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[Submitted electronically]

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Re: Draft National Adult Immunization Plan [Docket No. 80 FR 6721]

The American Pharmacists Association (APhA), the National Alliance of State Pharmacy Association Executives (NASPA), the National Community Pharmacists Association (NCPA), the American Association of Colleges of Pharmacy (AACP), and the American Society of Health System Pharmacists (ASHP) indicate their organizational support and are pleased to submit these comments on the draft National Adult Immunization Plan (NAIP). Comments contained within this letter were generated from a review by staff and input received from our memberships.

We appreciate NVPO’s continued work to promote vaccination, collaboration and communication among immunization stakeholders that will result in increased adult vaccination rates. In particular, we applaud the plan’s recognition of the value pharmacists contribute towards addressing the immunization needs of the adult population. We thank you for the opportunity to comment on the draft plan.

Overall, we believe the plan captures the key areas necessary for effecting positive changes in adult immunization rates. The development of indicators to track progress on the plan goals and objectives is critical to achieving success. The comments shared in this letter were assembled to provide further insight from the pharmacist’s perspective, and to identify areas where the profession of pharmacy might contribute to progress towards achieving established goals and objectives. Please note that our comments utilize the term “pharmacy” versus “retail pharmacy” as the former term encompasses all of the pharmacy settings serving patients (ambulatory care, chain, health-system, independent, long-term care, super-market based, mass-merchandiser based, etc.) We would respectfully request the plan use the term “pharmacy” in all areas it currently has “retail pharmacy”. In addition, pharmacists across the healthcare spectrum are ready and able to contribute to advancement of the NAIP.

Barriers to Adult Immunizations (page ix)

In the list of barriers that are consistently highlighted by stakeholder groups and the research community we suggest including “limited access to, and coverage for, immunization services provided by accessible providers.”1 This is a challenge many patients wishing to receive a vaccination from a pharmacist, public health department, and other providers experience, particularly vaccinations beyond influenza.

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Objective 1.1 – Monitoring and Reporting Trends (page xvii)

We applaud efforts by Centers for Disease Control and Prevention (CDC), Association of State and Territorial Health Officials (ASTHO), and the state public health departments to overcome jurisdictional barriers to Immunization Information Systems (IIS) reporting and data access, especially for providers who provide immunization services in multiple states or across state lines. Critical to success in this area is the provision of financial resources to state health departments to support provider onboarding and continual support for providers reporting to and utilizing the IIS.

Objective 1.2 – Vaccine Safety Monitoring Systems (page xviii)

We recognize the importance of continuous learning and assessment of the vaccines administered to patients, and support continual maintenance and enhancement of the Vaccine Adverse Event Reporting System (VAERS). Pharmacists and student pharmacists, as part of the immunization certificate training program, are educated about VAERS, its importance and the process for reporting. We encourage the development of additional education programs and materials, in collaboration with professional associations, for all immunization providers based on analysis of VAERS and other available data. In addition, we encourage the use of data from other monitoring systems such as the Institute for Safe Medication Practice’s Vaccine Error Reporting System which collects process errors related to vaccine administration.

Objective 1.4 – Use of Electronic Health Records (EHR) and IIS Systems (pages xix and xx)

We recognize the importance of seamless, multidirectional mechanisms for the reporting and sharing of patient information related to immunizations. Critical to the success of achieving the immunization neighborhood for the adult population is the ability to document vaccinations and to communicate that information to a patient’s other clinicians. We advocate for multidirectional access to EHRs and healthcare data systems, including IIS, for pharmacists. Supporting pharmacy’s integration within the HIT environment is the work conducted by the Pharmacy Health Information Technology Collaborative (herein after, Collaborative). The Collaborative is a group nine pharmacy professional associations, representing 250,000 members, who assure the nation’s health care system is supported by meaningful use of HIT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of HIT and the inclusion of pharmacists within a technology-enabled integrated health care system. The collaborative developed a road map for pharmacy engagement in HIT connectivity, that includes a section addressing immunization data interchange (http://www.pharmacyhit.org/pdfs/RoadmapUpdate_2015.pdf) While pharmacists are not eligible for the meaningful use incentives identified in the American Recovery and Reinvestment Act of 2009, pharmacists are working towards integration within developing systems in order to have access to patient information needed to best serve patient needs and to communicate relevant patient information to other clinicians. The inclusion of sufficient funding to state public health systems for the onboarding of pharmacies and other immunization providers as authorized reporters and utilizers of IIS systems, as well as EHR system connectivity by pharmacists, is critical to make progress in this area.

