



# AMERICAN ASSOCIATION OF BIOANALYSTS

906 Olive Street, Suite 1200 • Saint Louis, Missouri 63101-1448 • Phone: (314)241-1445  
Fax: (314)241-1449 • Email: aab@aab.org • Web: www.aab.org

July 25, 2016

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

Dear Sir/Madam:

The following comments are submitted in response to “RIN 2900-AP44-Advanced Practice Registered Nurses.”

We are the American Association of Bioanalysts (AAB), a national association whose members include clinical laboratory directors, supervisors, medical technologists and laboratory technicians.

This proposed rule permits Advanced Practice Registered Nurses (APRNs) to “order, perform, supervise, and interpret laboratory testing...”

We presume that the laboratory testing referenced in the proposed rule includes moderate and high complexity testing as defined under the Clinical Laboratory Improvement Act (CLIA).

If so, the rule permits APRNs with no laboratory training or experience to perform and supervise high complexity tests, such as mass spectrometry, liquid and gas chromatography, fluorescent in situ hybridization (FISH), DNA/RNA sequencing, gene amplification, Polymerase Chain Reaction (PCR), Advanced Diagnostic Laboratory Tests (ADLTs), and NextGen Sequencing (NGS), without any required training/experience in the clinical laboratory, or passing an appropriate clinical laboratory certification examination.

As stated in the Supplementary Information about the proposed rule:

“...VHA has an obligation to ensure that patient care is appropriate and safe and its health care practitioners meet or exceed generally-accepted professional standards for patient care.”

Allowing APRNs to perform and supervise highly complex clinical laboratory tests for which they are not specifically educated or trained creates an unsafe environment for VHA patients.

We therefore recommend striking the words “perform” and “supervise” in regard to high complexity tests, as follows: “order, ~~perform, supervise,~~ and interpret laboratory testing...” [Section 17.415(d)(i)(B)].

Sincerely yours,

Mark S. Birenbaum, Ph.D.  
Executive Director