

October 31, 2019

President Karen Fann
Speaker Rusty Bowers
1700 West Washington Street
Phoenix, AZ 85007

Dear President Fann and Speaker Bowers,

Pursuant to sections 32-3104 and 32-3106, Arizona Revised Statutes, the Arizona Pharmacy Association (AzPA) hereby submits the attached report requesting an expansion of the scope of practice for the profession of pharmacy.

The proposal would modify current law to allow pharmacists to furnish and administer immunizations that are recommended by the U.S. Centers for Disease Control and Prevention without a prescription for patients that are at least six years of age and with a prescription for patients that are at least three years of age.

The Arizona Pharmacy Association has begun meeting with stakeholders on this proposal with the hope of addressing questions and concerns prior to the introduction of legislation. Thank you for your consideration.

Sincerely,

Kelly Fine, RPh, FAzPA
Executive Director and CEO
Arizona Pharmacy Association



BACKGROUND

Arizona pharmacists have been administering immunizations to adult patients since 2005¹ and to certain children since 2011². Our current law, which passed in 2016³, allows Arizona pharmacists to provide any immunization pursuant to a prescription to patients at least six years of age and to, without a prescription:

- Administer immunizations to patients at least 13 years of age that are recommended by the U.S. Centers for Disease Control and Prevention (CDC),
- Administer influenza vaccines to children at least three years of age,
- Administer booster doses to children 11-12 for the primary adolescent series as recommended by the CDC,
- Administer travel vaccines with some exceptions⁴,
- Administer emergency medications needed to treat adverse reactions from a medication or vaccine administration, and
- Administer immunizations to any person regardless of age during a public health emergency pursuant to A.R.S. 36-787.

The Arizona Pharmacy Association is seeking to amend A.R.S. 32-1974 to allow pharmacists to furnish and administer CDC-recommended immunizations to patients six years of age or older without a prescription and to children three years of age or older with a prescription.

The CDC's immunization schedule, which can be found in Appendix A, recommends most childhood immunizations be provided by age six, with several additional immunizations for 11 and 12-year olds. This scope expansion would enable pharmacists to provide the 11 and 12-year old immunizations and catch-up immunizations to younger children who are late in receiving their early childhood immunizations. Children who receive immunizations pursuant to the CDC schedule's recommended time frames would not receive their early childhood immunizations from a pharmacist.

Pharmacists have administered over 4 million doses of vaccine in Arizona since 2009 (see Appendix B) and demonstrated their impact on and dedication to providing this valuable service to Arizona's communities. In addition, over half of the country already authorizes pharmacists to administer immunizations to the population included in this scope expansion request.

INCREASED SCOPE FACTORS PURSUANT TO A.R.S. 32-3106

1. Why an increased scope of practice is beneficial, including the extent to which health care consumers need and will benefit from safe, quality care from practitioners with this scope of practice.

Expansion of pharmacists' ability to provide immunizations will enhance health care consumers' ability to easily access immunizations and improve public health. Ease of access to immunizations is critical to public health at a time when incidence of vaccine-preventable diseases (VPDs) is on the rise. Approximately 40,000 to 50,000 adults die annually of VPD in the United States⁵ and the number of VPDs reported in Arizona more than quadrupled from 2008 to 2013⁶. The rise in VPDs in Arizona correlates with increasing rates of personal belief exemptions (PBEs). Arizona is one of 20 states that allows parents to waive the immunizations required for enrollment in a public school due to personal beliefs. In the 2016-2017 school year, Arizona was tied for fourth place nationwide for most PBEs, with 4.9% of Arizona kindergarteners opting out of recommended immunizations for nonmedical reasons⁷, and this percentage has continued to increase to 5.4% in 2017-2018 and 5.9% in 2018-2019⁸. These PBEs are even

higher in some counties; the Arizona Department of Health Services' (DHS) 2018-2019 data shows PBEs for kindergarteners to be highest in Yavapai (12.5%), Mohave (10.3%), and Maricopa (6.5%) counties⁹. These increasing PBE rates have caused many communities to fall below the recommended 95% coverage level to maintain herd immunity – DHS estimates that only forty percent of Arizona's kindergarten classrooms currently have coverage levels necessary to stop a measles outbreak¹⁰.