We also encourage the development and utilization of quality measures that analyze the reporting rate of vaccinations to IIS systems and whether clinicians can access to IIS systems to assess patient immunization status. The Pharmacy Quality Alliance (PQA) is currently developing a quality measure concept that health plans and the government could utilize to measure progress in provider reporting to, and utilization of, immunization registries. We encourage inclusion of this as a source of data for the indicator tracking progress in this area.
As stated above, we applaud efforts by CDC, ASTHO and the state public health departments to overcome jurisdictional barriers to IIS reporting and data access, especially for clinicians who provide immunization services in multiple states or across state lines.

Objective 1.5 – Quality Improvement (page xxi)
We encourage the development and utilization of quality measures that look at the key areas of the National Vaccine Advisory Committee (NVAC) Adult Immunization Standards, such as assessing immunization status, patient referrals, administration of vaccines, and the reporting of vaccines administered. PQA is exploring the development of quality measures that analyze the report rate of vaccinations to IIS Systems and mechanisms to assess patient immunization status. PQA is currently developing quality measure concepts that health plans and the government could utilize to measure progress in this area. We encourage inclusion of these PQA measures as a data source for the indicator tracking progress in this area.

Objective 1.6 – Economic Impact (page xxi)
One component of the financial impact is directly related to the burden of preventable adverse patient outcomes. The Agency of Healthcare Research and Quality (AHRQ) reports that 2009 emergency department visits from H1N1 influenza were 417.5 (per 100,000) up from 161.8 (per 100,000) in 2008. Hospitalizations (per 100,000) were 53.1 in 2009 up from 29.1 in 2008, and the cost of inpatient stays was 11,000 up from 8,500 in 2008.2

We support continued exploration of the economic impact and importance of adult immunizations and particularly encourage research on lost work days and medical cost avoidance due to influenza.

Objective 2.1 – Financial Barriers (pages xxii-xxiii)
We encourage the monitoring of cost sharing policies implemented by public and private health benefit programs that may create barriers to patient access and ability to receive needed vaccinations. A barrier to increasing access to pharmacists-administered immunization services is their lack of recognition as health care providers in public and private programs. While pharmacists have the authority in many states to administer the Advisory committee on Immunization Practices (ACIP)-recommended adult immunizations, changes in the number of public and private health plans who recognize pharmacists as immunization providers would be an important indicator of progress in increasing access. We would encourage CMS to collect this data across public health programs, including Medicaid, Medicare and other programs they have oversight. If this is not possible, the pharmacy community would be interested in having dialogue with NVPO regarding how we might be able to collect and report this data on an annual basis.

Objective 2.2 – Understanding Provider Financial Barriers (pages xxiii)
We continuously monitor legal changes in pharmacists’ authority and support changes to legislative and regulatory language that permit pharmacists to administer ACIP-recommended vaccines to adult patients. As vital members of the immunization neighborhood, pharmacists have the training and ability to assess patients’ immunization status, administer vaccines and communicate those immunizations to IIS and medical records. We have identified best practices for immunization delivery within our periodical publications, educational programming and awards programs.

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An important objective within the plan should be a reduction in patient confusion on where and what vaccines they can receive from a pharmacist. Embracement of the immunization neighborhood and keeping the needs of the patient as our focal point will support improvement in our immunization rates. Reducing provider and patient confusion regarding needed vaccines, the timing of those vaccines and providers from whom they can receive those vaccines should be an objective that is added to the plan.

Objective 2.3 – Expanding Adult Immunization Provider Network (page xxiv)

We applaud recognition of pharmacists’ as valued members of the immunization neighborhood. More than 260,000 pharmacists have been trained and are positioned to work with other stakeholders to increase patient access to recommended vaccinations and to utilize currently available and future systems that support the exchange of patient information to medical records and IIS systems. We also support connectivity between immunizing pharmacists and the patient’s identified medical home, when one exists. In addition, pharmacists can efficiently coordinate care, serving as referral sources and patient reminders of other screenings and follow-up a patient might need. However, the challenge continues in many communities in finding a medical practice that is accepting new patients in a timely manner. This is a challenge all stakeholders are faced with.

