

September 12, 2025

[Submitted electronically via Federal eRulemaking Portal: [Regulations.gov](https://www.regulations.gov)]

Advisory Committee on Immunization Practices
Department of Health and Human Services, Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30329

Re: Docket No. CDC-2025-0454 Meeting of the Advisory Committee on Immunization Practices (September 18-19, 2025)

Dear Advisory Committee on Immunization Practices (ACIP):

The American Pharmacists Association (APhA) is the largest association in the United States, advancing the entire pharmacy profession and representing our nation's over 340,000 pharmacists, 30,000 student pharmacists, and more than 400,000 pharmacy technicians. For over 25 years, APhA has served as a non-voting liaison representative to ACIP, sharing the expertise of pharmacists from across the country and ensuring that the voice of the nation's top and most trusted provider of adult vaccines, pharmacists, is considered.

Pharmacy accessibility

Pharmacies are incredibly accessible locations in communities, with nearly 90% of the American population living within 5 miles of a community pharmacy and their local, trusted pharmacist. According to available 2024–2025 season influenza data, over 60% of adult influenza vaccines were administered in pharmacies.¹ During the 2024–2025 respiratory virus season, 96% of RSV vaccines were administered in pharmacies.² As of April 12, 2025, nearly 90% of COVID-19 vaccines have been administered in pharmacies.³ This data shows that the vast majority of Americans opted to receive their safe and effective respiratory virus vaccines conveniently, at a location of their choice, on their own schedule, and covered via their insurance at their pharmacy, without additional requirements placed on health care clinicians or patients.

Pharmacists and pharmacy personnel authority to vaccinate

As one of the most accessible immunizing professionals, pharmacists' authority to immunize is crucial in the health care system, providing the scientifically proven best defense possible against vaccine-preventable diseases. In many states, pharmacists' authority to administer immunizations is tightly bound to ACIP and CDC guidance through state statutes, regulations,

¹ *Influenza vaccinations administered in pharmacies and physician medical offices*, adults, United States.* (2025, April 9). FluVaxView. <https://www.cdc.gov/fluvoxview/dashboard/adult-vaccinations-administered.html>

² *Respiratory syncytial virus (RSV) vaccinations administered in pharmacies and physician medical offices*, adults, United States.* (2025b, May 7). RSVVaxView. <https://www.cdc.gov/rsvvoxview/dashboard/adult-vaccinations-administered.html>

³ *COVID-19 vaccinations administered in pharmacies and medical offices*, adults 18 years and older, United States.* (2025, May 7). COVIDVaxView. <https://www.cdc.gov/covidvoxview/weekly-dashboard/vaccinations-administered-pharmacies-medical.html>

and protocols.⁴ Most patients, particularly in rural and underserved areas, come to pharmacists first when they have a health question or concern. Often, pharmacists are the only health care providers for miles.⁵ Because pharmacies are in nearly every rural community and inner-city neighborhood, pharmacists and pharmacy personnel provide unparalleled access to care within the health care system. Patients will lose access to vaccine services in almost every state if ACIP integrity is not maintained or if undue restrictions are placed on vaccine access by ACIP.

As an example, for the 2025 – 2026 updated COVID-19 vaccine, there have been issues for eligible patients to receive the vaccine in its short time of availability. This is due to a few factors:

- Timing between when the FDA issued its approved indications and when the ACIP is scheduled to consider recommendations, followed by issuance of endorsement by the current or acting CDC director.
- FDA, or the HHS Secretary, is modifying approved indications to a smaller population than previously eligible.
- Differences in state pharmacy practice acts and the interpretation of those state rules and regulations. A pharmacist's authority to vaccinate is based on each state's pharmacy practice acts.

In the past few weeks, since the updated COVID-19 vaccine indications from FDA have been released, pharmacists have been navigating daily confusion with their patients. Across the entire country, patients are going to their pharmacy to get their vaccine. This is how they have done it for many years. Americans are confused, frustrated, and upset that they cannot easily obtain their updated COVID-19 vaccine due to the lack of an ACIP recommendation and its effect on pharmacists' and pharmacy personnel's authority. In the meantime, there have been rapid changes in state rules and regulations to address these issues and ensure patients have the medical freedom to choose a vaccine by their local trusted pharmacist.