While some parents have sincerely held beliefs causing them to utilize PBEs, some parents obtain PBEs out of convenience or because of poor access to immunization services¹¹. Particularly in rural areas, convenience has been the primary determining factor in mothers' decisions on where to take their children for immunizations¹². We are seeking to expand pharmacist scope to allow pharmacists to administer recommended immunizations to children that are at least six years of age without a prescription; this will improve availability of immunizations and reduce the number of PBEs filed out of convenience. Currently, 93% of Americans live within five miles of a community pharmacy and pharmacists are among the most accessible health care professionals in the country¹³. Pharmacists are available to patients without scheduling appointments and generally have longer business hours and shorter wait times than many other health care professionals. Additionally, pharmacists tend to have more regular contact with their patients and more frequent opportunities to counsel patients on recommended immunizations and follow-up for immunizations that require multiple doses.

Studies have long showed that allowing pharmacists to provide immunizations improves immunization rates, particularly where community pharmacies have extended hours. A 2004 study showed that immunization rates for states that allow pharmacists to vaccinate were higher than states that did not allow this practice, suggesting pharmacists were not just shifting patient populations from medical clinics but identifying new populations¹⁴. Another study estimated that if states granted pharmacists full immunization privileges, there would be a 148% increase in pneumococcal vaccination and a 77% increase in herpes zoster vaccination¹⁵. Although increased availability of immunizations may not sway parents seeking PBEs due sincerely held beliefs – which, to be clear, is the purpose of the PBEs – it certainly could improve immunization rates in cases in which parents are seeking PBEs out of convenience.

2. Whether those health professionals seeking an increased scope of practice currently have or will be required to have didactic and clinical education from accredited professional schools or training from recognized programs that prepare them to perform the proposed scope of practice, and details on what that education or training includes for that proposed scope of practice.

The Accreditation Council of Pharmacy Education (ACPE) is recognized by the U.S. Department of Education (USDE) for the accreditation and pre-accreditation of professional degree programs in pharmacy leading to the degree of Doctor of Pharmacy within the United States. ACPE is recognized by the Council for Higher Education Accreditation (CHEA), which is a private, nonprofit, national organization that coordinates accreditation activity in the United States. CHEA represents more than 3,000 colleges and universities and 60 national, regional, and specialized accreditors. ACPE Standards outline required elements for accreditation. Accreditation decisions are based upon the extent to which a PharmD program meets the expectations of ACPE Standards. ACPE requires the PharmD programs it accredits meet the expectations of all 25 standards. One of these standards is included on the following page to demonstrate the rigor and depth of a pharmacist's education as it pertains to population-based preventive health.

Standard 2: Essentials for Practice and Care

The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to provide patient-centered care, manage medication use systems, promote health and wellness, and describe the influence of population-based care on patient-centered care.

Key Elements:

- 2.1. Patient-centered care – The graduate is able to provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).
 - 2.1.1. Collect subjective and objective evidence related to patient, medications, allergies/adverse reactions, and disease, by performing patient assessment (including physical assessment) from chart/electronic health records, pharmacist records and patient/family interviews.
 - 2.1.2. Interpret evidence and patient data.
 - 2.1.3. Prioritize patient needs.
 - 2.1.4. Formulate evidence-based care plans, assessments, and recommendations.
 - 2.1.5. Implement patient care plans.
 - 2.1.6. Monitor the patient and adjust care plan as needed.
 - 2.1.7. Document patient care related activities.
- 2.2. Medication use systems management – The graduate is able to manage patient healthcare needs using human, financial, technological, and physical resources to optimize the safety and efficacy of medication use systems.
- 2.3. Health and wellness – The graduate is able to design prevention, intervention, and educational strategies for individuals and communities to manage chronic disease and improve health and wellness.
 - 2.3.1. Describe systematic preventive care, using risk assessment, risk reduction, screening, education, and immunizations.
 - 2.3.2. Provide prevention, intervention, and educational strategies for individuals and communities to improve health and wellness.
 - 2.3.3. Participate with interprofessional healthcare team members in the management of, and health promotion for, all patients.
 - 2.3.4. Evaluate personal, social, economic, and environmental conditions to maximize health and wellness
- 2.4. Population-based care – The graduate is able to describe how population-based care influences patient-centered care and the development of practice guidelines and evidence-based best practices.
 - 2.4.1. Assess the healthcare status and needs of a targeted patient population.
 - 2.4.2. Develop and provide an evidence-based approach that considers the cost, care, access, and satisfaction needs of a targeted patient population.
 - 2.4.3. Participate in population health management by evaluating and adjusting interventions to maximize health.

Pharmacists are currently trained on all adult and childhood immunizations according to the training requirements in A.A.C. R4-23-411 (included on the following page). In addition to the required post-graduate training required by law, the ACPE includes immunology as a required didactic component of a doctor of pharmacy curriculum for educational institutions offering a doctor of pharmacy degree¹⁶.

