



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Scopes of Practice for Unlicensed Physicians Engaged in Veterans Health Administration Research Activities

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Executive Summary

We determined in a previous inspection that certain unlicensed physicians functioned outside their scopes of practice, engaging in activities that may constitute the practice of medicine. In an effort to identify whether this problem was systemic in nature, we initiated a Combined Assessment Program (CAP) focused review, which began June 1, 2007, to evaluate whether this problem existed at additional facilities. The purpose of this review was to determine whether research activities performed by unlicensed physicians fell outside their scopes of practice, as determined by state law.

We performed this review in conjunction with 14 CAP reviews of VA medical facilities conducted from June 1, 2007, through September 30, 2007. We found that 5 of the 14 facilities did not employ unlicensed physicians in their research departments. The remaining 9 facilities identified 25 unlicensed physicians assigned to 59 human subjects research studies.

We did not find evidence that unlicensed physicians, with the exception of one, were performing activities that would constitute the practice of medicine. However, the majority of the scopes of practice were not in compliance with the Office of Research and Development's (ORD) 2003 guidance in one or more criteria and occasionally did permit providers to engage in activities generally performed by licensed personnel, such as nurses.

We did not find uniform documentation of educational verification. The lack of a clearly defined, published Veterans Health Administration (VHA) policy for educational verification of unlicensed physicians functioning as research assistants is also symptomatic of the lack of policy and guidance in this area on a national level. VHA's Office of Research Oversight does not consider that guidance posted on ORD's website has the full force of formal VHA policy.

We recommended that the Under Secretary for Health ensure that the scopes of practice for all research personnel engaged in research activities do not permit activities requiring licensure. We further recommended that the credentialing of unlicensed personnel engaged in research involving human subjects complies with the requirements of VHA policy.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health

SUBJECT: Healthcare Inspection – Scopes of Practice for Unlicensed Physicians Engaged in Veterans Health Administration Research

Purpose

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) completed a review of Veterans Health Administration (VHA) medical facilities' unlicensed physicians' practices in human subjects research. The purpose of this review was to determine whether research activities performed by unlicensed physicians fell outside their scopes of practice, as determined by state law.

Background

During the course of an inspection generated by a confidential complainant, OHI determined that certain unlicensed physicians involved in research studies were conducting activities traditionally considered to constitute the practice of medicine, such as performing invasive procedures, conducting physical examinations, and altering medications. In an effort to identify whether this problem was systemic in nature, we initiated a Combined Assessment Program (CAP) focused review, which began June 1, 2007, to evaluate whether this problem existed at additional facilities.

Research is one of the core missions of VHA. Every research project in VHA is headed by a principal investigator (PI), who is ultimately responsible for protecting the rights of human research subjects involved in the project in accordance with the Common Rule (45 C.F.R.¹ 46 Subpart A) as adopted by VA at 38 C.F.R. 16.

The Common Rule is a set of Federal regulations that contains numerous requirements for the protection of human subjects, including the requirement that all researchers (known as investigators) have the requisite skills, training, and experience to conduct the research. PIs often have several other investigators working with them on a given

¹ C.F.R. is the Code of Federal Regulations, which codifies all rules of the executive departments and agencies of the Federal government. It is divided into fifty volumes, which are known as titles.

project. Investigator refers to “an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the Institutional Review Board (IRB).”²

An IRB is a committee of researchers and community members that is charged with ensuring the protection of human subjects at a given facility. VA facilities may utilize their own IRB to review research involving human subjects or they may use an affiliated university’s IRB, providing that the university IRB complies with all applicable VA-specific regulations. Investigators may include research assistants, who are hired to perform certain tasks related to research projects. Examples of these tasks would include obtaining informed consent from individuals participating in a research project, asking research subjects questions related to the research, and compiling and managing data relevant to the projects. Research assistants may be licensed personnel, such as nurses or respiratory therapists, or they may be unlicensed personnel, such as individuals who obtain medical degrees in other countries but have not obtained licensure as physicians in the United States. Regardless of their licensure status, they are considered investigators within the meaning of the Common Rule if they are engaged in human subjects research.

Research assistants, including unlicensed physicians, operate under a scope of practice. “Scope of practice” is a term used to describe activities that may be performed by health care workers regardless of whether they are licensed independent health care providers. The scope of practice is specific to the individual and the facility involved.