We appreciate inclusion within the plan document acknowledging the challenge that pharmacists and patients experience in the provision of immunization services caused by the lack of recognition for pharmacists as “in-network” providers. The challenges of patient vaccine hesitancy is a barrier healthcare providers address every day. When a patient is ready to be vaccinated, the last thing you want is to turn them away because you cannot administer the vaccine. Patients should be offered the ability to receive their vaccinations from a provider of their choice, whether it be in a medical office, pharmacy or public health clinic. It is an appropriate expectation of providers who administer vaccines that they coordinate, collaborate and communicate with other immunization providers who might be serving the patient and to refer patients when appropriate. The provision of immunization services has additional challenges that other healthcare services do not. Those challenges include vaccine hesitancy, vaccine shortages, cost issues, etc. Implementation of the national plan should explore aspects of the patient expectation regarding receipt of immunization services. Measures for patient expectation and network adequacy should be articulated within an indicator (time to receive an immunizations, geographic distribution, etc). NVPO and CMS should consider support for research monitoring progress within this area. (Addresses 2.3.3)

We support inclusion of the indicator that monitors state authority for pharmacists to administer vaccines to adult patients as the ultimate goal is to reach 100% of states authorizing pharmacists to administer 100% of ACIP recommended vaccines to the adult population. As state authority can change with each state legislative session or changes in regulations, the need for continuous monitoring is important and APhA and NASPA are committed to maintain its monitoring activities and share the information with NVPO as indicated in the draft plan. While state authority is a good indicator of progress, it is only one component of the equation. The other components include the recognition and compensation for pharmacists as providers of the vaccinations. Therefore, we recommend an additional indicator monitoring the percent of health plans (Medicaid, Medicare and private sector plans) who include pharmacists as in-network providers of adult immunizations. We encourage CMS to collect data from the plans they approve or have oversight of (ie. Medicaid, Medicaid Managed Care, Medicare, etc), as well as other federally funded programs regarding the inclusion of pharmacies, public health departments, etc. as in-network providers. If this cannot be accomplished, APhA and NASPA would be willing to collect and share with NVPO available information on state Medicaid program inclusion of pharmacists as adult immunization providers. (Addresses 2.3.1)

There is also a need for standardization and consistency in reporting and sharing of data across IIS systems. We support continued collaboration between public and private stakeholders in the development of systems and
processes that support multidisciplinary and standardized multi-jurisdictional sharing of data. In addition, pharmacists’ ability to have multi-directional access and reporting of patient data will support coordination of services among immunization providers. Critical to the connectivity between pharmacies and electronic health record systems is a recognition of the importance of all immunization providers having access to this information and for EHR vendors to acknowledge the importance of having this feature as an active component (i.e. needs to be a priority) (Addresses 2.3.1)

We appreciate recognition within the plan of the importance of identifying best practices among immunization providers and encourage continued engagement of the professional associations and the National Adult and Influenza Immunization Summit (NAIIS) to facilitate cooperation and collaboration among stakeholders. (Addresses 2.3.2)

We recognize and acknowledge that there is a need to collect data from payers and providers regarding vaccine administration rates. This data is important to identify the impact various providers are having on vaccine access and administration. APhA conducts sample surveys and extrapolates those numbers to a national perspective. Attempts at obtaining actual numbers from providers is hampered by proprietary interests but if desired, we can continue to attempt to collect actual practice data and would facilitate a discussion with NVPO to identify use of this data or alternative approaches. In addition, large payers like CMS (Medicare) are encouraged to establish provider-type specific coding so that the number of claims for a particular vaccine from pharmacists could be measured and analyzed. (Addresses 2.3.7)

A concern raised by pharmacists and other health professionals that impacts immunization rates is that some health plans categorize adult vaccines in a higher copay tier, thereby creating an additional financial barrier. Providers are challenge with educating patients about the need for vaccination, gaining agreement to be vaccinated, determining and communicating to the patient the cost of the vaccination, only to have the patient decide to not get vaccinated based upon their out of pocket cost (also known as “vaccine abandonment”). We recommend NVPO explore how health plans are categorizing adult vaccines in regards to copays and address the impact of these categories on patient health and wellness.