A.R.S. 32-1974 requires that a pharmacist who wishes to administer immunizations must be certified by the Arizona Board of Pharmacy to do so. To receive this certification, the Board requires proof of completion of a training program as specified in A.A.C. R4-23-411 and a current certificate in basic cardiopulmonary resuscitation. Additionally, certificate holders are required to complete a minimum of two hours of ACPE-approved immunization-related CE for each license renewal. The required training must include the following components:

- a. Basic immunology and the human immune response;
- b. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
- c. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine and diphenhydramine to counteract the adverse effects of an immunization given based on a patient-specific prescription order received before administering the immunization;
- d. Administration of intramuscular and subcutaneous injections;
- e. Other immunization administration methods; and
- f. Recordkeeping and reporting requirements.

3. Whether the subject matter of the proposed increased scope of practice is currently tested by nationally recognized and accepted examinations for applicants for professional licensure and the details of the examination relating to the increased scope of practice.

All pharmacists nationwide must pass the North American Pharmacist Licensure Examination (NAPLEX) to become licensed. Additionally, the Arizona Board of Pharmacy requires pharmacists pass an exam concerning Arizona's pharmacy laws. The NAPLEX covers all ACPE standards including those relevant to this scope expansion as discussed above.

4. The extent to which the proposed increased scope of practice will impact the practice of those who are currently licensed in this state or the entry into practice of those individuals who have relocated from other states with substantially equivalent requirements for registration, certification or licensure as this state.

This scope expansion will not impact the practice of current licensees. Pharmacists who have obtained a certification to administer immunizations from the Arizona Board of Pharmacy will be allowed to administer immunizations pursuant to this expansion. Other pharmacists, including pharmacists relocating from other states, will continue to have the opportunity to seek Board of Pharmacy certification to administer immunizations. The training received during their didactic training as well as the post-graduate training covers the pharmacist to travel from state to state and use that training to administer immunizations according to that state's scope of practice. The training covers all immunizations and administration to all patients regardless of age.

5. The extent to which implementing the proposed increased scope of practice may result in savings or a cost to this state and to the public.

The impact of this scope expansion on health care costs generally is difficult to calculate, as there are a variety of facets to consider. For instance, immunizations are widely accepted as cost-effective by the health insurance and public health communities in their ability to deter future costs associated with VPDs, which include direct costs associated with outbreaks and hospitalizations and indirect costs including

losses in productivity and premature mortality¹⁷. To the extent that improved access to immunizations through this scope expansion increases immunization rates, the health care community and patients should see a long-term cost savings.

In addition to cost savings associated with immunizations generally, expanding pharmacists' immunization authority can lead to decreased health care costs for consumers, health insurers, and other third-party payers, including Medicaid. As noted by the Department of Defense in a 2011 final rule expanding the portfolio of vaccines that TRICARE beneficiaries may obtain from community pharmacies, significant savings were achieved under the TRICARE program when the program was first implemented to allow beneficiaries to obtain flu and pneumococcal vaccines from retail pharmacies. It was estimated that for the first six months that beneficiaries could obtain their immunizations from pharmacists, 18,361 immunizations for H1N1, flu, and pneumococcal were administered at a cost of nearly \$300,000; had those immunizations been administered under the medical benefit, the cost to TRICARE would have been \$1.8 million¹⁸. Subsequently, the Department of Defense opted to expand the types of immunizations that TRICARE beneficiaries may obtain from community pharmacies to include all CDC-recommended immunizations.

Furthermore, as previously noted, a patient does not need to make an appointment to obtain an immunization at a pharmacy, wait times for pharmacists are generally much shorter than for other health care professionals, and many pharmacies also offer extended hours. These factors reduce time costs for patients and their parents and minimize potential lost productivity and wages since the patient or parent is less likely to need to take time off work to obtain the immunization.

6. The relevant health profession licensure laws, if any, in this or other states.

Pursuant to A.R.S. 32-1974, Arizona pharmacists may provide any immunization pursuant to a prescription to patients at least six years of age. Arizona pharmacists may, without a prescription:

- Administer immunizations to patients at least 13 years of age that are recommended by the U.S. centers for disease control and prevention (CDC),
- Administer influenza vaccines to children at least three years of age,
- Administer booster doses for the primary adolescent series as recommended by the CDC,
- Administer travel vaccines to adults with some exceptions, and
- Administer immunizations to any person regardless of age during a public health emergency pursuant to section 36-787.

