

August 22, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

Re: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories [CMS-3326-P]

Dear Administrator Brooks-LaSure:

The American Nurses Association (ANA) appreciates the opportunity to provide comment on the Centers for Medicare & Medicaid Services' (CMS') proposed update to the CLIA fees and associated regulations. ANA appreciates the agency's focus on decreasing burden and improving access to laboratory services. In response to the proposed rule, ANA urges CMS to:

- 1) Codify existing testing personnel qualifications; and**
- 2) Not categorize APRNs as midlevel practitioners.**

ANA is the premier organization representing the interests of the nation's over 4.3 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. ANA members also include the four advanced practice registered nurse roles (APRNs): nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs). RNs serve in multiple direct care, care coordination, and administration leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions including essential self-care, and provide advice and emotional support to patients and their family members.

1. CMS should codify existing qualifications for testing personnel.

CMS proposes to amend the CLIA regulations to specify that the qualifying degrees for testing personnel include an associate or bachelor's degree in nursing for moderate complexity and a bachelor of nursing degree for high complexity testing. This proposal would codify in regulation current policy that the agency has promulgated through previous guidance. ANA agrees with

CMS that nurses are providing the majority of point-of care-testing in many different situations, and underscores the recognition of the nurse role in ensuring access to laboratory services. As such, ANA urges CMS to finalize its proposal to include these degrees in nursing as qualifying degrees for testing personnel.

2. CMS must refrain from categorizing CRNAs and CNSs and all APRNs as midlevel practitioners.

CMS proposes to add CRNAs and CNSs to the definition of “midlevel practitioners,” which would allow them to fill laboratory director or testing personnel roles. While ANA supports the inclusion of these clinicians authorized to fill these roles, we remain concerned about categorizing these clinicians as midlevel practitioners. This outdated terminology does not fully capture these clinicians’ authority to practice to the full extent of their education and expertise. APRNs are licensed, independent practitioners that are integral parts of the health care delivery system—providing needed, quality services to patients. Further, the term midlevel practitioner denotes an inaccurate hierarchy within clinical practice and only serves to confuse the APRN role for patients. ANA urges the agency to either use these practitioner’s professional titles or refer to them as advanced practice providers in this and other regulations, guidance, and other agency documents.

ANA appreciates the opportunity to submit these comments and looks forward to continued engagement with CMS. Please contact Ingrida Lusic, Vice President, Policy and Government Affairs, at (301) 628-5081 or Ingrid.Lusic@ana.org, with any questions.

Sincerely,



Debbie Hatmaker, PhD, RN, FAAN
Chief Nursing Officer/EVP

cc: Ernest Grant, PhD, RN, FAAN, ANA President
Loessa Cole, DNP, MBA, RN, NEA-BC, FAAN, ANA Chief Executive Officer