A facility may not grant to an unlicensed individual a scope of practice permitting him or her to engage in activities that would otherwise require licensure or certification. We were unable to locate any specific guidance from the National Institutes of Health (NIH), the National Science Foundation, or any other Federal agency specifically addressing the appropriate scope of practice for unlicensed physicians functioning as research assistants. Activities constituting the practice of medicine are defined by state law and vary from state to state.

Because unlicensed physicians are not licensed independent health care providers or individuals claiming licensure, registration, or certification, neither the provisions of VHA Directive 2006-067, *Credentialing of Health Care Professionals*,³ nor the requirements of VHA Handbook 1100.19, *Credentialing and Privileging*,⁴ clearly applied to the process of granting these individuals a scope of practice. We do note that under the revised version of VHA Handbook 1100.19, issued October 2, 2007, the credentialing of unlicensed research personnel must now follow the requirements of this

² U.S. Department of Health and Human Services, Office for Human Research Protections, “Who are ‘investigators’?” *Human Research Questions and Answers*, <http://answers.ohrp.hhs.gov>.

³ Issued December 22, 2006.

⁴ Issued March 6, 2001. We note that the policy has since been revised as of October 2, 2007, but we applied the 2001 version as this was in effect at the time of this review.

Handbook. While this version of the Handbook was not in effect at the time of this review, we do note that a January 22, 2007, VHA Office of Research and Development (ORD), Field Conference Call, stated that VHA Directive 2006-067 did apply “to all research staff including research administrative personnel, who by the nature of their position have the potential to assume patient care-related duties.” This communication further provided an example of an unlicensed physician performing phlebotomy, stating that the unlicensed physician would be required to meet all the requirements that a phlebotomist would have to meet. ORD also stated that it would now require that unlicensed physicians, among others, be credentialed through VetPro.

VetPro is a computer program used in the VA for the credentialing of licensed independent health care providers. It contains information on licensure, disciplinary actions, and education. In addition, on March 2, 2007, VHA published Handbook 1200.1, *The Research and Development Committee Handbook*. This handbook requires the facility Research and Development (R&D) Committee to conduct an annual quality assurance review of research employees involved in human subjects research “to ensure the employees are working within their scopes of practice and their privileges allowed by the facility’s By-laws and granted to them by the facility.”

The web-based *2003 Guidance on Verifying the Credentials of All Individuals Involved in Human Subjects Research*,⁵ which was created by ORD, stated that all individuals engaged in human subjects research who are not licensed independent health care providers must provide the facility’s Research Service or the facility Director’s designee with a dated copy of a curriculum vitae or resume, an education verification form, and a completed Standard Form (SF) 85, “Questionnaire for Non-Sensitive Positions.” The PI provides scopes of practice for research staff under his or her supervision. The requirement for verification of education applies to all “education that leads to a degree or certification, and any education or training that is relevant to the activities performed by the employee.” In addition, the guidance requires that all documents pertaining to credentialing be maintained and retrievable in the facility’s research office unless the individual is subject to credentialing and privileging by another facility’s office. VHA’s Office of Research Oversight (ORO)⁶ does not consider that guidance posted on ORD’s website has the full force and effect of formal VHA policy.

Scope and Methodology

We performed this review in conjunction with 14 CAP reviews of VA medical facilities, which were conducted from June 1, 2007, through September 30, 2007. The facilities we visited represented a mix of facility size, affiliation, geographic location, and Veterans Integrated Service Network (VISN). The OIG generated an individual CAP report for

⁵ <http://www.research.va.gov/programs/pride/credentialing/guidance.cfm>.

⁶ ORO is the primary VHA office on matters of compliance and assurance regarding human subject protections, animal welfare, research safety and security, research data security, and research misconduct.

each facility. For this report, the data from the individual facility CAP reviews were analyzed as a whole for the purpose of system-wide trend identification.

We reviewed 437 medical records of patients who consented to participate in human subjects research as well as R&D Committee files for those protocols. In order to determine if the use of unlicensed physicians complied with the national policy and ORD's guidance, we reviewed each facility's local policies and procedures, patients' signed consent forms, scopes of practice, and documentation of unlicensed physicians' education.

