June 28, 2018

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

Re: Development of 21st Century Cures Act Section 3060 Required Report: Request for Input (FDA-2018-N-1910)

Dear Sir/Madam:

APhA is pleased to submit these comments to the Food and Drug Administration's ("FDA"), "Development of 21st Century Cures Act Section 3060 Required Report: Request for Input" (hereinafter "RFI"). The American Pharmacists Association ("APhA") was founded in 1852, and represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and other parties invested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates FDA's regulation of device, including software that meets the definition of a device, to help ensure their appropriate, safe and effective use. APhA recognizes under law,[1] medical software functions intended (1) for administrative support of a health care facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as electronic patient records, (4) for transferring, storing, converting formats or displaying data, or (5) to provide limited clinical decision support, are not considered a device. APhA encourages FDA to provide information to pharmacists, patients and other health care practitioners regarding the findings from this RFI in a manner that is easy to understand. In response to FDA's RFI, APhA offers the following information related to non-device software's risks and benefits.

I.   Administrative Support

a. Billing and Claims

Software to facilitate billing and claims has significantly reduced administrative burdens on pharmacists, streamlined care and helped patients more efficiently obtain prescriptions. As prescription drug plan coverage has become more complex, such as through prior authorization and other drug utilization review tools, software has evolved to provide coverage information that is consistent with the payer's coverage policies. Therefore, billing and claims software

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[1] 21 U.S.C. 360j(o)(1)(A)-(D))

influence the medication a patient will receive based on coverage policies.

b. Metric Tracking

As with other health care professions, metric tracking has become the norm for many pharmacists. Several common metrics are intended to reflect productivity and operating efficiency, however, it is not clear how these measures, including those used to dictate workflow, impact patient safety. The risks and benefits of software that tracks metrics are unknown due to their variable application by employers and other entities. APhA encourages the adoption of patient-centered quality and performance measures that align with safe delivery of patient care services, and opposes the setting and use of operational quotas or time-oriented metrics that negatively impact patient care and safety. To the extent software enables metric tracking (e.g., prescriptions processed per hour, average prescription processing time), APhA believes patient care and safety can be negatively affected by software functionality that only considers productivity and operating efficiency.

II. Limited Clinical Decision Support

Pharmacists often utilize clinical decision support tools when caring for patients. For example, support tools identifying drug-drug interactions can be helpful to pharmacists reviewing patients' medications. Such tools can help improve efficiency, act as a source of information and improve patient safety when used by a pharmacist. However, information and training regarding how certain clinical decision support tools make recommendations or issue an alert is often not provided or easy to find. In addition, some alerts pharmacists receive, such as those from payers, may not indicate whether the issue pertains to safety or coverage policies. As FDA continues to evaluate whether or not certain clinical decision support tools meet the definition of device, APhA encourages FDA to consider different users, such as pharmacists, and the impact of different software applications at different points along the care continuum.

Thank you for your leadership and work on this issue. If you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan

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Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government
        Affairs