October 4, 2013

U.S. Department of Health and Human Services
Office of Disease Prevention and Health Promotion
1101 Wootton Parkway, Suite LL100
Rockville MD 20852

[Submitted electronically to ADE@hhs.gov]

Re: Draft National Adverse Drug Event (ADE) Action Plan

Dear Sir/Madam:

APhA is pleased to submit these comments regarding the federal Department of Health and Human Services’ draft National Action Plan for Adverse Drug Event (“ADE”) Prevention (hereinafter, the “Action Plan”). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 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, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

APhA thanks HHS for its ongoing work regarding the prevention of ADEs. ADEs have a significant impact on individual patients and the U.S. health care system, and we applaud HHS’s efforts to address this multi-faceted, complex problem. The Action Plan is an excellent first step in creating a much-needed system to address and prevent ADEs in this country. Leveraging a variety of resources, including federal systems, health care providers, and patients, is necessary to address this important patient safety issue.

In reviewing the Action Plan, it is clear that HHS not only appreciates the critical role of pharmacists in preventing ADEs, but also recognizes the dramatic difference pharmacists can make in improving the overall quality of patient care. APhA believes that pharmacists, as part of the health care team, can effectively contribute to the six priorities outlined within the framework proposed in the Action Plan. We would also like to take this opportunity to thank HHS for acknowledging both the economic barriers to the uptake of ADE prevention strategies and APhA’s continuing efforts to secure compensation for pharmacists’ patient care services, which would enable pharmacists to provide enhanced services to all patients.

APhA knows that ADEs have a substantial impact on quality of care and outcomes for patients, and that they also generate substantial costs to our health care system. To that end, APhA firmly believes that the use of pharmacists’ knowledge and expertise in medication
therapy as part of the health care team would be beneficial in addressing not only the three drug classes included in the Action Plan, but also many other therapeutic agents that commonly contribute to ADEs.

APhA appreciates the Action Plan’s focus on quality measures and its emphasis on the need for meaningful measures to track ADEs. We encourage a coordinated, inter-professional approach to the development and implementation of new measures that reflect the roles and activities of all health care providers who work to prevent ADEs.

I. Pharmacist Contributions to Prevention of ADEs

Overall, APhA supports the steps for ADE prevention that HHS has laid out in the Action Plan. The use of the National Quality Strategy (“NQS”) standards as a framework for the Action Plan is a natural fit, as it aligns very closely with the principles pharmacists put into practice with their own patients on a daily basis. It is evident that HHS spent a great deal of time and energy crafting a comprehensive Action Plan. In particular, APhA was pleased with the inclusion of the following elements:

- **Patient-Centered, Coordinated Care:** For more than fifty years, pharmacists in the inpatient setting have worked collaboratively with other healthcare providers in a team-based approach to care. As a result, there have been significant improvements in medication safety, ADE reduction, and identification and resolution of medication-related problems. Now the collaborative care model has expanded to the ambulatory care and outpatient environments, with pharmacists working closely with prescribers to ensure that patients receive the most effective and safe medication regimens. Because of pharmacists’ medication expertise and accessibility, they are uniquely positioned to assist patients in their medication self-management, optimization of medication regimens, and minimization of risk.

  APhA considers patient-centered, coordinated care to be the gold standard, and supports its use where possible. We were pleased that HHS identified care teams (e.g., in anticoagulation clinics—p.74) as a means of providing quality, efficient patient care, and recognized pharmacists as members of those teams. Patients benefit from pharmacists’ medication therapy expertise, and pharmacists are well-equipped to assist in helping patients with the three medication categories profiled in the Action Plan. However, before expanding these activities to other conditions and care settings, payment models to support these activities must be identified and implemented.

