Care Services (ADPCS)
- (b) (6), MD, Acting CoS
- (b) (6), MD, Acting Chief of Primary Care
- (b) (6), PsyD, Mental Health Director
- (b) (6), PharmD, Chief of Pharmacy
- (b) (6), Chief, HR
- (b) (6), FNP
- (b) (6), Certified Registered Nurse Anesthetist (CRNA)
- (b) (6), CRNA
- (b) (6), Clinical Nurse Specialist (CNS)
- (b) (6), RN, RM
- (b) (6), RN, Acting Quality Manager, Patient Safety Manager
- (b) (6), Credentials Officer
- (b) (6), VetPro Dependent Coordinator
- (b) (6), Chief of Social Work

V. Findings, Conclusions, and Recommendations

Background

Advanced practice nursing is broadly defined as nursing interventions that influence health care outcomes, including the direct care of individual patients, management of care for individuals and populations, administration of nursing and health care organizations, and the development and implementation of health policy. The definition of an Advanced Practice Registered Nurse (APRN) is an umbrella term that includes the

four nationally recognized roles of advanced practice nursing: Certified Nurse Practitioners (CNP), Certified Nurse Midwife (CNM), Certified Registered Nurse Anesthetist (CRNA), and Clinical Nurse Specialist (CNS). The details of these specialties are:

CNP

CNPs diagnose and treat patients with undifferentiated symptoms, as well as those with established diagnoses, providing initial, ongoing, comprehensive care; including diagnosing, treating, and managing patients with acute and chronic illnesses.

CNM

CNMs provide a full range of primary health care services to women, including gynecologic care, family planning, preconception care, prenatal and postpartum care, childbirth, and care of the newborn, to include treating the male partner of the female patient for sexually transmitted diseases and reproductive health.

CRNA

CRNAs initiate anesthetic techniques (general, regional, local) and sedation, provide post-anesthesia evaluation and discharge; order and evaluate diagnostic tests; request consultations; perform point-of-care testing; and respond to emergency situations for airway management.

CNS

CNSs provide diagnosis and treatment of health or illness states, disease management, health promotion, and prevention of illness and risk behaviors among individuals, families, groups, and communities within their scope of practice.

APRNs must be licensed to practice in one of the four APRN roles; hold a graduate-level degree from an accredited program, hold national certification in an APRN role from a nationally recognized certifying body, and possess advanced clinical knowledge, experience and skills.²

Qualifications for Employment as a VA APRN

Under 38 U.S.C. § 7402(b), VA health care practitioners, including nurses, must be licensed in "a" state to professionally practice, and may practice under that license at any VA health care facility in any state, regardless of its location or the practitioner's

² APRN Joint Dialogue Group Report, July 7, 2008, *Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education*. Completed through the work of the APRN Consensus Work Group & the National Council of State Boards of Nursing APRN Advisory Committee
https://www.ncsbn.org/Consensus_Model_for_APRN_Regulation_July_2008.pdf

state of licensure. VA often employs advanced practice nurses who obtain their license in one state, but are employed by VA to practice in another state.

To be eligible for VA employment as an APRN, the individual APRN must meet the qualification standards set forth in VA Handbook 5005/27, Part II, Appendix G6, which provides, at paragraph 2, section B.a.(6):

“(6) Nurse Practitioners and Clinical Nurse Specialists. On and after March 17, 2009, registered nurses appointed or otherwise moving into these assignments must meet and maintain the following additional qualifications:

(a)Nurse Practitioners. A nurse practitioner must be licensed or otherwise recognized as a nurse practitioner in a State, possess a master's degree from a program accredited by the National League for Nursing Accrediting Commission or American Association of Colleges of Nursing, and maintain full and current certification as a nurse practitioner from the American Academy of Nurse Practitioners (AANP) or the American Nurses Credentialing Center (ANCC). [The certification must be in the specialty to which the individual is being appointed or selected.]”

Regulation of Practice

States assume the responsibility within their borders for ensuring, through licensure and certification, that health care professionals provide services appropriate to their training.³ The 50 States and the District of Columbia have differing laws governing APRN practice. Some states employ a joint board of Nursing and Medicine or a separate nursing board or medicine board to regulate APRNs, while others require physicians to enter into supervisory relationships with APRNs (Attachment B). Some states consider APRN practice a medically delegated act and require direct physician supervision of APRNs, while other states require physicians to be in contact with the APRN periodically, or to be physically within a defined radius of the APRN. Some states require a written agreement between the APRN and the collaborating physician, while others do not.

The State of Georgia requires the filing of Nurse Protocol Agreements with both the Board of Medicine (BOM) and Board of Nursing (BON), ongoing collaboration between the NP and the delegating physician, and that the physician complete chart reviews on at least 10 percent of the NP's charts. There are 17 APRNs employed by the Medical Center licensed in the State of Georgia who must comply with these licensing regulations. The remaining APRNs are licensed in California, Florida, Texas, and Virginia; there are no similar Nurse Protocol Agreement requirements in these states.

Each APRN must possess a nursing license from one of the 50 States or the District of Columbia. APRNs with more than one license must designate one as their primary. As

³ National Governors Association, *The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care*, Washington, D.C. (Dec. 20, 2012). <http://nga.org/cms/center>

such, the Medical Center must follow the requirements for licensure of the state that the APRN has designated as primary, even if they possess licenses from other states that might allow for less restrictive practice. The possession of licenses from less restrictive practice states does not alter the requirement for adherence to whichever license the APRN has chosen to designate as their primary license of practice.

The Medical Center created internal Collaborative Agreements to govern supervisory responsibilities of physicians regarding NP practice. The Collaborative Agreements establish practice parameters for NPs, but are not submitted externally to the BON and BOM. Several interviewees were under the impression that the VA Collaborative Agreement could serve as the state's Nurse Protocol Agreement.

VA Policy for APRNs

Under title 38, United States Code (U.S.C.), VA is authorized to prescribe all rules and regulations which are necessary and appropriate to carry out its statutory role as a provider of a national health care system for the Nation's Veterans. Under this authority, VA establishes the qualifications of its health care practitioners, including APRNs, and regulates their professional conduct. See 38 U.S.C. §§ 7401-7464.

VA generally authorizes practice within the scope of a practitioner's state license. However, per Article VI of the U.S. Constitution (Supremacy Clause), VA may exercise its title 38 authorities to establish clinical practice standards that are more expansive or otherwise inconsistent with state practice standards.⁴ The exception is controlled substances prescribing, which by Federal law requires adherence to state licensure requirements for such prescribing. See the Controlled Substances Act at 21 U.S.C. § 823(f), and implementing regulations at 21 C.F.R. § 1306.03(a)(1). While VA nurses must be licensed to practice their profession, state scope of practice standards do not apply to VA APRNs to the extent they are inconsistent with those established by VA.

It is VA policy to provide high quality health care to its patients. All VHA health care professionals who are permitted by law and the facility to provide patient care services independently must be credentialed and privileged (C&P) as defined in VHA Handbook 1100.19, *Credentialing and Privileging*.⁵ Health care professionals who are not permitted by their license to practice independently (i.e., without physician supervision

⁴ See, e.g., VHA Directive 2008-049, Establishing Medication Prescribing Authority for Advanced Practice Nurses (August 22, 2008), which includes guidance for establishing the non-controlled substances prescribing authority of APRNs through scope of practice statements. To the extent that state scope of practice standards conflict with this policy, this Directive would control.

⁵ The term "credentialing" refers to the systematic process of screening and evaluating qualifications and other credentials, including, but not limited to: licensure, required education, relevant training and experience, and current competence and health status. VHA Handbook 1100.19, *Credentialing and Privileging*, paragraph 3.d. (October 15, 2012). Clinical Privileging is "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." VHA Handbook 1100.19, paragraph 3.e. Clinical privileges must be specific to the facility and the individual provider. *Id.*

or collaboration) are credentialed and granted a scope of practice statement.⁶ C&P must be completed prior to the initial appointment or reappointment to the medical staff and before transfer from another medical facility. Prior to the Medical Center Director's signature granting approval of practice, he/she must ensure that the privileging or scope of practice for each APRN is approved by the appropriate facility-based authorizing body, i.e., Clinical Executive Board (CEB), Medical Executive Committee (MEC), or Nurse Professional Standards Board (NPSB) and the Chief of Staff (CoS) and the Nurse Executive. All applicants applying for clinical privileges must be provided with a copy of the facility *Medical Staff Bylaws, Rules, and Regulations*, and must agree in writing or via electronic signature to accept the professional obligations reflected therein.

APRNs who are not licensed to practice independently must be credentialed under VHA Handbook 1100.19 and 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 and/or a written collaborative agreement (where required).⁷ They may be granted prescriptive authority as allowed by Federal law and/or state licensure law.

To ensure that VA practitioners are providing high quality patient care, VA policy requires their individual clinical performance to be regularly monitored. This is accomplished through various mechanisms, such as the C&P process, including biannual reappraisal and re-privileging; ongoing professional practice evaluations (OPPE) conducted at a minimum of every 6 months; supervisory reviews by collaborating physicians; etc. See VHA Handbook 1100.19.

