

September 26, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

Dear Administrator Brooks-LaSure,

On behalf of the undersigned organizations representing Advanced Practice Registered Nurses (APRNs) and advanced practice nursing education, we appreciate the opportunity to comment on this proposed rule; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories.

The APRN Workgroup is comprised of organizations representing Advanced Nursing Education, Certified Nurse-Midwives (CNMs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs), and Nurse Practitioners (NPs). As of 2020, over 233,000 APRNs were treating Medicare patients, making it essential that the Centers for Medicare & Medicaid Services (CMS) remove barriers to care for APRNs and their patients. America's growing numbers of highly educated APRNs advance healthcare access, quality improvement and cost-effective healthcare delivery across all settings, regions and populations, particularly among the rural and medically underserved. According to the Medicare Payment Advisory Commission (MedPAC), APRNs (and PAs) comprise approximately one-third of our primary care workforce, and up to half in rural areas.¹

Testing Personnel Qualifications

CMS is proposing to amend the regulations for testing personnel (TP) to reflect current policy which includes an associate's or bachelor's degree in nursing as a qualifying degree for moderate complexity TP, and to include a bachelor's degree in nursing as a qualifying degree for high complexity TP. We agree with CMS that the majority of point of care testing is being performed by nurses in many different scenarios. As noted by CMS, this policy has been in place since 2016 under Survey and Certification memo 16-18-CLIA, and this proposal would simply codify this policy in regulation. Accordingly, we support this proposal to codify in regulation that these degrees should be added for the purposes of meeting the qualifying degree requirements for testing personnel.

Use of Term Midlevel Practitioner

In this proposed rule, CMS is proposing to add CRNAs and CNSs to the definition of "midlevel practitioner" which under CLIA regulations are "personnel qualified to serve as a LD (laboratory director) or TP in PPM laboratories." **While we support the inclusion of CRNAs and CNSs in the category of clinicians authorized to perform these functions, we strongly object to the continued use of the term "midlevel practitioner" in agency regulations, guidance, surveys and other documents.** As CMS is proposing to revise this category of clinicians in this rulemaking, it is imperative that this outdated terminology also be amended to be more reflective of APRN practice. APRNs are licensed, independent practitioners who work throughout the entire health care spectrum from health promotion and disease

¹ https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_SEC.pdf (see Chapter 2.)

prevention to diagnosis and treatment of patients with acute and chronic illnesses. The “midlevel” label originated decades ago and is not compatible with APRN licensure. It is important to note that the United States Department of Health and Human Services (HHS) has stated they are no longer using the term ‘mid-level providers’ given the ‘increasingly critical and advanced roles that PAs and APRNs play within the clinic environment.’²

The term fails to recognize the established scope of practice for APRNs and their authority to practice to the full extent of their education and clinical preparation. It confuses health care consumers and is not a true reflection of the APRN role. The term “midlevel practitioner” implies an inaccurate hierarchy within clinical practice. APRNs have a steadfast reputation for safe practice and the provision of high-quality care. It is well established that patient outcomes for APRNs are comparable to that of physicians. CMS should fully retire the use of this term as it is outdated language that does not reflect the quality of care provided by APRNs and their role in the health care system. We strongly encourage CMS to fully transition to the use of the practitioner’s professional title (e.g. nurse practitioner) or to utilize the term “advanced practice providers” when necessary and remove all references to ‘midlevel practitioner’ within regulations, guidance and information collection instruments.

We thank you for the opportunity to comment on this proposed rule 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,

American Academy of Nursing
American Association of Colleges of Nursing
American Association of Nurse Anesthesiology
American Association of Nurse Practitioners
American Nurses Association
Gerontological Advanced Practice Nurses Association
National Association of Clinical Nurse Specialists
National Association of Nurse Practitioners in Women’s Health
National Organization of Nurse Practitioner Faculties

²84 FR 7714, 7728 (see footnote 42).