Currently, 14 states (Alabama, Alaska, California, Colorado, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, Oklahoma, Tennessee, Utah, and Washington) allow pharmacists to administer CDC-recommended immunizations to patients of any age. Idaho allows pharmacists to administer CDC-recommended immunizations to patients at least six years of age, and Wyoming allows pharmacists to administer CDC-recommended immunizations to patients at least seven years of age. Notably, all of Arizona's neighboring states currently allow pharmacists to practice pursuant to the scope expansion sought herein.

7. Recommendations, if any, from the applicable regulatory entity or entities, from the department of health services and from accredited educational or training programs.

To the best of our knowledge, the Department of Health Services and other applicable regulatory entities have not made recommendations concerning this scope expansion.

ENDNOTE

¹ Pursuant to A.R.S. 32-1901, pharmacists have long had the authority to administer drugs to patients pursuant to a prescription order. The Board of Pharmacy clarified that this authority included immunizations by adding R4-23-411 by final rulemaking at 10 A.A.R. 3967, effective November 13, 2004 (Supp. 04-3).

² Laws 2011, Chapter 103 (SB 1298 sponsored by Senator Nancy Barto) authorized pharmacists to administer influenza vaccines and immunizations in response to a public health emergency to children who are at least six year of age without a prescription. It also allowed pharmacists to administer other immunizations to children at least six years of age pursuant to a prescription order.

³ Laws 2016, Chapter 267 (SB 1112 sponsored by Senator Nancy Barto) amended A.R.S. 32-1974 to its current form.

⁴ Statute requires the Arizona Department of Health Services to establish by rule a list of travel vaccines that pharmacists may only administer with a prescription order.

⁵ Bach, A. and Goad, J. (2015). The role of community pharmacy-based vaccination in the USA: current practice and future directions. *Integrated Pharmacy Research and Practice*, 4: 67-77. DOI: 10.2147/IPRP.S63822

⁶ Pottinger, H. and Jacobs, E. (2018). Parental attitudes and perceptions associated with childhood vaccine exemptions in high-exemption schools. *PLOS ONE*, 13(6): e0198655. DOI: 10.1371/journal.pone.0198655

⁷ Seither, R., Calhoun, K., Street, E.J., et al. (2017). Vaccination coverage for selected vaccines, exemption rates, and provisional enrollment among children in kindergarten – United States, 2016–17 school year. *Morbidity and Mortality Weekly Report*, 66:1073-1080. DOI: 10.15585/mmwr.mm6640a3

⁸ Arizona Immunization Program – Statistics & Reports – Immunization Coverage Levels. Retrieved from <https://www.azdhs.gov/preparedness/epidemiology-disease-control/immunization/index.php#reports-immunization-coverage>

⁹ Arizona Immunization Coverage Levels. Retrieved from <https://apps.azdhs.gov/IDRREportStats>

¹⁰ 2018 Immunization Coverage and Exemptions Status in Arizona. Retrieved from <https://azdhs.gov/documents/preparedness/epidemiology-disease-control/immunization/statistics-reports/2018-2019/2018-arizona-immunization-coverage-status.pdf>

¹¹ Wang, E., Clymer, J., Davis-Hayes, C., and Buttenheim, A. (2014). Nonmedical exemptions from school immunization requirements: a systematic review. *American Journal of Public Health*, 104(11): e62-e84. DOI: 10/2105/AJPH.2014.302190

¹² Ndiaye, S., Madhavan, S., Washington, M., Shui, I., et al. (2003). The use of pharmacy immunization services in rural communities. *Public Health*, 117(2): 88-97. DOI: 10.1016/S0033-3506(02)00022-7

¹³ Bach, A. and Goad, J. (2015)

¹⁴ Steyer, T., Ragucci, K., Pearson, W. and Mainous, A. (2004). The role of pharmacists in the delivery of influenza vaccinations. *Vaccine*, 22(8):1001-6. DOI: 10.1016/j.vaccine.2003.08.045

¹⁵ Ibid.

