



March 12, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3326-NC
P.O. Box 8016
Baltimore, MD 21244-8016

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) [Docket No. CMS-2017-0165; CMS-3326-NC]

Dear Sir/Madam:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the Centers for Medicare & Medicaid's, "Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)" (hereinafter, "RFI"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is supportive of CMS's efforts to improve CLIA personnel requirements. Pharmacists play an important role in optimizing medications and also provide disease management and prevention services, among others. In addition, pharmacists are the most accessible health care practitioner with 89% of Americans living within 5 miles of a community pharmacy. Therefore, pharmacists are well positioned to improve the impact of tests, such as point of care tests, on patient care. We offer the following suggestions in response to the RFI.

I. Clarification of Degree(s)

As CMS considers equivalency of different degrees, such as the equivalence of a bachelor's in nursing, APhA encourages CMS to also consider the equivalence of pharmacists'

education and training.¹ APhA recognizes the role pharmacists play in optimizing the impact of medications and believes CMS should use this opportunity to improve patient care by expanding access to certain tests by taking advantage of pharmacists' expertise.

II. Other Requirements for CLIA Personnel Categories

As CMS is aware, advancements in technology have spurred development of laboratory tests with different functionalities, results, and speed in which results are produced, among other changes. Currently, pharmacists perform CLIA-waived tests, generally at the point of care, to help patients manage their medications and certain chronic diseases, in addition to providing other health and wellness services. Pharmacists are also playing a key role in antibiotic stewardship, where rapid diagnostic testing is playing a growing role. Some moderate and possibly high risk tests could benefit patients if access to them were improved by providing more regulatory flexibility to increase their availability while maintaining patient safety. Because of pharmacists' expertise, such as in the management of medications and chronic diseases, pharmacists could help alleviate the risk of certain tests if they were included in relevant CLIA personnel categories. Better including pharmacists in CLIA personnel categories would allow patients to more seamlessly and safely receive results and subsequent interventions.

Although CMS uses personnel categories when determining who may perform certain tests and where those tests are to be performed, APhA also encourages CMS to consider relevant factors such as tests types, results content and format, and care settings and models, to better address patient access and needs across the care continuum. APhA recognizes the various settings in which health care providers practice and how care models are evolving. To the extent possible, APhA recommends CMS consider how CLIA personnel categories can be modified to better reflect the current health care landscape.

III. Proficiency Testing Referral

For proficiency testing referral sanctions, APhA requests CMS consider alternative sanctions for CoW laboratories, like it does for other CLIA laboratories. Additionally, APhA appreciates CMS's decision to seek evidence, research and trends before deciding whether alternative sanctions should be an option.

IV. Recommended Changes to CLIA

Many pharmacies obtain a CLIA Certificate of Waiver (CoW) to perform CLIA-waived tests such as cholesterol tests and fasting blood glucose at the point of care. As CMS is aware, FDA-approved Class I and sometimes Class II devices may become CLIA-waived, thus accessible in a pharmacy with a CoW. APhA encourages CMS when establishing policies to improve CLIA regulations to improve patient care, to recognize pharmacists' education and training and ability to mitigate risk tests and devices may pose.

¹ Accreditation Council for Pharmacy Education, Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy, Approved January 25,2015, available at: <https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf>, last accessed: March 5, 2018.

Thank you for the opportunity to provide feedback regarding steps FDA can take to reduce burdens while still achieving the agency's public health goals. If you have any questions or require additional information, please contact, Jenna Ventresca, Director of Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs