



December 7, 2017

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Review of Existing Center for Devices and Radiological Health Regulatory and Information Collection Requirements [Docket No. FDA-2017-N-5105-0001]**

Dear Sir/Madam:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the Food and Drug Administration's, "Review of Existing Center for Devices and Radiological Health Regulatory and Information Collection Requirements" (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 FDA's efforts to modify, repeal or replace existing regulations to meaningfully reduce burdens while FDA continues to achieve its public health mission and fulfill statutory requirements and in particular, with regard to Center for Devices and Radiological Health (CDRH) regulations. Because pharmacists play such an important role in optimizing medications, as well as being an important access point for monitoring and prevention services, they are well-positioned to improve the impact of certain devices, including point-of-care tests used for drug therapy management. APhA believes that the pharmacist's education, training and experience places them in an excellent position to advance the development and use medical devices throughout the patient care continuum and offer the following suggestions in response to the RFI.

**I. Pharmacists Role in Risk Mitigation**

Currently, FDA's risk-benefit paradigm categorizes tests used for drug therapy management purposes, including pharmacogenomics, into three classes. Although there are general and special controls, they do not take into account the role of the pharmacists in interpreting and communicating test results and their ability to decrease the level of risk associated with a device. With the most education and training regarding medications and optimizing their impact, pharmacists are the medication experts on care teams. Currently, schools of pharmacy are required to include pharmacogenomics into curriculums, and we see

pharmacogenomics and point-of-care testing only increasing in significance both in school curriculums and in practice settings. Additionally, there is a growing number of continuing education offerings on pharmacogenomics and point-of-care testing available for pharmacists, and certain residency programs include a focus on pharmacogenomics and/or laboratory methods. APhA believes pharmacists' education and training enables them to mitigate risks associated with certain Class II devices and encourages FDA to consider how pharmacists can be utilized such that certain Class II devices are made more accessible, including through reclassification.

## **II. CLIA Improvements**

Many pharmacies obtain a CLIA certificate of waiver so they may perform CLIA-waived tests such as cholesterol tests and fasting blood glucose at the point of care. As FDA is aware, Class I and in more limited cases, Class II devices, may become CLIA-waived, thus accessible in a pharmacy with a CLIA certificate of waiver. However, APhA believes some Class II devices, such as those with drug therapy management applications, could be CLIA-waived, provided pharmacists were utilized in administration, interpretation and/or communication of results, to reduce associated risks. APhA is supportive of FDA's efforts to concurrently consider device applications for approval and CLIA-waiver. However, to meet FDA's intended goals of increasing access and reducing burden, APhA believes FDA's efforts to expand patient access to devices through CLIA-waiver can be enhanced by considering alternative methods, such as the use of pharmacists, to mitigate risks of devices, including those which are Class II.

In addition, APhA recommends FDA work with CMS to enable pharmacists to perform certain moderate risk tests, including those related to drug therapy management (e.g., pharmacogenomics). In some states, pharmacists are, under certain conditions, explicitly authorized to order and interpret moderate complexity tests. 42 CFR, Part 493, Subpart M regulations dictate who may perform a moderate complexity test with a carve-out specifically for provider-performed microscopy procedures. Given the variation in types of devices and tests emerging, APhA encourages FDA and CMS to consider how regulations regarding moderate complexity testing could be modified and modernized to reflect new tests and devices, and incorporate additional health care professionals whose roles also continue to evolve.

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](mailto:jventresca@aphanet.org) or by phone at (202) 558-2727.

Sincerely,



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