

March 12, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
Attn: CMS-3326-NC
P.O. Box 8016
7500 Security Blvd
Baltimore, MD 21244-80162

Re: Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (83 FR 1004).

Dear Secretary Azar,

The American Association of Nurse Practitioners (AANP), representing more than 234,000 nurse practitioners (NPs) in the United States, appreciates the opportunity to provide comment in response to the request for information on revisions to the personnel regulations under CLIA.

NPs are advanced practice registered nurses (APRNs) who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. Daily practice includes: assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs practice in nearly every health care setting including clinics, hospitals, Veterans Affairs and Indian Health Care facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health. NPs hold prescriptive authority in all 50 states and the District of Columbia. It is important to note that 89.2% of NPs are certified in primary care, the majority of whom see Medicare and Medicaid patients. NPs complete more than one billion patient visits annually.

Personnel Requirements

CMS is considering drafting proposals to amend the regulations for moderate and high complexity testing personnel to reflect current policy which includes a bachelor's degree in nursing as a qualifying degree. We agree with CMS that this policy should be codified in regulation, and a bachelor's degree in nursing should be considered as a separate qualifying degree from a biological science degree for the purposes of meeting the educational requirements for testing personnel.

CMS also requested feedback on personnel experience, training and skills requirements for positions such as medical director in a moderate complexity laboratory. Under the current regulatory framework, the only clinicians authorized to serve as medical directors in moderate complexity laboratories are physicians who are licensed by their State to serve as a laboratory director and meet the additional

education or experience requirements. Nurse practitioners who are licensed by their states to serve as laboratory directors and who meet these same education or experience requirements should have the same opportunity to fulfill this role as their physician colleagues.

As mentioned previously, daily practice for NPs includes: assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests. All nurse practitioners must complete a masters or doctoral nurse practitioner program and become nationally certified to become licensed to practice. Didactic and clinical courses prepare these advanced practice nurses with specialized knowledge and clinical competency to practice in primary care, acute care and chronic care settings, giving them advanced clinical preparation beyond their professional nursing education. We recommend that HHS amend the laboratory director qualifications to authorize NPs to serve in the role of medical director for moderate complexity laboratories.

We thank you for the opportunity to comment on this RFI and we look forward to continued discussion on improving CLIA. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

David Hebert
Chief Executive Officer