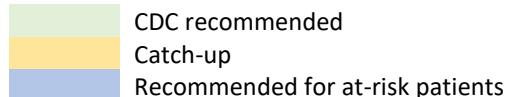
¹⁶ Accreditation standards and key elements for the professional program in pharmacy leading to the doctor of pharmacy degree. 2016 edition. Accreditation Council for Pharmacy Education. Chicago, Illinois, 2015. Retrieved from <https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf>

¹⁷ VFC Publications: Supplement (2014). Retrieved from <https://www.cdc.gov/vaccines/programs/vfc/pubs/methods/index.html>

¹⁸ DOD CHAMPUS/TRICARE: inclusion of retail network pharmacies as authorized TRICARE providers for the administration of TRICARE covered vaccines. Vol. 76, No. 134 (July 13, 2011). 32 CFR Part 199. Retrieve from <https://www.govinfo.gov/content/pkg/FR-2011-07-13/pdf/2011-17516.pdf>

APPENDIX A

	Birth	1 mo.	2 mo.	4 mo.	6 mo.	12 mo.	15 mo.	18 mo.	19-23 mo.	2-3 yrs	4-6 yrs	7-8 yrs	9-10 yrs	11-12 yrs	13-15 yrs	16-18 yrs
HepB	Dose 1	Dose 2				Dose 3										
RV		Dose 1	Dose 2	Dose 3												
DTaP		Dose 1	Dose 2	Dose 3		Dose 4				Dose 5			Dose 6			
Hib		Dose 1	Dose 2	Dose 3	Dose 4											
PCV13		Dose 1	Dose 2	Dose 3	Dose 4											
IPV		Dose 1	Dose 2	Dose 3						Dose 4						
Influenza				Yearly												
MMR					Dose 1					Dose 2						
Varicella					Dose 1					Dose 2						
HepA					2 doses, 6 months apart									2 doses		
HPV														Dose 1		Dose 2
MenACWY																
MenB																



HepB protects against hepatitis B.

RV protects against rotavirus.

DTaP protects against diphtheria, pertussis (whooping cough), and tetanus.

Hib protects against Haemophilus influenzae type b.

PCV13 protects against pneumonococcus.

IPV protects against polio.

Influenza protects against the influenza virus.

MMR protects against measles, mumps, and rubella.

Varicella protects against chickenpox

HepA protects against hepatitis A.

HPV protects against human papillomavirus.

MenACWY protects against four different strains of the meningococcal bacteria.

MenB protects against meningococcal disease caused by serogroup B.

APPENDIX B

	<u>AZ Pharmacy Reported Vaccine Doses November 2009-December 2018</u>									
	Arizona State Immunization Information System (ASIIIS) data									
	<u>2009-2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>Grand Total</u>
Cholera oral	0	0	0	0	0	0	0	8	13	21
DTaP	206	26	61	8	68	21	1	78	22	491
HPV (2,4,9)	107	110	221	525	594	542	1,003	2,028	1,636	6,766
Hep A	89	282	553	1,907	1,491	1,479	2,045	3,411	3,753	15,010
HepA/HepB	159	162	417	781	699	1,247	1,940	2,380	2,906	10,691
Hep B	512	839	1,321	3,665	2,437	2,682	3,450	5,238	5,735	25,879
Hib	1	4	12	13	10	9	8	13	7	77
IPV	15	22	52	95	128	117	92	319	179	1,019
Seasonal influenza	229,115	180,170	230,916	482,571	232,361	391,186	496,757	539,084	672,424	3,454,584
Influenza H1N1	53,059	0	0	0	0	0	0	0	0	53,059
Japanese encephalitis	1	4	15	27	37	50	65	77	90	366
MMR	334	972	1,243	1,506	1,733	3,366	3,351	3,823	3,724	20,052
Men B Bexsero	0	0	0	0	0	1	46	83	140	270
Men B Trumenba	0	0	0	0	1	6	90	212	309	618
Men ACYW	381	710	414	1,223	2,052	1,506	2,133	3,155	2,114	13,688
PCV13	0	4	1	54	4,554	55,377	57,324	45,231	42,456	205,001
PPSV23	7,136	8,973	13,342	15,596	10,972	21,428	17,493	26,252	30,853	152,045
Rabies	56	13	18	12	50	50	74	107	100	480
Tdap	1,966	3,742	15,494	16,852	16,104	23,218	29,908	38,582	38,681	184,547
Td adult	651	869	490	456	470	490	500	770	917	5,613
Typhoid ViCPs	50	60	116	172	386	613	859	1,454	1,066	4,776
Typhoid oral	370	732	747	416	273	126	237	463	751	4,115
Varicella	87	275	417	666	971	1,098	1,232	1,582	1,874	8,202
Yellow fever	79	65	135	306	407	489	602	592	4	2,679
Zoster live	14,921	21,019	39,603	35,921	24,711	29,277	25,430	20,016	986	211,884
Zoster recombinant	0	0	0	0	0	0	0	3	92,976	92,979
TOTAL	309,295	219,053	305,589	562,772	300,509	534,378	644,640	694,961	903,716	4,474,913