

September 26, 2022

The Honorable Chiquita Brooks-LaSure, MPP
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-3326-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Notice of Proposed Rulemaking: Clinical Laboratory Improvement Amendments Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories; CMS-3326-P

Dear Administrator Brooks-LaSure:

On behalf of the undersigned organizations, we are writing to provide comment on the Centers for Medicare & Medicaid Services (CMS) recent Notice of Proposed Rulemaking (NPRM) concerning Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees: Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories. We are strongly opposed to CMS's proposal to list nursing degrees as qualifying degrees to perform high complexity testing.

In the proposed rule, CMS proposes to recognize nursing degrees for the purpose of performing non-waived testing.¹ This proposal would not require these degree holders to satisfy either the proposed bachelor's degree equivalency algorithm or complete a specific training regimen, such as that outlined in proposed § 493.1489(b)(3)(ii)(B).

Nurses provide critical patient care services, and according to CMS many perform point-of-care testing (POCT) services. Typically, POCT are simple, "waived" tests requiring little clinical training. Despite limited experience in performing such easy tests, CMS now believes that nurses should be authorized to perform highly complex laboratory tests. While we have great respect for the nursing profession and for nursing degrees as tools to provide training pertinent to the practice of nursing, these degrees do not provide the requisite scientific coursework or clinical laboratory training necessary to perform high complexity laboratory testing.

The lack of a role in test performance is apparent from the American Association of Nurse Practitioners' (AANP) State Practice Environment Map web page, which holds that "state practice and licensure laws permit all NPs to...diagnose, order and interpret diagnostic tests."² Moreover, AANP's website notes that "this is the model recommended by the National Academy of Medicine, formerly called the Institute of Medicine, and the National Council of State Boards of Nursing."

We must emphasize that high complexity testing is fundamentally different than the waived testing provided in POCT settings. Laboratory professionals complete advanced scientific coursework in

¹ Specifically, the rule would allow individuals with a bachelors (or higher) degree to perform high complexity testing and individuals with an associate degree (or higher) to perform moderate complexity testing.

² [State Practice Environment Map: Full Practice](#). American Association of Nurse Practitioners. Updated 4/15/2022. Accessed 8/17/2022.

medical laboratory science, biology, and chemistry and undergo clinical laboratory training and/or laboratory experience to hone their clinical and diagnostic expertise. CMS acknowledges that nursing degrees are *not* equivalent to medical laboratory science, biology, and chemistry degrees, yet by placing nursing degrees alongside these degrees in proposed § 493.1423(b)(2), § 493.1423(b)(4) and § 493.1489(b)(3), *CMS is effectively treating nursing degrees as equivalent.*

CMS states in the rule that it believes academic degrees recognized for high complexity testing “*should be in a science that deals in the kind of clinical laboratory testing, that is...related to testing of human specimens (emphasis added)*...” CMS says it would not consider degrees such as environmental sciences, biotechnology, and marine biology “to be appropriate degrees under the CLIA program because these degrees do not generally appear to be focused on clinical laboratory testing or focused on the testing of human specimens, which is the scope of the CLIA regulations.” We strongly agree but are left wondering why CMS would treat nursing degrees differently.

An examination of a typical bachelor of science in nursing (BSN) degree reveals it obviously lacks scientific coursework comparable to degrees in medical laboratory science, biology, and chemistry. The BSN requires, on average, between 14-19 semester hours of the requisite science coursework, almost all of which is introductory level coursework. Compared to CMS’s proposed bachelor’s degree equivalency algorithm,³ which requires 48 semester hours of biology or chemistry, BSN degrees contain only 29-40 percent of the requisite academic science.

CMS’s proposal, as written, could jeopardize the quality of laboratory testing and patient safety. We recommend that nursing degree holders be subject to the same equivalency standard that it expects every other non-Medical Laboratory Scientist (MLS) bachelor’s degree holder to meet. If an individual’s nursing degree satisfies CMS’s proposed bachelor’s degree algorithm, then that individual should be eligible to begin training to perform laboratory testing.

We recommend that CMS: (1) create a pathway similar to that outlined at § 493.1489(b)(6) for blood gas analysis to enable nursing degree holders to perform POCT, provided they are under the direction and oversight of a CLIA-qualified high complexity laboratory director; (2) remove nursing degrees from proposed § 493.1489(b)(2), and (3) add the proposed bachelor’s degree equivalency route to § 493.1489(b). This would allow high complexity testing by nursing degree holders in the domain with which they are familiar. This would also expand the laboratory workforce to allow clinical laboratories to hire individuals with non-traditional degrees who have significant scientific coursework.

As for moderate complexity testing, it is unnecessary for CMS to add the associate’s degree in nursing as this degree should easily satisfy the “equivalency” requirement specified in § 493.1423(b)(6). This route

³ CMS proposed bachelor’s degree equivalency algorithm requires: (ii) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(A) 48 semester hours of medical laboratory technology courses; or

(B) 48 semester hours of science courses that include—

(1) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(2) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(3) 24 semester hours of chemistry, biology, or medical laboratory technology in any combination.

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also outlines laboratory testing competencies that may not be received if nursing degrees are listed alongside with medical laboratory science, biology or chemistry degrees in § 493.1423(b)(2) & (b)(4).

We appreciate the opportunity to comment on this proposed rule and look forward to working with the Agency to ensure quality testing. If we can be of any assistance, please contact Matthew Schulze, Director of the ASCP Center for Public Policy, at 202-735-2285 or Matthew.Schulze@ASCP.org.

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists
American Association for Clinical Chemistry
American Medical Technologists
American Pathology Foundation
American Society for Clinical Pathology
American Society for Clinical Pathology Board of Certification
American Society of Dermatopathology
Association of Directors of Anatomic and Surgical Pathology
Association of Pathology Chairs
Association of Public Health Laboratories
College of American Pathologists
Philippine Association of Medical Technologists - USA, Inc.
Society of Black Pathologists
Society for Pediatric Pathology