  In addition, with regard to anticoagulation, the Action Plan (p. 84) references the contributions of pharmacogenomics testing to reducing anticoagulation therapy related to ADEs. APhA supports the role of pharmacists in interpreting these test results and using those results, in collaboration with prescribers, to customize therapy for each patient. APhA recently published a white paper titled “Integrating Pharmacogenomics into Pharmacy Practice via Medication Therapy Management”, which identifies strategies and recommendations for greater integration of pharmacists into patient care that HHS may want to consider in the prevention of ADEs.¹

¹ This white paper was published after a meeting held at the request of HHS’s Personalized Health Care Initiative. A copy of the paper can be found here: [http://www.pharmacist.com/sites/default/files/files/mtm_integrating_pharmacogenomics.pdf](http://www.pharmacist.com/sites/default/files/files/mtm_integrating_pharmacogenomics.pdf).
Medication Reconciliation: Several sections of the Action Plan cited medication reconciliation as an effective tool in preventing ADEs (e.g., anticoagulation clinics, care transitions, and long term care). APhA supports the use of medication reconciliation as a proactive approach to improving patients’ health, safety, and well-being through patient education, empowerment, and active engagement in care. The pharmacist’s role in medication management during care transitions is critical to effectively minimizing the risk of ADEs from all medications. Pharmacists providing medication management and coordination of medication-related care help patients understand the proper use and self-management of their medications. In addition, pharmacists can share relevant information with other health care providers; such coordination is especially important when patients transition among multiple providers and multiple health care settings.

While medication reconciliation is commonly referred to as a reconciled medication list, effective medication reconciliation requires the knowledge, training and expertise of the pharmacist to identify and address medication-related problems. APhA, in collaboration with the American Society of Health-System Pharmacists, has done substantial work in this area and has publicly released a white paper titled “Improving Care Transitions: Optimizing Medication Reconciliation” and a report detailing best practice models titled “ASHP-APhA Medication Management in Care Transitions Best Practices” which may provide HHS with additional information to assist in effectively implementing the Action Plan.

As systems are reengineered to address ADEs for all medications, smooth care transitions, including uninterrupted medication management, are essential. APhA believes that pharmacists are well-suited to the task of designing, implementing, and conducting medication management services during care transitions, thus billing and compensation systems for such transitions should include pharmacists. Investments in these systems and services would produce a very favorable return on investment for the health care system due to improved quality of care, patient safety, and reduced morbidity and mortality.

While HHS has enumerated a number of areas where pharmacist services are being used to great advantage (i.e., Community-Based Care Transitions Program, Multi-Payer Advanced Primary Care Practice), APhA has identified some areas of concern, as well as some areas where pharmacist services could be better utilized to enhance patient care, as set forth below.

Surveillance—Medication Use and Drug Denominators (p. 26). APhA agrees that the data regarding medication use provides important information related to ADEs. HHS acknowledges that interpreting this data involves consideration of diverse factors, including “prescribing, medication use, and chronic disease burden.” Given that pharmacists’ work often occurs at the intersection of these factors, pharmacists reviewing the data may be able to tease out trends that might not be apparent to those

---

in another discipline. Thus, we suggest that, when possible, HHS involve pharmacists in the review of this data.

Additionally, while HHS states that national surveillance for ADEs attributable to under-treatment or medication omissions is outside of the scope of the Action Plan, these are serious issues that can have a dramatic impact on patient outcomes. APhA strongly encourages HHS to consider these factors in future efforts.

In considering other opportunities for surveillance, APhA advocates data capture at the pharmacy level to collect ADE data at the patient-level “point of sale”. Expanding systems of post-market surveillance in such a way may provide additional raw ADE data for analysis.

• **Affordable Care Act—Health Care Delivery Models** (p. 35). APhA supports the continued expansion of the coordinated service delivery models included in the Affordable Care Act. If these care models are central to ADE prevention, as HHS opines in the Action Plan, it is important there are no regulatory or administrative barriers to hinder pharmacists’ participation in accountable care organizations (“ACOs”) and patient-centered medical homes (“PCMHs”).

• **Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs** (p. 44). While pharmacists could greatly benefit from access to incentives for use of electronic health records (“EHR”) and other health information technology (“HIT”), they are not currently “eligible professionals” within the meaning of these programs. 4 Pharmacies and pharmacists do invest in HIT, they just have to use more of their own resources to do so, meaning that HIT adoption is uneven and underserved or rural communities often lack the access that is considered standard in more urban, prosperous regions. HHS should support efforts to promote adoption and use of HIT and health information exchange in medication management to prevent ADEs. Recognizing pharmacists as “eligible professionals” for the EHR incentive program would contribute significantly to this effort.