The solution to these issues is to allow individual patients to exercise their medical freedom by self-attesting to their desire and interest to receive a COVID-19 vaccine at a pharmacy by a pharmacist or technician under a pharmacist's supervision. This would mitigate timing challenges, limited FDA-approved uses, and differences in state pharmacy practice acts. Alternatively, the use of shared clinical decision-making, with the pharmacist serving as the clinician working with the patient to discuss their individual risks and benefits, would also allow those patients who want a COVID-19 vaccine to obtain it with minimal barriers.

Impact of a prescription requirement on vaccine access at pharmacies

Requiring a patient-specific prescription by a health care provider for a safe and effective vaccine that a patient desires to receive and is indicated for them introduces a host of barriers and increases health care costs. As it stands currently, whether a 'prescription' is needed to get vaccinated by a pharmacist depends on state law; a 'prescription' in the traditional sense is not required to get a vaccine at nearly every pharmacy across the country.

- If the state law authorizes pharmacists to administer a vaccine to a patient (for example, state law grants broad authority, or limits authority to ACIP/CDC recommendations and the patient falls within those recommendations), then no prescription is necessary.

⁴ AL, AZ, CA, CT, DC, FL, GA, HI, IL, IN, LA, MA, ME, MI, MN, MO, MT, NC, ND, NH, NV, OR, SC, UT, VA, VT, WI, WV.

⁵ Lucas A. Berenbrok, et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 J Am Pharm Assoc. 1816 (2022). Available at: <https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3>.

- If patient eligibility is outside of ACIP's recommendation, but state law authorizes pharmacists to vaccinate pursuant to a prescription, then a prescription is necessary and sufficient. Some states authorize pharmacists to order/prescribe the vaccine in this case via state law, statewide protocol, or standing order.
- A standing order issued by a state health officer is equivalent to a prescription. However, if a state law limits a pharmacist's authority to administer vaccines to individual, patient-specific prescriptions, then a standing order would not be sufficient to meet that requirement. A standing order may nevertheless provide an independent basis for authority to administer vaccines, depending on state law.

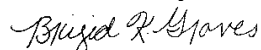
Requiring a separately issued patient-specific prescription would limit access, increase health care provider administrative burden, increase unnecessary time spent obtaining a prescription, and increase health care costs with time and effort spent to request and obtain a prescription. Given the fact that 100 million Americans do not have a primary care provider⁶, it is a reasonable assumption that obtaining a prescription in many cases would be incredibly difficult and one that would prohibit many eligible patients from receiving a desired and needed vaccine. APhA highly recommends against placing a patient-specific prescription requirement on any vaccine.

Pharmacists assess risks and benefits

Pharmacists routinely perform individualized patient assessments to determine whether a medication or vaccine is clinically indicated, weighing the risks and benefits in the context of each patient's health status, history, and preferences. This process is embedded within the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process⁷, which guides pharmacists to collect relevant patient information, assess clinical needs, and engage in shared decision-making with that patient or via their caregiver. When evaluating vaccines, pharmacists consider factors such as age, comorbidities, immunization history, and potential adverse effects, and they discuss these considerations directly with the patient to ensure informed consent. This risk-benefit analysis is not only a standard practice but also mirrors the shared clinical decision-making approach previously applied to vaccines such as HPV, pneumococcal conjugate, and meningococcal B. Pharmacists document these evaluations and recommendations in accordance with professional standards, ensuring transparency and continuity of care. Given their training, accessibility, and experience in vaccine counseling and administration, pharmacists are exceptionally qualified to conduct these interventions independently. We strongly urge ACIP to continue recognizing pharmacists as capable providers of shared clinical decision-making for vaccines without imposing additional barriers.

Thank you for the opportunity to comment on the upcoming ACIP meeting. We look forward to continued collaboration.

Most sincerely,



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⁶ National Association of Community Health Centers, HealthLandscape, & American Academy of Family Physicians. (2023). *Closing the gap: How community health centers can address the nation's primary care crisis*. https://www.nachc.org/wp-content/uploads/2023/06/Closing-the-Primary-Care-Gap_Full-Report_2023_digital-final.pdf

⁷ Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process. May 20, 2025. Available at: <https://jcnp.net/wp-content/uploads/2018/10/Pharmacists-Patient-Care-Process-Document-2025.pdf>.