Medical staff leadership and all staff (clinical and nonclinical) with responsibility in the C&P process must complete the one-time-only training as determined by the Office of Quality and Performance.⁸ This training must be completed within 3 months of assuming this position and may be accessed through the VA Learning Management System.

APRN prescriptive authority

To be granted prescriptive authority within VA, an APRN must:

- (a) Hold current licensure as an APRN in any state,
- (b) Complete graduate level pharmacology coursework,

⁶ Scope of practice is used to define the actions, procedures, etc. that are permitted by law for a specific profession. It outlines restrictions to what the law permits, based on specific experience and educational qualifications.

<http://www.nursestogether.com/understanding-the-different-scope-of-nursin#sthash.YUJJDavq.dpuf>

⁷ A collaborative practice agreement is a written statement that defines the joint practice of a physician and an APRN in a collaborative and complementary working relationship. It states the rights and responsibilities of both the APRN and physician. *Collaborative Practice Agreements for Advanced Practice Nurses: What you should know*. Herman, J. & Ziel, S. (1999). American Association of Critical-Care Nurses Clinical Issues, volume 10, number 3, pp 337-342.

⁸ The target audience includes Medical Staff and Credentialing Professionals; Clinical Service and Product Line Chiefs; Credentials Committee Members (Professional Standards Boards); Executive Committee of the Medical Staff members; CoS and medical facility Directors; Quality and Performance Improvement professionals; and Risk Managers.

- (c) Hold a masters or doctoral degree from an accredited nursing program, and
- (d) Maintain current certification from a nationally recognized credentialing body such as the ANCC, AANP, or American Association of Nurse Anesthetists (AANA) depending on APRN role.

See VHA Directive 2008-049, *Establishing Medication Prescribing Authority for Advanced Practice Nurses*, at paragraph 4h(2) and VA Handbook 5005/27, Part II, Appendix G6, paragraph 2, section B.a.(6). A locally-determined scope of practice must be prepared for each APRN which identifies the individual's prescriptive authority, describes the routine and non-routine professional duties, and describes the general areas of responsibility to be performed. *Id.* at paragraph 4(h)(1). APRNs who meet these requirements may have prescriptive authority for non-controlled substances. Any APRN inpatient pharmaceutical orders and outpatient prescriptions for medications not specifically included in the scope of practice must be co-signed by a physician prior to being filled. *Id.* at paragraph 4g. Under the Federal Controlled Substances Act, 21 U.S.C. § § 801, et seq., and implementing regulations in 21 C.F.R. Part 1300, a health care practitioner may prescribe controlled substances only if his or her state license authorizes such prescribing and they are either registered, or exempt from registration with the Drug Enforcement Administration.⁹ Accordingly, in defining the inpatient and outpatient medication prescribing privileges for APRNs, VA policy provides that APRNs, including NPs, may prescribe controlled substances within VA only if they are authorized to do so by their state of licensure or registration. VHA Directive 2008-049, at paragraph 2b.

The State of Georgia requires APRNs to hold a master's degree (or higher) in nursing or another related field, and national board certification at entry into practice (except for CRNAs educated prior to 1999). APRNs' authority to practice is granted by one of two statutes: Official Code of Georgia Annotated (OCGA) § 43-34-25, *Nurse Protocol Agreements* and OCGA § 43-34-23, *Delegation of Authority to Nurse or Physician Assistant*.¹⁰

APRNs authorized to practice under § 43-34-23 are regulated by BON and may perform advanced nursing functions and certain medical acts through a "nurse protocol," a written document signed by the NP and physician in which the physician delegates authority to the nurse to perform certain medical acts and provides for immediate consultation with the delegating physician. Medical acts that may be delegated include, but are not limited to, ordering drugs, treatments, and diagnostic studies. APRNs authorized to practice under § 43-34-23 may be delegated the authority to administer, order or dispense drugs, either as prescribed by a physician or authorized by the

⁹ DEA permits VA practitioners to prescribe under either an individual, fee-exempt DEA registration or the registration of the VA facility where they work, with suffix unique to the individual.

¹⁰ 26th Annual Legislative Update: Progress for APRN authority to practice, Phillips, Susanne J., *The Nurse Practitioner* Vol. 39, No. 1, 29-52.

http://journals.lww.com/tnpj/Fulltext/2014/01000/26th_Annual_Legislative_Update_Progress_for_APRN.7.aspx
Collaborative nurse protocol agreements between APRNs and physicians are used by states to define what activities an individual professional can undertake. Agreements must be in compliance with state law and filed with the appropriate state agency as required by state of licensure.

protocol. They also may call medication orders into a pharmacy and request and receive pharmaceutical samples. However, the issuance of written prescriptions is prohibited. BON regulations governing protocols require that the APRN document preparation and performance specific to each medical act.