• **Provider Education.** Education of health care providers and patients will be critically important to advancing the Action Plan. While supplying resources, tools, and algorithms is consistently mentioned throughout the Action Plan, education, especially of health care providers, seems to be missing from the “Effective Communication and Coordination of Care” sections of the anticoagulant inpatient and outpatient strategies (p. 67 and 72) and the diabetes inpatient and outpatient strategies on (p.141 and 142).

• **Reimbursement** (p. 70). In the discussion of reimbursement and incentives, HHS notes that not all providers have access to all opportunities. Pharmacists provide essential services, but are not recognized as “providers” within the Social Security Act. As a result, reimbursement for pharmacists is severely limited. APhA supports

---

4 Under the Incentive Program regulations, an “eligible professional” refers to “a physician as defined in section 1861(r) of the Act, which includes, with certain limitations, all of the following types of professionals: (1) A doctor of medicine or osteopathy; (2) A doctor of dental surgery or medicine; (3) A doctor of podiatric medicine; (4) A doctor of optometry; (5) A chiropractor.” 45 C.F.R. § 495.100.
alignment of incentives to further the goals of the Action Plan, including appropriate reimbursement models for all pharmacists and other providers.

- **Diabetes Agents.** As noted in the Action Plan, errors in prescribing insulin can be grave. Pharmacists in the inpatient and outpatient environment serve an important role in the evaluation of treatments and medication dosing related to diabetes. The Action Plan notes (p. 110) that medication errors often occur at discharge due to poor communication with the patient regarding dosing and usage instructions. As mentioned previously in the medication reconciliation section, pharmacists can play a significant role in this area as part of a care team—an approach the American Diabetes Association advocates. Additionally in the outpatient setting, once patients leave the hospital, the engagement of these patients in diabetes self-management programs (which emphasize shared decision-making and patient engagement) results in improved patient outcomes.\(^5\)

To build on the steps outlined in the Action Plan, HHS should also consider the use of a standardized process to assess individual patient need for glucagon devices for self-administration in the event of an urgent or emergent hypoglycemic event. APhA actively supports pharmacist training in this area, the development of standardized processes/algorithms, and the implementation of programs by which pharmacists could safely and effectively increase access to glucagon devices. These efforts would support initiatives currently being undertaken by the FDA to expand access to certain medications with conditions of safe use pursuant to the Non-Prescription Safe Drug Use Regulatory Expansion ("NSURE") initiative.

- **Opioids** (p. 175). In addressing the opioid class within the Action Plan, APhA appreciates and fully understands the unique challenge of balancing patient pain control with ADE risk minimization and the prevention of abuse. Through effective medication management, pharmacists working with patients with pain in all care settings can help to assure the appropriateness and safety of these medications, focusing on the highest-risk patients. Further, for products that have extremely narrow therapeutic indices, engaging pharmacists in standardized REMS programs that include structured medication management services provided by pharmacists may be an effective strategy for addressing this complex problem.

## II. Importance of Health Information Technology

APhA is committed to the use of health information technology to improve the quality of patient care and to reduce burdens on providers. We recommend that HIT integration be included in the “Effective Communication and Coordination of Care” strategies for all three drug classes in both the inpatient and outpatient settings. We also believe that pharmacists, as integral members of the patient care team, should have read/write access to EHR, and we support integrated systems, where possible. However, improved technology is a long-term commitment that requires a substantial investment, which often results in irregular implementation, unequal access, and interoperability issues. The inclusion of pharmacists’ patient care services in EHRs

\(^5\) The APhA Foundation has been involved in extensive research related to diabetes self-management. A paper detailing findings related to diabetes self-management programs can be found here: [https://www.aphafoundation.org/AM/Template.cfm?Section=Patient_Self_Management_Program_Diabetes&Template=/CM/ContentDisplay.cfm&ContentID=21484](https://www.aphafoundation.org/AM/Template.cfm?Section=Patient_Self_Management_Program_Diabetes&Template=/CM/ContentDisplay.cfm&ContentID=21484).
is essential to integrate the medication management services into the patient’s overall care record.