We acknowledge the importance of improved access on achieving desired immunization rates. In many communities pharmacies are being asked to provide on-site (worksite) immunization and other clinical services. Depending on the vaccine and the insurance coverage of the employer, these services are paid directly by the employer or thru their insurance plan. In addition, some employers have established programs with pharmacies where an employee and their family can get vaccinated at the pharmacy at a time when convenient for the patient and the employer will pay for it.

Objective 2.4 – Vaccine Supply (page xxvi)

We strongly believe all pharmacy stakeholders should collaboratively coordinate emergency preparedness plans amongst themselves and with other responders to ensure appropriate stock, protocols, communications and procedures in the event of emergencies.

We applaud the plan’s recognition that pre-planning before a public health emergency is declared is important. We recommend that language also be included to recognize the need to engage existing health care providers in the community in existing immunization administration programs to support their continued existence and smooth engagement when called upon in public health emergency response.

Objective 3.1 – Individual awareness (page xxviii)

The equivalent of the US population enters a community pharmacy each week and can be exposed to important immunization messaging whether they are a member of the general population, consumer or a patient of
that pharmacy. A patient’s first point of contact to healthcare is usually a pharmacy where they can be informed on important immunization messages. Internal and external messaging serves as a reminder of the importance of vaccination and empowers the public to make individual decisions on where they would like to receive their vaccination or to discuss with a healthcare provider questions or concerns they might have. We have witnessed the ability of pharmacies to increase public awareness – just look at the signs and messages from pharmacies offering flu and zoster vaccinations. From experience, increased resources towards public education and messaging will occur as inclusion of pharmacists as in-network vaccine providers for all ACIP recommended adult vaccines occurs.

We agree that further research around vaccine awareness and acceptance is needed. We also agree that further insight is needed in this area within medically underserved and minority communities to identify the providers they trust and utilize within their communities, as well as concerns with vaccines and gaps in service delivery that need to be addressed. We encourage NVPO to engage organizations who serve these populations to gather, analyze, develop, and implement plans to address identified issues. (Addresses 3.1.1)

New methods for engaging and communicating with consumers are emerging every day. Many pharmacy providers are utilizing social media and communication mechanisms to engage customers. They are also utilizing these systems to deliver immunization messages, information and resources. We encourage NVPO to explore best practices with providers utilizing social media and other communications regarding immunizations at the practice level. (Addresses 3.1.2)

Objective 3.2 – Educate and encourage health care professionals (page xxix)

Pharmacy organizations have conducted education and training, as well provided print and electronic resources around the adult immunization standards and their implementation. Adult learners require multiple exposures to information and concepts before they begin engaging in the change process. We are committed to continuing the engagement with pharmacists and measuring progress, from their perspective, in the implementation of the standards. We are willing to share this information with NVPO. (Addresses 3.2.1)

We agree with the plan’s recognition of the importance of inclusion of education and experiential opportunities regarding the adult immunization standards. The importance of public health and the engagement of pharmacists in embedded within the standards for colleges/schools of pharmacy and residency accreditation programs. In addition, student pharmacists have been engaged in immunization activities for over 15 years (APhA-ASP’s Operation Immunizations) and almost all colleges of pharmacy have included immunization training within their curriculum. Our philosophy early on was to engrain the importance of immunizations early in a professional’s career so they carry it forth into practice. We have seen this happen as new graduates seek employment in practices that offer immunizations and employers require such training of employees. Also, college campuses provide fertile ground for developing the immunization neighborhood approach to immunizations.