APRNs practicing under OCGA § 43-34-25 must practice under a Nurse Protocol Agreement defined and approved by the BOM. Practice is delegated and supervised under the agreement. They may have prescriptive authority, issue a written prescription drug order, and sign for and dispense medical samples. Under a joint regulation by the BON and BOM, APRNs requesting prescriptive authority must submit a Nurse Protocol Agreement that must be approved by the BOM. Practice under § 43-34-25 prohibits APRNs from ordering certain radiographic imaging tests, such as magnetic resonance imaging and computerized tomography scans, unless there are "life-threatening situations." There is a universal requirement for periodic review of a minimum of 10 percent of patient records, as well as a requirement for patient evaluation or examination by the delegating physician in certain circumstances. For patients who receive any controlled substance prescription pursuant to a nurse protocol agreement, the delegating physician must evaluate or examine the patient on at least a quarterly basis and review and sign 100 percent of the patient's records. The delegating physician also must review and sign 100 percent of patient records in which an adverse outcome has occurred. APRNs may hold hospital privileges in certain situations.

The Medical Center authorized the APRNs assigned to Mental Health and Primary Care to practice under OCGA § 43-34-25, which requires Nurse Protocol Agreements. The APRNs licensed in Georgia did not meet the requirements for prescriptive authority. The four APRNs licensed in California, Florida, Texas, and Virginia met their states' requirements for prescriptive authority.

Of the 21 APRNs on staff at the Medical Center, 17 of them order/prescribe medications in accordance with VA's requirements for medication ordering and prescribing non-controlled substances. The remaining four APRNs do not order/prescribe medications as a part of their VA duties.

Allegation 1.

Ten APRNs in two departments at Vinson VAMC lack state prescribing privileges, but routinely write orders for prescription medication.

Findings

The whistleblower began her employment with VA in July 1989 in Salisbury, North Carolina, and in 2006 began working as a Family Nurse Practitioner (FNP). She was later recruited to the Medical Center in March 2011, where she worked until December 2012. During this period, the whistleblower worked under a North Carolina license; however, her employment was terminated when it was determined that her NP license from North Carolina was inactive because she did not have a sponsoring physician.

After a break in service, she applied for and accepted her current position to perform Compensation and Pension evaluations. She works under a Georgia license obtained in March 2014.

A Compensation and Pension disability examination may be requested for determining whether a current diagnosed disability is related to an event, injury, or disease incurred or aggravated in military service or to provide other medical evidence necessary for the Veterans Benefits Administration to render a decision concerning entitlement to VA benefits. (VHA Directive 1046, *Disability Examinations*, April 23, 2014). A Compensation and Pension examination does not create a therapeutic relationship between the provider and the Veteran requesting benefits. During these examinations, the provider does not treat any conditions or prescribe medications, but rather focuses upon evaluating medical conditions that may qualify for disability compensation or pension. Duties may include ordering laboratory and radiographic studies. Compensation and Pension examinations differ from primary care in that the latter provides continual, comprehensive, diagnostic care, including health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment of acute and chronic illnesses.

Upon her entry into this position, the whistleblower presented the Nurse Protocol Agreement form from the Georgia Medical Board to her direct supervisor (the Chief of Primary Care, who was then transitioning to the role of Acting CoS). At that time, her supervisor did not sign the form because the Acting CoS felt as if her new role would not allow for direct supervision of the whistleblower as required. The whistleblower then discussed the form with the C&P officer, who was not familiar with it and informed the whistleblower that she would follow up with the BON and BOM.

An email from the Acting CoS to the whistleblower on May 27, 2014, noted that the whistleblower would not need to submit a request for prescriptive authority to the BOM, since she was working in the Compensation and Pension section where there was no need to write prescriptions.

The whistleblower provided VA with a transcript of a personal conversation that occurred July 7, 2014, between herself and the Acting Chief of Primary Care, regarding a need "to inquire to regional counsel as to whether or not the other NPs here at the facility [were] required to have this same protocol agreement in place." According to her statement, the whistleblower did not realize until after July 21, 2014, that it was an individual's responsibility to submit forms to the BOM for approval. From May 19 to August 12, 2014, the whistleblower did not see patients.

On June 19, 2014, the RM sent the following email message to service line managers, referencing the NP Collaborative Agreements:

"I contacted the Georgia Composite Board this morning to seek answers regarding the NPs.