Additionally, exchanging information with other providers and facilities using standards-based systems and health information exchanges (“HIEs”) supported by the Office of National Coordinator for Health Information Technology is critical for pharmacists. APhA, through our involvement with the Pharmacy HIT Collaborative, continues to engage in efforts to promote the adoption and expansion of EHR systems within all care settings and to contribute to the development of electronic structured documents through HL-7 and NCPDP that facilitate the exchange of standardized information between EHR systems.

HHS noted some of these concerns in the Action Plan, including the need for more centralized, real-time data from EHRs to reduce the lag time for provider action in anticoagulation clinics, as well as improved integration of pharmacy order entry systems and laboratory systems. While there are obvious limitations associated with HIT, APhA supports HHS’s emphasis on EHR and other HIT throughout the Action Plan and the need for increased application of clinical decision support, automated EHR reporting of ADEs, and the exchange of surveillance and patient care information to increase efficiencies. We do have some areas of concern related to HIT, which are set forth below:

- **Defining HIT** (p. 10-11). HHS states that the Federal Interagency Workgroups identified HIT “as a potential resource which could enhance the work” associated with all areas of the Action Plan. However, it is unclear from the discussion throughout the Action Plan whether HIT is limited only to EHR or other systems, or whether it extends to innovative technologies such as mobile apps. APhA recognizes that not all patients will have access to the hardware and software necessary to take advantage of these new programs, but because they are becoming increasingly common (and will likely continue to gain in popularity), excluding them from the Action Plan could be a lost opportunity to stay on top of evolving technology.

- **Multi-Payer Advanced Primary Care Practice (MAPCP)** (p. 42). In discussing the role of HIT, it is essential that results are not conflated with the HIT alone. For instance, in the discussion of MAPCP, HHS seems to suggest that use of the “advanced HIT system” alone provides patient benefits. While HIT can supplement the work of providers, the real results associated with the program stem from the descriptions of clinical pharmacy activities and findings entered by pharmacists. Technology solutions including clinical decision support and other automated solutions should enhance, not replace, the care that health care professionals are providing to patients.

- **Purchasing and Upgrading HIT**. The Action Plan does not specifically address how providers will finance new or upgraded HIT that will be essential to implementing some of the ideas laid out in the Action Plan. Clearly, HIT enables providers to do a great deal more for patients, but not all providers have access to the same resources. As mentioned above, pharmacists are not eligible for meaningful use incentives and state-of-the-art technology is within reach only for a select number of providers and organizations. More support will be needed for providers to purchase the necessary software and hardware for even basic HIT systems necessary to implement programs to prevent ADEs.
Again, APhA thanks HHS for recognizing both the contributions of pharmacists in preventing ADEs, as well as the structural barriers, including reimbursement and resources, preventing pharmacists’ full potential to improve patient outcomes and care from being realized. As HHS moves forward to finalize the Action Plan, APhA encourages HHS to explore and implement strategies to more effectively integrate pharmacists as members of the health care team. Incorporating pharmacist patient care services into care models contributes to better patient outcomes and quality in a cost-effective manner — a win for patients and the health care system.

APhA strongly encourages HHS to continue working with stakeholders to refine and implement the Action Plan. We welcome the opportunity to work collaboratively with other provider organizations and federal agencies to improve patient care and outcomes. We hope to be a resource for HHS and are happy to be of assistance in any way possible.

Thank you for the opportunity to provide comments on this important issue. If you have any questions or require additional information, please contact Jillanne Schulte, JD, Director of Regulatory Affairs, at jschulte@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs
James Owen, BS Pharm, PharmD, BCPS, Associate Vice President, Practice and Science Affairs
Jillanne M. Schulte, JD, Director, Regulatory Affairs