

July 22, 2016

Director, Regulations Management (02REG)
Department of Veterans Affairs
810 Vermont Avenue NW, Room 1068
Washington, DC 20420

Subj: RIN 2900-AP44-Advanced Practice Registered Nurses

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide comments to the Department of Veterans Affairs (VA) regarding its May 25, 2016 proposed rule (*FR* pages 33155-33160), which would expand the scope of practice for advanced practice registered nurses (APRNs) within VA facilities.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation. Although AACC values the agency's willingness to enter into a public dialogue on this important issue, there are a number of questions and concerns about this proposal that the association would like to see addressed.

17.415(d)(i)(A)-(E)

The VA is proposing that a Certified Nurse Practitioner (CNP) have the authority to provide the following services: Comprehensive histories, physical examinations and other health assessment and screening activities; diagnose, treat, and manage patients with acute and chronic illnesses and diseases; order, **perform, supervise**, and interpret **laboratory** and imaging studies; prescribe medication and durable medical equipment and; make appropriate referrals for patients and families; and aid in health promotion, disease prevention, health education, and counseling as well as the diagnosis and management of acute and chronic diseases.

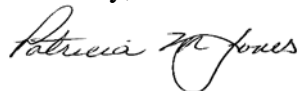
AACC requests that the VA define what CNPs would "supervise" in the context of the Clinical Laboratory Improvement Amendments (CLIA) regulations, as well as what tests they would be allowed to perform. The federal laboratory regulations have specific titles and qualifications associated with different duties within a testing facility. In addition, the personnel requirements differ based on the complexity of the test. The VA should specify what job function the Department deems the CNP qualified (e.g. high or moderate complexity laboratory director, technical supervisor, general supervisor, etc...). AACC also suggests the VA specifically detail the education, experience and specialized training of CNPs that qualifies them for those positions.

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Although AACC agrees that nurse practitioners are invaluable members of the healthcare team, their education and training covers a breadth of medical disciplines and therefore does not delve into the depths of scientific concepts underlying clinical laboratory testing. Permitting CNPs to serve in a supervisory capacity or as testing personnel, without first assuring they have the requisite experience, training and skills, could lead to unnecessary medical errors that may jeopardize patient care. AACC strongly suggests that the VA remove these provisions from the proposed rule. We further suggest that the VA enter into a dialogue with the laboratory community to discuss its specific needs and a possible solution that meets the needs of the Department, while protecting patient care.

AACC looks forward to working with the VA to improve the delivery of care to our nation's veterans. If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at vsstine@aacc.org.

Sincerely,

A handwritten signature in cursive script that reads "Patricia M. Jones".

Patricia M. Jones, PhD, DABCC, FACB
President, AACC