- *This Law has been in effect since 2007 and applies to all Nurse Practitioners practicing with a Georgia License and Certification. The Nurses already who are currently working, ordering, and prescribing without agreement or protocols will have to be processed. Otherwise the provider will have to place the orders.*
- *The Collaborative Agreement is exclusive to the VA and the designated setting only. The supervising physician is responsible only for the agreement as it pertains to the VA and the setting.*
- *The supervising physician must have an unrestricted license.*
- *Nurse Protocol Agreements must be received by the board within 30 days from the execution of the agreement.*

The following day, the RM sent an email to the previous Medical Center Director, the Acting CoS, ADPCS, and the Associate Director informing them that:

"The Medical Staff has been in the process of completing a Collaborative Agreement between the NP (whistleblower) and supervising physician. The NP will be working in Compensation and Pension section. After contacting the State Composite Board, I was told this was a new Law for Georgia. I contacted the Board later to ask if the existing NPs would require the Agreements. I was informed that all NPs are required to have an agreement with their supervising physician. NPs in the facility have always had a supervising physician; prescribed, ordered and functioned as Physician Extenders but have not had the Collaborative Agreement since the law became in effect in 2007.

Four of the existing NPs have had Collaborative Agreements while practicing in the private sector, prior to coming to Dublin. Application packets have been copied and are ready for distribution to all areas of concern Monday (6/23). The plan is have them complete and approved by 6/25." The email then lists 14 NPs who need Collaborative Agreements.

On June 27, 2014, the RM sent an email to the former CoS informing her that she "spoke with staff from VHA Office of Regulatory Affairs, and that we must follow the state law. All APRNs must have a Collaborative Agreement and they must be filed with the State Composite Board as directed by the state."

Conclusions

- **VA substantiated** that 10 APRNs in two departments (the Mental Health and Primary Care clinics) at the Medical Center lack state authority to order/prescribe medications, but routinely write orders/prescriptions for non-controlled substances under their VA scope of practice. At the time of the site visit, none of the Georgia licensed certified NPs who prescribe medication had state-approved Nurse Protocol Agreements with a physician that permitted them to order/prescribe medications. NPs from other states of licensure met the requirements for prescriptive authority. The Medical Center authorized these 10 APRNs to practice under OCGA § 43-34-25 which requires Nurse Protocol Agreements. Nurse Protocol Agreements between APRNs and physicians are collaborative in nature and used by some states to define

what activities an individual professional can undertake. Where required and not inconsistent with VA rules, regulations and policies, such agreements must be in compliance with applicable state law and filed with the appropriate state agency. The State of Georgia requires the filing of Nurse Protocol Agreements with both the BOM and BON, ongoing collaboration between the NP and delegating physician, and that the physician complete chart reviews on at least 10 percent of the NP's charts. With the exception of state requirements for non-controlled substances prescribing authority, which VA regulates, VA nurses who are licensed in the State of Georgia must comply with applicable licensing regulation.

- While we found a violation of state law on collaborative agreements and prescribing authority, we did not find any substantial risk to public health and safety. Under the Medical Center's Collaborative Agreements, APRNs work with supervisory physicians. Further, the APRNs at the Medical Center who order/prescribe non-controlled substances do so in compliance with VHA Directive 2008-049 and their VA Collaborative Agreements (where required). None of the NPs were permitted to directly prescribe controlled substances medications without co-signature from a physician. In addition, none of the NPs had been given the electronic key required to e-prescribe controlled substances. VA reviewed peer reviews, quality reviews by supervising physicians, and patient safety records and found no adverse incidents in patient care provided by the NPs.
- Medical Center Leadership became aware of the requirement for Nurse Protocol Agreements with the State of Georgia this past June, prepared a corrective plan, but did not execute it.

Recommendations to the Medical Center:

1. The C&P department must verify that all APRNs, including contract and fee-based providers, are adhering to applicable state licensure laws and VA requirements for APRN prescribing authority.
2. Ensure that APRNs are knowledgeable about their state's licensure laws and requirements, including continuing education requirements.
3. Make sure that all NPs who require collaborative agreements with their supervising physicians have them, that they are approved by each NP's state licensing board (as applicable), and are updated according to applicable state law. State laws and regulations relating to medication orders and prescriptions for non-controlled substances do not affect VA scope of practice statements.
4. Immediately implement a process to ensure that appropriate monitoring of NPs by physician collaborators occurs in accordance with applicable state licensure requirements and is documented.
5. Make sure that leadership (Medical Staff and Credentialing Professionals; Clinical Service and Product Line Chiefs, Credentials Committee Members (Professional

Standards Boards), Executive Committee of the Medical Staff members; CoSs and medical facility Directors, RMs, and Quality and Performance Improvement professionals) are educated and have a working knowledge of state licensure requirements for professional clinical staff.