Five of the 14 facilities did not employ unlicensed physicians in their research departments. The remaining nine facilities identified 25 unlicensed physicians assigned to 59 human subjects research studies. We validated our data during our briefings with facility managers at each site; all concurred with our findings.

This review was performed in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Results and Conclusions

Issue 1: Activities Performed by Unlicensed Physicians That May Have Required Licensure.

With the exception of one, we found no evidence that unlicensed physicians functioning as research assistants performed activities that could require medical licensure. The one unlicensed physician (hereafter Researcher 1) identified as potentially performing activities that required licensure performed physical examinations in the absence of a licensed independent provider. Initially, the facility defined Researcher 1's scope of practice to include performing physical examinations. Prior to our arrival onsite, the facility took action to stop Researcher 1 from performing this activity. Additionally, facility managers revised the scopes of practice for all unlicensed physicians to exclude this function.

Issue 2: Scopes of Practice of Unlicensed Research Personnel That Permitted Activities Generally Requiring Licensure or Certification.

The 2003 guidance on verifying the credentialing of all individuals involved in human subjects research, posted on the ORD's website, requires that the PI provide a scope of practice for research staff under his or her supervision. The scope of practice is granted and signed by the PI and reviewed and approved by the Associate Chief of Staff (ACOS) for R&D. All education that leads to a certification and any education or training that is relevant to the activities performed by the employee (such as venipuncture and technological skills) must be documented and verified.

After identifying the activities of unlicensed physicians functioning as investigators, we then sought to determine whether these activities were appropriate for their scopes of practice. All but one unlicensed physician had a scope of practice. The facility reported that this unlicensed physician was a PI on another study; therefore, a scope of practice was not deemed necessary.

We found elements in some scopes of practice that were inappropriately granted. In total, 16 of 25 scopes of practice were not in compliance with the 2003 guidance in one or more criteria. Review of the documents disclosed that unlicensed physicians were granted privileges to:

- Initiate intravenous (IV) therapy and administer IV solutions and medications.
- Perform venipuncture.

These activities generally require licensure or specialized training. Several scopes of practice were not signed by the ACOS for R&D, and one was not signed by the unlicensed physician.

Issue 3: Educational Verification of Unlicensed Physicians.

We did not find uniform documentation of educational verification. All education that leads to a degree or certification and any education or training that is relevant to the activities performed by the employee must be documented and verified. If certificates are presented, the original should be copied and noted as authentic; it should also be initialed and dated by the individual making the copy. In addition, verification by an individual who can substantiate the individual unlicensed physician's participation in the school/program should be considered and could be obtained through something comparable to a reference letter verifying participation. This verifying individual could be a professor, supervisor, or peer whose own current position can be verified.

We found that the diplomas and certifications presented by the unlicensed physicians were not true certified copies. In addition, the education verification forms were not signed by a research official to designate completion of the verification process. While these deficiencies were noted in educational verification processes, however, we note that VHA Handbook 1100.19 now requires this process to be executed through VetPro, which may alleviate concerns raised by our findings in this area.

Conclusions

The lack of a clearly defined, published VHA policy for educational verification of unlicensed physicians functioning as research assistants is also symptomatic of the lack of policy and guidance in this area on a national level. While the revised version of VHA Handbook 1100.19, dated October 2, 2007, represents a significant improvement in policy guidance for the credentialing (including educational verification) of research

personnel, we are concerned about the scopes of practice identified in this report which permitted unlicensed individuals to perform activities which might require licensure under other applicable laws. VHA Handbook 1200.1, dated March 2, 2007, requires R&D Committees to conduct annual quality assurance reviews to ensure that research employees work within their scopes of practice, but does not address the problem of ensuring that activities permitted under an individual's scope of practice do not require licensure. A scope of practice permitting an unlicensed individual to administer IV medications, for example, would not be consistent with the guidance of many state licensure authorities. We therefore made the following recommendations:

Recommendations

Recommendation 1. We recommended that the Under Secretary for Health ensure that the scopes of practice for unlicensed research personnel do not permit activities requiring licensure.

Recommendation 2. We recommended that the Under Secretary for Health require Medical Center Directors to ensure that the credentialing of unlicensed personnel engaged in research involving human subjects complies with the requirements of VHA Handbook 1100.19, dated October 2, 2007.

