American Hospital Association™
Advancing Health in America

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August 23, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445–G
Washington, DC 20201

RE: CMS-3326-P, Clinical Laboratory Improvement Amendments (CLIA) Fees: Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories: Proposed Rule (Vol. 87, No. 142), July 26, 2022.

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Clinical Laboratory Improvement Amendments (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories.

The objective of CLIA is to ensure high quality laboratory testing; indeed, since CLIA was enacted, the quality of laboratory testing has improved. In this rule, CMS proposes to update several components of the CLIA regulations, which the agency notes have not been substantially updated since 1992. In our comments below, the AHA offers feedback on the proposed changes to the testing personnel requirements and the application of alternative sanctions to certificate of waiver (CoW) laboratories.

<u>Testing Personnel Requirements</u>
The nation's clinical laboratory professionals play a crucial role in health care. The testing they perform is key to the early detection, diagnosis and treatment of disease in patients. The more complex the test is to perform or interpret, the more stringent are the CLIA personnel, instrument and testing requirements.

In the rule, CMS proposes to add nursing degrees, including an earned doctoral, master's and bachelor's degree in nursing, as a means to qualify as high complexity testing personnel. **The AHA does not support this proposal.** The types of laboratory tests classified by CMS as high complexity require a level of knowledge, training and result interpretation that we believe exceeds the typical nurses training — even at the doctoral and masters' levels. High complexity tests also require extensive expertise in the technical aspects of clinical laboratory testing, such as complex and consistent sample preparation, which is critical to proper test completion and accurate interpretation of results, but is not taught in nursing programs.

Further, nursing degrees generally include a lower amount and level of academic science and clinical training in non-waived laboratory testing that is necessary for qualified laboratory professionals. For example, bachelor's degrees in medical laboratory science, biology and chemistry generally require at least 35 to 45 semester hours of academic science, with significant upper-level coursework. By contrast, bachelor's degrees in nursing often require less than 14 semester hours in biology and/or chemistry, and usually only at the introductory level. By proposing that nursing degrees should be considered as equivalent to clinical laboratory science, biology and chemistry degrees, CMS' proposal also would result in individuals with nursing degrees not being required to meet any other coursework or clinical training requirements under CLIA. We are concerned that this would weaken CLIA's regulatory structure and its ability to continue to ensure the highest quality of laboratory testing.

In its rationale, CMS states that nurses perform the majority of point-of-care (POC) testing, and therefore the agency does "not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing." It is true that advances in the technology of laboratory testing have allowed more testing to be provided closer to where patients are located, through the expansion of POC testing in hospitals and health systems, and that nurses play an important role by performing such testing. However, these tests are mostly simple waived tests (such as dipstick urinalysis tests) performed at the patient's bedside, for which there are no CLIA personnel requirements. Given the substantial difference in test complexity between waived and high complexity tests, we are not convinced by CMS' rationale.

The AHA encourages the agency not to finalize this proposal, which we believe would weaken CLIA's intent to safeguard the quality of laboratory testing.

<u>Alternative Sanctions for Certificate of Waiver (CoW) Laboratories</u>
In the current CLIA regulations, CMS may impose alternative sanctions (i.e., directed plan of correction, civil money penalty, state onsite monitoring) in lieu of, or in addition to, the more onerous principal sanctions (i.e., revocation, suspension, or limitation sanctions) for non-compliance in all CLIA-certified laboratories, *except for* CoW laboratories. CoW laboratories are laboratories that only perform waived tests, that is, simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. In our comments to a January 2018 CMS request for information, the

AHA recommended that the imposition of alternative sanctions should be an option for all CLIA-certified laboratories, and noted that it should particularly be an option for proficiency test (PT) referral violations for waived tests.

CMS notes that during the COVID-19 public health emergency, this additional authority was temporarily granted via an interim final rule related to the pandemic. **The AHA supports CMS' proposal to make this a permanent change by continuing to permit the use of alternative sanctions in CoW laboratories.** The use of alternative sanctions instead of principal sanctions should continue to be an option to create parity for all certificate types, especially in cases of PT referral.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director of policy, at rschulman@aha.org or 202-626-2273.

Sincerely,

/s/

Stacey Hughes
Executive Vice President