Recommendations to VISN 7:

6. The QMO must verify that all C&P officers within the VISN have received proper education and annual training and/or certification appropriate to their positions.
7. The QMO must verify that VA medical centers within the VISN are following applicable state and VA guidelines for APRN practice, in accordance with each APRN's state of license and VA policies on APRN credentialing, privileging and prescribing.

Recommendation to VHA:

8. Issue an Instructional Letter to all medical centers reinforcing the requirement for compliance with VA national policies on APRN credentialing, privileging and prescribing, and applicable state licensure requirements for APRNs.

Allegation 2.

This deficiency potentially extends to all APRNs at Vinson VAMC, and constitutes a violation of state law, VA Directives, and a substantial and specific danger to public health.

NPs employed by the Medical Center

There are a total of 18 NPs, 2 contracted CRNAs, and 1 CNS employed at the Medical Center and CBOCs. VA interviewed 9 NPs, both CRNAs, and the CNS. We learned that 16 of the NPs and the CNS had Georgia licenses. One NP had a California license and another had a Florida license. In her current position, the CNS is not functioning as an APRN. Both CRNAs hold out-of-state licenses (one from Texas, the other from Virginia). State practice and licensure law in California, Florida, Texas, and Virginia restricts the ability of a nurse practitioner to practice independently and requires supervision, delegation, or team-management by a physician in order for the NP to provide patient care; however, there are no Nurse Protocol Agreements established in these states.

There are four NPs with Georgia licenses working in Compensation and Pension who do not require prescriptive authority. The remaining NPs (12) prescribe legend medications within the scope of their Federal employment.¹¹ Two NPs currently have active DEA numbers; neither has prescribed any controlled substances because local

¹¹ VHA Directive 2008-049, State laws and regulations relating to medication orders and prescriptions for non-controlled substances do not affect scope of practice statements under this Directive.

Medical Center policy does not allow this practice. The electronic ordering/prescribing package given to NPs does not include any controlled substances. The scope of practice for each NP contains documentation that NPs are not allowed to prescribe controlled substances. VA verified that all NPs are currently certified by a national credentialing body such as the American Nurse Credentialing Center or the American Academy of Nurse Practitioners.

Many of the NPs we talked to did not know the state statutes under which their practice is regulated. Most of them had the misconception that Federal supremacy precluded them from having to adhere to the regulations stipulated by their state of licensure. We also found that NPs were prescribing medications within the scope of their Federal employment, but none could directly prescribe controlled medications without co-signature from a physician. Several NPs stated that when they needed to prescribe a controlled substance, they contacted their supervising physician to discuss. The Chief of Pharmacy affirmed that none of the NPs had been given the electronic key required to prescribe controlled substances.

We found that supervising physicians performed record reviews of the NPs assigned to them as part of their supervisory responsibility. These physicians reviewed five records per month per NP supervised, and per Georgia state law, none of them had more than four NPs assigned to them.

On the first day of the MEC meeting of June 18–19, 2014, the RM presented a copy of the Scope of Practice form to the committee and informed them that it needed to be updated. According to the minutes, they took no action and the item was closed.

On the second day, the RM again brought the Scope of Practice form to the Committee's attention and this time, per the minutes, the Committee noted that Nurse Protocol Agreements were discussed and, "Now that we are aware of this, we need to comply with the Georgia Composite Medical Board." The minutes went on to say that the RM sent an email to the NPSB, informing them of the Georgia state law, that the Regional Counsel should be contacted, and that leadership should talk to service line managers. This subject was also to be discussed at the next scheduled meeting of the MEC on June 25, 2014.

As stated previously, according to the supervisor of the Credentialing and Privileging section in an email from June 20, 2014, she had prepared packets to be processed in order to meet state requirements for 14 APRNs. This message was sent to the former Medical Center Director (since retired), the former CoS (transferred to another VA facility), the Acting ADPCS, the Associate Director, the former Chief of Primary Care and current Acting CoS; Chief of HR, and C&P staff. However, VA could find no evidence that anyone at the Medical Center followed up to make sure that this action was carried out.

The responsibility for a culture of safety rests squarely with leadership. Supervisors can be held responsible for the actions of subordinate employees if they had or should have

had knowledge of specific information, or if there are policies or practices that cover the actions in question. In this case, both supervisors and employees had knowledge of the actions required to prevent a violation of Georgia state law and failed to ensure that they were carried out.