A challenge identified by practitioners is the integration of immunization activities within the care process, as practitioners are being asked to consider numerous care activities within the limited time they have with a patient. Health professions should be encouraged to explore the integration of immunization services within their patient care processes and at every care transition. The profession of pharmacy recently adopted a pharmacist’s patient care process that includes assessment of the patient’s conditions, as well immunization status. Pharmacists are increasingly providing chronic disease management services like diabetes management, cardiovascular management, etc. In programs like the Asheville and Diabetes Ten City Challenge, pharmacists increased the rate of influenza vaccination in those patients by including immunizations as part of the care process. Disease

management activities provides opportunity for immunization service integration, but there exist system challenges. ACIP recommends patients with diabetes receive Hepatitis B vaccinations, yet CMS does not recognize pharmacists as a covered provider of those vaccines. This creates a missed opportunity and is a good example of an issue that needs addressing as providers attempt to integrate immunization services into patient care processes. *(Addresses 3.2.5)*

**Key Indicator Review**

We reviewed the key indicator chart included within the draft plan and have compiled the following recommendations, in addition to those stated above:

- **Goal 1:** Consider inclusion of measures under development by the Pharmacy Quality Alliance (PQA) regarding percentage of immunizations reported to IIS, and assessment of patient immunization status.
- **Goal 2:** Tracking of state authority will be performed, as has been done for many years, through collaboration between the American Pharmacists Association (APhA) and National Alliance of State Pharmacy Association Executives (NASPA)
- **Goal 2:** Recommend additional indicator: *Percentage of Medicaid and other public health benefit programs that include pharmacists as immunization providers.* This could be accomplished through encouraging CMS to gather this information (also could possibly be included in the contracted CDC research with George Washington University indicated in the plan if CMS and AHIP can’t; in addition, APhA/NASPA would be willing to collect and report available data.)
- **Goal 2:** Recommend additional indicator: *Percentage commercial health benefit programs that include pharmacists as immunization providers.* This could be accomplished through encouraging AHIP to gather this information (also could possibly be included in the contracted CDC research with George Washington University indicated in the plan if CMS and AHIP can’t; in addition, APhA/NASPA would be willing to collect and report available data)
- **Goal 2:** Recommend additional indicator: Consider adding, *percentage of primary care providers who refer patients to other immunization providers if they don’t administer or stock vaccines.* This provides a more complete picture related to the Adult Immunization Standards. Tracking of this information could be included in research/surveys stated in the plan being conducted by/contracted by NVPO and CDC.
- **Goal 2:** Recommend additional indicator: *Percentage of health benefit plans that categorize all adult vaccines as Tier One, No-copay products/services.* Data collection for this indicator could be conducted by AHIP, CMS, or through contracted research.
- **Goal 3:** Recommend expansion of health care professionals who assess adult patient immunization status. Pharmacy associations are willing to share current and future data available in this area.
Role and Responsibilities for Private Sector

We reviewed each plan objective and identified the following areas where pharmacists and pharmacy associations can contribute to the achievement and monitoring of the plan:

Objective 1.4: Increase the use of EHRs and IIS to collect and track adult immunization data.
- Role/Responsibility Identification: Pharmacists and Pharmacy Associations

Objective 1.5: Evaluate and advance targeted quality improvement initiatives.
- Role/Responsibility Identification: Pharmacists and Pharmacy Associations

Objective 2.2: Assess and improve understanding of providers’ financial barriers to delivering vaccinations, including stocking and administering vaccines.
- Role/Responsibility Identification: Pharmacy Associations working with HHS/ CDC/researchers

Objective 2.3: Expand the adult immunization provider network.
- Role/Responsibility Identification: Pharmacists and Pharmacy Associations

Objective 2.4: Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.
- Role/Responsibility Identification: Pharmacies and Pharmacy Associations

Objective 3.1: Educate and encourage *individuals* to be aware of and receive recommended adult immunizations.
- Role/Responsibility Identification: Pharmacists and Pharmacy Associations

Objective 3.2: Educate and encourage *health care professionals* to recommend and/or deliver adult vaccinations.
- Role/Responsibility Identification: Pharmacists and Pharmacy Associations

Objective 4.1: Develop new vaccines and improve the effectiveness of existing vaccines for adults.
- Role/Responsibility Identification: Pharmacies and Pharmacists in health-systems and large academic medical centers

Objective 4.2: Encourage new technologies to improve distribution, storage, and delivery of adult vaccines.
- Role/Responsibility Identification: Pharmacies and Pharmacists

Thank you for the opportunity to provide feedback on the draft National Adult Immunization Plan and for your consideration of our comments. We look forward to working with NVPO and other immunization stakeholders on implementation of the final plan that results in increased adult immunization rates.

Sincerely,

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