AMERICAN PHARMACISTS ASSOCIATION
Improving medication use. Advancing patient care.

December 11, 2017

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

Re: Format and Content of a REMS Document Guidance for Industry (FDA-2009-D-0461)

Dear Sir/Madam:

APhA is pleased to submit these comments to the Food and Drug Administration's ("FDA") revised drafted guidance, "Format and Content of a Risk Evaluation and Mitigation Strategy Document" (hereinafter "Draft Guidance"). The American Pharmacists Association ("APhA") was founded in 1852, and represents 64,000 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 ongoing efforts to gather input from stakeholders on issues related to REMS and to operationalize that feedback to enhance the REMS program for patients, providers and sponsors. Pharmacists are frontline providers of REMS drugs who also often become the default coordinators of REMS programs. As work continues, APhA's goal is to be a resource for FDA and manufacturers as they further refine and enhance REMS programs to meet the needs of patients and the health care system. APhA supports FDA's efforts to encourage submission of a REMS document in a clearer, more informative, and standardized document. We offer the following recommendations in response to the Draft Guidance.

I. REMS Requirements

The Draft Guidance indicates safe use conditions, such as verifying prescriber certification or the completion of a required lab test, are administrative or clinical requirements, and are often completed at the pharmacy level. The Draft Guidance indicates a pharmacy may be responsible for setting up their own system to verify that the safe use conditions have been met. While pharmacists do currently develop verification procedures, APhA believes certain verification procedures could be standardized to alleviate the need to develop separate

procedures for each REMS program. APhA encourages FDA to work with pharmacists and other stakeholders to identify standardized verification methods for safe use conditions to help decrease burdens associated with REMS programs for all stakeholders.

II. REMS Development and Evaluation

Recently, FDA identified changes to the REMS program, such as the modifications noted in the Draft Guidance and those discussed in the Platform Standards Initiative.[1] APhA continues to advocate for manufacturers to proactively include pharmacists in their REMS programs starting at development and continuing after implementation. We also encourage ongoing evaluation of program-wide changes evaluation.

III. Team-based Care

The Draft Guidance helps clarify prescriber and pharmacist responsibilities by highlighting those tasks each provider must perform in provider-specific tables. However, the tables do not recognize other potential members of the care team or identify opportunities for collaboration. APhA believes that the initial apportionment of REMS elements should be done with prescriber and pharmacist input in order to provide insight to current models of care and workflows. Leveraging clinician knowledge to pinpoint potential problems and areas for improvement offers sponsors the opportunity to improve REMS requirements proactively, rather than relying on disruptive remedial modifications post-implementation. While APhA agrees with the decision to clarify each providers' responsibilities, we believe additional efforts, such as prescriber and pharmacist input for REMS requirements, are needed to help ensure that requirements are not unnecessarily burdensome and reflect current care models.

IV. Integration of REMS Into Clinician Workflows

APhA has consistently advocated the incorporation of REMS programs into existing prescriber and pharmacist patient care work flows. Leveraging existing electronic systems and infrastructures, including electronic health records ("EHR") systems, e-prescribing systems, pharmacy management systems, and claims communications technologies creates the possibility of interoperability and enhances information-sharing among providers without the necessity of expensive new information technology ("IT"). APhA appreciates FDA efforts, including the REMS Integration Initiative and Platform Standards Initiative, to start to better integrate REMS into clinician workflows. We encourage FDA to continue to collaborate with pharmacists and other stakeholders on these efforts as the REMS program and health care industry evolve.

Thank you for your leadership and work on this issue. We look forward to supporting FDA's efforts to improve patients' access to affordable and safe medications through feasible

[1] *See* Food and Drug Administration (November 7, 2017). FDA is Making It Easier to Meet Required Extra Safety measures for Certain FDA-Approved Drugs, available at: https://blogs.fda.gov/fdavoice/index.php/tag/risk-evaluation-and-mitigation-strategy-rems/, last accessed: December 4, 2017.

implementation approaches. If you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

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Executive Vice President and CEO

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