During the site visit, Medical Center Leadership shared with VA the initiatives they had taken to comply with Georgia state law, including: developing a tracking sheet to monitor compliance with C&P requirements; reviewing each APRN's status with licensure requirements for the state in which he or she is licensed along with that state's applicable laws and guidelines; and ensuring that C&P staff and supervisors completed training in the Talent Management System.

Conclusions for Allegation 2

- **VA substantiated** that all APRNs at the Medical Center licensed in the state of Georgia lack state-approved Nurse Protocol Agreements, which constitutes a violation of state law; however, we **did not substantiate** that these violations represent a substantial and/or specific danger to public health because the Medical Center had internal Collaborative Agreements in place between the APRNs and physicians. Under the Medical Center's Collaborative Agreements, APRNs work under the supervision of physicians. VA reviewed peer reviews, quality reviews by supervising physicians, and patient safety records and found no adverse incidents in patient care provided by the NPs. Although they lacked state authority to order/prescribe medications, the APRNs at the Medical Center were authorized to order and prescribe non-controlled substances in accordance with VHA Directive 2008-049 and their VA Collaborative Agreements (where required).
- VA concludes that the 17 APRNs at the Medical Center who order/prescribe medications met VA's requirements for medication ordering and prescribing. The remaining five APRNs do not order/prescribe medications as a part of their VA duties.
- VA concludes that Medical Center leadership failed to ensure that APRNs met applicable state requirements for Nurse Protocol Agreements, where required and not inconsistent with VA rules, regulations and policies. However, state requirements for the ordering/prescribing of non-controlled medications do not apply to APRNs at the Medical Center. The ordering/prescribing of non-controlled medications by APRNs is in accordance with VA rules, regulations and policies.

Recommendations to the Medical Center:

9. Make sure that all APRN licenses are verified and that each APRN declares under which state license he or she is operating (if more than one license).
10. C&P must develop a tracking system that identifies when the licenses of APRNs are about to expire, must notify the individual, and must monitor whether continuing

education and training requirements have been satisfied, and what remedial actions are necessary.

Recommendation to VA:

11. Take appropriate administrative action against individuals who had knowledge of applicable state requirements for Nurse Protocol Agreements, but failed to act promptly to ensure that APRNs had state-approved Collaborative Agreements, where required.

Summary Statement

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center employees have engaged in conduct that may constitute a violation of law, rule, or regulation, and a substantial and specific danger to public health. In particular, OGC has provided a legal review, and OAR has examined the issues from an HR perspective to establish accountability, when appropriate, for improper personnel practices. VA found violations of state law, but did not find a substantial and specific danger to public health and safety. The ordering/prescribing of non-controlled substances by NPs at the Medical Center was done in accordance with VHA Directive 2008-049. VA reviewed peer reviews, quality reviews by supervising physicians, and patient safety records and found no adverse incidents in patient care provided by the NPs.

Attachment A

Documents reviewed

Dublin VAMC, *APRN list*, December 4, 2014.

Dublin VAMC Nursing Standard Operating Procedure (SOP) 00P-24, *Scope of Practice for Nurse Practitioners*, May 3, 2013.

Dublin VAMC Nursing SOP 00P-47, *Clinical Nurse Practice Committee*, September 29, 2010.

Dublin VAMC Medical Center Memorandum 00-294, *Clinical Peer Review Process*, February 29, 2012.

Dublin VAMC, *Medical Center Bylaws and Medical Staff Rules*, May 7, 2014.

Dublin VAMC, *Medical Executive Committee Minutes/Credentialing and Privileging Minutes*, June 18, 2014.

Dublin VAMC, *Medical Executive Committee Minutes/Credentialing and Privileging Minutes*, June 19, 2014.

Dublin VAMC, *Peer Review Committee Minutes*, December 9, 2013 – November 17, 2014.

Dublin VAMC, *Pharmacy APRN electronic prescribing checklist*, November 24, 2014.

Dublin VAMC, *Quality Management Organizational Chart*, December 2014.

Georgia Composite Medical Board, *Frequently Asked Questions regarding Nurse Practitioners and Protocol Agreements*, December, 2011.

<http://medicalboard.georgia.gov/>

Georgia Composite Medical Board, *Valid Prescribing Rules for PAs and APRNs Legal requirements of a prescription for an APRN.*

<http://medicalboard.georgia.gov/valid-prescribing-rules-pas-aprns>

<http://medicalboard.georgia.gov/sites/medicalboard.georgia.gov/files/imported/GCMB/Files/APRN%20Valid%20Prescription.pdf>

Georgia State Board of Nursing, *Frequently Asked Questions*, © 2012 Georgia Secretary of State. <http://sos.ga.gov/index.php/licensing/plb/45/faq>
Indian Health Manual, Part 3, Chapter 4, Section 11, *Advanced Practice Nurses*, Transmittal Notice 06-15, July 5, 2006

http://www.ihs.gov/IHM/index.cfm?module=dsp_ihm_tn_2000_09&tn=ihs_tn_06-15

Talent Management System Training Records.

