



## IMMUNIZATIONS UPDATE

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**I know this is a long statement but it is important – please review carefully! The first part is some clarification around the previous immunization announcement. The second concerns an announcement released September 9 which adds in COVID vaccines, when ready. These are huge opportunities for pharmacies.**

### **August 19 Declaration Amendment – Childhood Vaccines 3 to 18**

The U.S. Department of Health and Human Services (HHS) [issued a third amendment - PDF](#) to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

"Today's action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic," said HHS Secretary Alex Azar. "The Trump Administration has worked to allow pharmacists—alongside all of America's heroic healthcare workers—to practice at the top of their license, empowering the public with more options to protect their health and well-being."

The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements:

- The vaccine must be approved or licensed by the Food and Drug Administration (FDA).
- The vaccination must be ordered and administered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, **submitting the required immunization information to the State or local immunization information system (vaccine registry)**, complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- **The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.**

The above requirements are consistent with many States that already permit licensed pharmacists to order and administer vaccines to children.

You can view the full press release [here](#).

### Limited Guidance and Statement:

**PPA is providing the following as guidance or information only.**

Since most of the above requirements are already Pennsylvania requirements, it seems that most pharmacists should be able to comply with the above and expand their services.

**The items bolded above are two different areas to be sure to pay close attention to as you prepare.**

1. **Reporting:** Not all pharmacies may be registered with and reporting to PA SIIS and since that was NOT previously a requirement; I have been told it isn't required NOW. However, it is a good idea to become a reporter. Information, including the enrollment agreement, on the SIIS can be found here: <https://www.health.pa.gov/topics/Reporting-Registries/PA-SIIS/Pages/PA-SIIS.aspx>

Pharmacies located in Philadelphia do need to report to PhilaVax, as this has previously been a requirement: <https://vax.phila.gov/index.php/reporting-to-philavax/>

2. **Well Visit Promotion: We have tools to help comply with this piece:**

### Well-Child Visit Templates: Tools to Meet HHS Requirement (September 9)

A Task Force on Pharmacist Engagement in State-Based COVID Vaccination comprising APhA, NASPA, and NCPA and state pharmacy association executives developed three tools for use by pharmacists to satisfy the requirement under the HHS Amendments authorizing pharmacists to administer childhood and COVID-19 vaccines. The latest HHS Amendment states: "the licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate." Two tools are Word documents, so individuals may customize or add data.

[Well-Child Visit Brochure \(PDF\)](#)  
[Template Referral Form Well-Child Visit \(Word\)](#)  
[Well-Child Checkup Letter \(Word\)](#)

## Additional Questions and Concerns

**Protocols:** Many members have asked about needing to update their protocols. This is a bit tricky as despite our requesting it -- we have no absolute clarification, as yet, from our PA State Board of Pharmacy and we have heard a variety of opinions.

It is the opinion of APhA and others, that the word **order** appears in the amendment and hence gives the pharmacist authority (outside of a protocol) to order the needed vaccine. This appears to make perfect sense.

**Students:** This allows students (who meet the requirements, which in Pennsylvania include having a license to administer) to provide immunizations under a pharmacist permitted to do immunizations. **The Pennsylvania Department of State is planning to have the PALS site up and running for student interns to apply and get their license to immunize sometime in October.** There is a nuance, interns cannot ORDER (pharmacists can per above) but they can administer.

## September 9 Amendment – COVID 19 Vaccine Administration Authority

The U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health, issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) to expand access to safe and effective COVID-19 vaccines when they are made available. This guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.

"This action builds upon our Administration's progress toward delivering a safe, effective, and widely available vaccine by 2021," said Assistant Secretary for Health ADM Brett P. Giroir, M.D. "Allowing pharmacists to order and administer COVID-19 vaccines will greatly expand convenient access for the American people."

To qualify as "covered persons" under 42 U.S.C. § 247d-6d((i)(8)(B) when administering COVID-19 vaccines authorized or licensed by the U.S. Food and Drug Administration (FDA) to persons ages 3 or older, state-licensed pharmacists and pharmacy interns licensed or registered by their state board of pharmacy must satisfy the following requirements:

- The vaccine must be FDA-authorized or FDA-licensed.
- The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine recommendation.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must

include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic CPR.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including reviewing the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

**The authorization preempts any state and local laws that prohibit or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above. The authorization does not preempt state and local laws that permit additional individuals to administer COVID-19 vaccines to additional persons.**

Access a copy of the [guidance - PDF\\*](#)

Information on [Operation Warp Speed](#)

Clinical [resources](#) on vaccines, including continuing education training on best practices

## **Need some Refreshers:**

As part of our upcoming Virtual Conference – we have this particular session:

### **CE: Diving into Pandemic Vaccine Planning**

*Presented by: Kim C. Coley, PharmD, FCCP, Professor of Pharmacy and Therapeutics, University of Pittsburgh School of Pharmacy & Chiara Gessler, PharmD, Clinical Pharmacist Coordinator and Shared Faculty, Giant Eagle, Inc. & Duquesne University School of Pharmacy*

Check out the Conference schedule and plan to join us:

<https://www.papharmacists.com/page/Annual2020> .

# Information from a Special PPCN Coffee and Conversation

PPCN pharmacy owner Vince Hartzell presented on important immunization updates that impact PA pharmacists- you won't want to miss it!

[Watch Coffee and  
Conversation](#)

[Watch Injection  
Technique for  
Children](#)

[Link to CDC  
Vaccine Schedule](#)

Please also note we have some immunization CEs in our online catalog:

[https://www.papharmacists.com/page/Recorded\\_CE\\_Webinars](https://www.papharmacists.com/page/Recorded_CE_Webinars)