Comments

The Under Secretary for Health concurred with the findings and recommendations and submitted appropriate action plans. (See Appendix A, pages 7–10, for the full text of the Under Secretary's comments.) We will follow up on the planned actions until they are completed.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 3, 2008

From: Under Secretary for Health (10)

Subject: OIG Draft Report, *Healthcare Inspection: Scopes of Practice for Unlicensed Physicians Engaged in Veterans Health Administration Research Activities*, Project No.: 2007-01202-HI-0290, (WebCIMS 400383)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the report and recommendations. I agree that scopes of practice for unlicensed individuals performing activities within the Veterans Health Administration should be consistent with the guidance of other applicable laws.

2. To further ensure that unlicensed physicians engaged in research activities are not engaging in activities that require licensure, the Office of Research and Development will issue a new Directive that will require all unlicensed physicians to be credentialed through VetPro. The credentialing of research staff, including unlicensed physicians, has been required since 2003, but not all are credentialed using VetPro. The new Directive will require that all currently employed unlicensed physicians be placed in VetPro within 90 days of the issuance of the new Directive.

3. In addition, this new guidance will also require that immediate supervisors develop a scope of practice and a description of research duties for each unlicensed physician. The Associate Chief of Staff for Research and Development must approve the scope of practice as appropriate for the position held by the unlicensed physician. Further, medical center Directors will be required to approve the appointment of all unlicensed physicians and review the steps taken to credential the unlicensed physician. Once the Directive has been published, the Office of Research Oversight will be responsible for the oversight and compliance with the policies therein.

4. I believe that improved guidance and increased oversight of the credentialing process and the scope of practice development for unlicensed physicians will increase compliance with VHA Handbook 1100.19, *Credentialing and Privileging*, and applicable licensure laws. Thank you for the opportunity to review the draft report. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 565-7638.

(original signed by:)

Michael J. Kussman, MD, MS, MACP
Attachment

**Under Secretary for Health's Comments
to Office of Inspector General's Report**

Action Plan in Response to OIG Draft Report, *Scopes of Practice for Unlicensed Physicians Engaged in VHA Research Activities* (WebCIMS 400383)

Project No.: 2007-01202-HI-0290

Date of Report: February 29, 2008

Recommendations/ Actions	Status	Completion Date
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Recommendation 1. We recommended that the Under Secretary for Health ensure that the scopes of practice for unlicensed research personnel do not permit activities requiring licensure.

Concur

The Office of Research and Development is developing a new policy that will address the issue of credentialing of research staff including unlicensed physicians and other unlicensed research staff. In addition, the policy will address the concept of a Scope of Practice for research staff members. This Scope of Practice would describe the staff member's research duties and responsibilities as well as define what research procedures they can perform.

The Scope of Practice would be consistent with the occupational category under which the staff member was hired, consistent with their qualifications, and be developed by the staff member and immediate supervisor. It would also be reviewed at intervals and undated as necessary. For unlicensed physicians the content of the Scope of Practice would not contain any duties that would constitute the practice of medicine.

In process Completion date: August 31, 2008

Recommendations/ Actions	Status	Completion Date
<p>Recommendation 2. We recommended that the Under Secretary for Health require Medical Center Directors to ensure that the credentialing of unlicensed personnel engaged in research involving human subjects complies with the requirements of VHA Handbook 1100.19, dated March 2, 2007.</p>	In process	Completion date: August 31, 2008
<p>Concur</p>		
<p>The new policy will address the credentialing of unlicensed personnel in VetPro. The medical center Director as the Institutional Official responsible for the facility’s research program and its compliance with all policies would also be responsible for this aspect of the research program and the compliance with VHA Handbook 1100.19, dated March 2, 2007, <i>Credentialing and Privileging</i>.</p>		

OIG Contact and Staff Acknowledgments

OIG Contact	Marisa Casado Director, OHI Follow-Up 202 461-4705
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Acknowledgments	Annette Acosta Daisy Arugay Andrea Buck, M.D., J.D. Dorothy Duncan Jennifer Kubiak James Seitz Wilma Reyes Annette Robinson Christa Sisterhen Toni Woodard
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