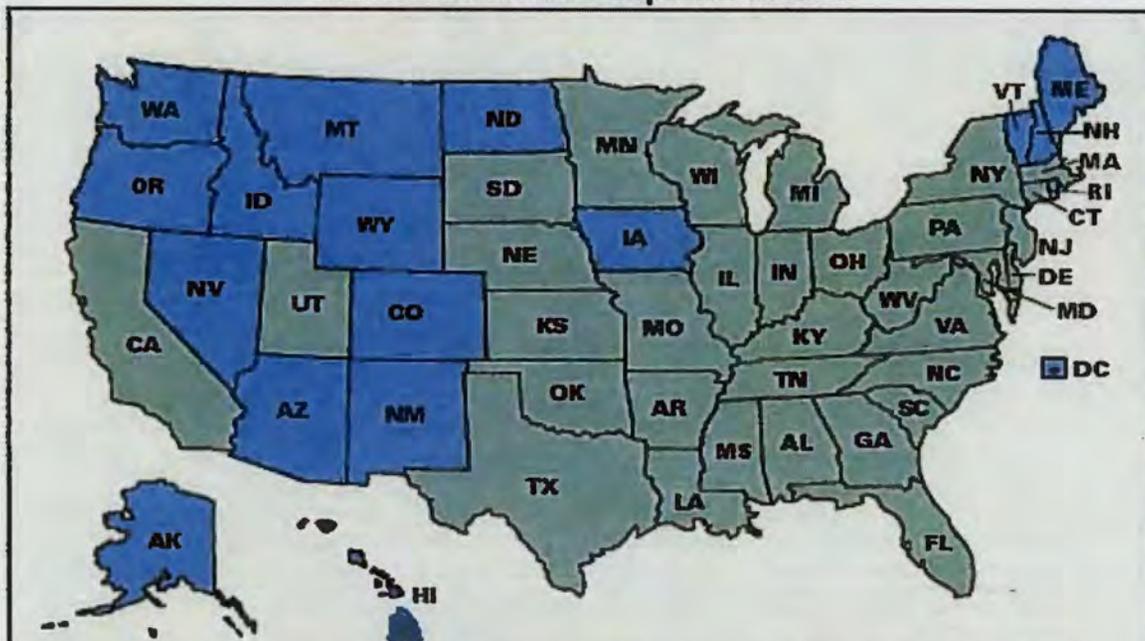
VHA Directive 2008-049, *Establishing Medication Prescribing Authority for Advance Practice Nurses*, August 22, 2008.

VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012

VHA Surgical Complexity listing of all VHA Facilities
<https://vaww.nso1.med.va.gov/vasqip/DUSHOMembeddedPages/complexity.aspx>

VHA Directive 1046, *Disability Examinations*, April 23, 2014

Attachment B Nurse Practitioner Scope of Practice



- NPs are regulated by a BON and have independent scope of practice and prescriptive authority without a requirement or attestation for physician collaboration, consultation, delegation, or supervision: AK, AZ, CO^{***}, DC, HI, IA, ID, ME^{**}, MT, ND, NH, NM, NV^{*}, OR, RI, VT^{*}, WA, WY
- NPs are regulated by a BON or a combination of BON and BOM oversight exists; requirement or attestation for physician collaboration, consultation, delegation or supervision in authority to practice and/or prescriptive authority. AL, AR, CA, CT, DE, FL, GA, IL[†], IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, NE, NJ, NY, OH, OK, PA, SC, SD, TN, TX, UT, VA, WI, WV

[Washington, D.C., is included as a state in this table.]

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- [†] This table provides a state-by-state summary of the degree of independence for all aspects of NP scope of practice and prescriptive authority. This information may or may not apply to other APRN roles; see individual states for statutory and regulatory detail on scope of practice and prescriptive authority including controlled substance authority.
 - ^{**} NPs may practice independently without physician or supervising NP involvement after 24 months of practice
 - ^{***} APNs practice independently without MD involvement after 3600 hours (1800 + 1800).
 - [#] APRNs practice independently without MD involvement after 2 years or 2000 hours of practice.
 - [^] NPs may practice independently after completion of a 2400 hour & 2 year practice agreement
 - [†] NPs with approved clinical privileges may practice independently without a collaborator agreement in a hospital or ambulatory surgical treatment center.

NURSE PRACTITIONER