Updated on September 24, 2021

# Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacy

Booster Doses: What You Need to Know
September 23, 2021

*For Every Pharmacist. For All of Pharmacy.*

pharmacist.com

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American Pharmacists Association

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*Host and Moderator*

# Today's Webinar

Discuss breaking updates and information to help you prepare to administer booster doses, including recommendations for use and considerations related to authority, documentation, and billing.

**Steve Foster, PharmD, FAPhA**
APhA Liaison to ACIP
CAPT (Ret.), U.S.P.H.S.

*Guest Speaker*

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Director of Scientific Communications,
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*Subject Matter Expert: Q&A*

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Senior Manager
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*Subject Matter Expert: Q&A*

# Format for Today's Webinar

**4:00pm:** Introductions

**4:05pm:** Discussion with Steve Foster & John Grabenstein

**4:30pm:** Open Forum Discussion: Share Your Questions & Thoughts

**4:50pm:** Review of APhA's Ongoing Activities & What's Coming

# Open Forum Ground Rules

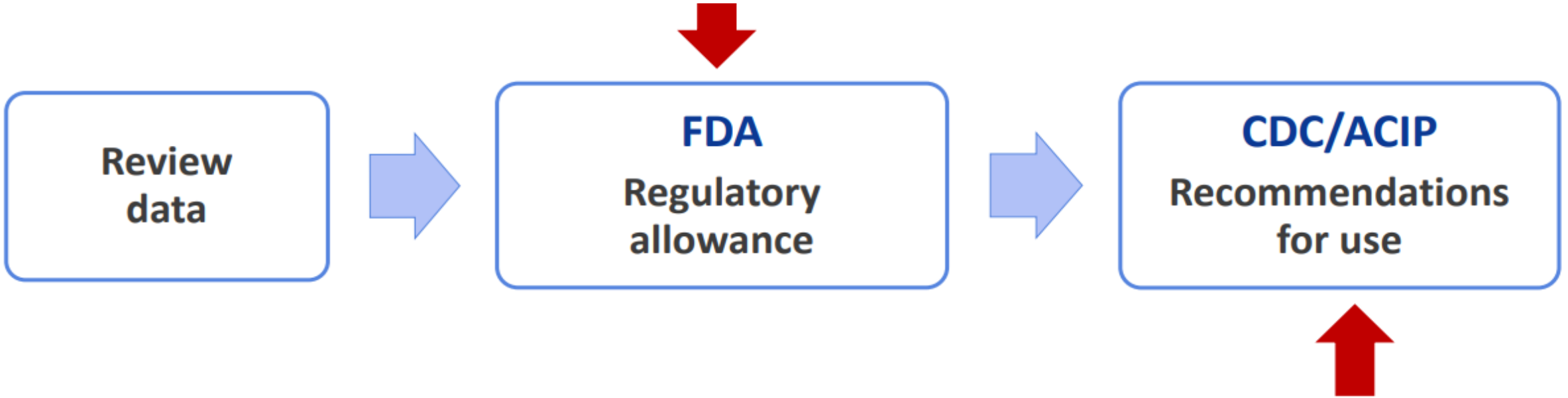
- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- We will try to get to as many comments and questions as possible!
- Refer to the **Handout** in the GoToWebinar toolbar to access today's slides and links to resources.

# Discussion with Steve Foster & John Grabenstein

Discuss breaking updates and information to help you prepare to administer booster doses, including recommendations for use and considerations related to authority, documentation, and billing.

# Booster Doses of COVID-19 Vaccines

Policy on booster doses will be coordinated with **FDA** for regulatory allowance, and **ACIP** for recommendations for use




After FDA regulatory action, ACIP will have additional discussions around recommendations for use

# FDA Authorization

## Pfizer-BioNTech COVID-19 Vaccine Booster

**FDA revised the Pfizer-BioNTech EUA to allow for use of a single booster dose administered at least six months after completion of the primary series in:**

- Individuals 65 yrs or older;
- Individuals 18 - 64 years of age at high risk of severe COVID-19; and
- Individuals 18 - 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

**Populations could include:**

- Health care workers
- Teachers and day care staff
- Grocery workers
- Those in homeless shelters or prisons

## Next Steps:

Actual groups to be included in recommendations to be released by CDC.

CDC recommendation needed for providers to begin administering Booster doses.

# Number of persons eligible (in millions) for a booster dose on September 27th, 2021

| | ≥6 months after primary series | | | |
|---|---|---|---|---|
| **Age group** | **Pfizer-BioNTech** | **Moderna** | **Janssen/J&J** | **Total** |
| 18-29 years old | 2.0 | 1.5 | 0.3 | **3.9** |
| 30-49 years old | 5.5 | 4.4 | 0.9 | **10.8** |
| 50-64 years old | 5.3 | 4.4 | 1.2 | **11.0** |
| 65+ years old | 13.6 | 12.9 | 0.8 | **27.4** |
| **Total** | **26.4** | **23.4** | **3.3** | **53.0** |

# ACIP Decision Discussions

**Policy question #1:**

Should adults **≥65 years of age** and **LTCF residents** receive a Pfizer-BioNTech COVID-19 vaccine booster dose?

**Policy question #2:**

Should adults **18–64 years of age** at risk for severe COVID-19 due to **underlying medical conditions** receive a Pfizer-BioNTech COVID-19 vaccine booster dose?

**Policy question #3:**

Should adults **18–64 years of age** at risk of SARS-CoV-2 exposure due to **occupation/setting** receive a Pfizer-BioNTech COVID-19 vaccine booster dose?

**Certain immunocompromised individuals include individuals who are moderately or immunocompromised**

| Additional Dose | Booster Dose |
|---|---|
| Administered when the immune response following an original vaccine series is likely **insufficient**. | Administered when the immune response following an original vaccine series is sufficient, but likely to have **waned overtime**. |
| **Recommendations** | |
| ← Certain immunocompromised individuals **SHOULD** receive an additional dose of mRNA COVID-19 vaccine to achieve a sufficient level of protection. | Certain individuals who received a primary series of Pfizer-BioNTech COVID-19 vaccine **SHOULD** receive a booster dose to maintain a sufficient level of protection. → |
| Updated Pfizer-BioNTech and Moderna **three-dose** vaccine series for certain immunocompromised individuals ≥28 days later: | Updated Pfizer-BioNTech **two-dose** COVID-19 vaccine series, followed by a **booster** for certain individuals ≥6 months later: |
| Dose 1 → Dose 2 → Dose 3 | Dose 1 → Dose 2 → Booster |

At least 6 months after a primary vaccine series:

- Persons aged ≥65 years
- Long-term Care Facility (LTCF) residents
- Persons aged 50-64 years with underlying medical conditions
- Persons aged 18-49 years with underlying medical conditions and based on individual benefit and risk
- Persons aged 18-64 at risk of exposure and transmission because of occupational or institutional setting.*

* would include health care workers, teachers and other essential workers

**As of 9/24/21**

# Underlying Medical Conditions

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

- Cancer
- Chronic kidney disease
- Chronic lung diseases, including COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Dementia or other neurological conditions
- Diabetes (type 1 or type 2)
- Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension)
- HIV infection
- Immunocompromised state (weakened immune system)
- Liver disease
- Overweight and obesity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease, which affects blood flow to the brain
- Substance use disorders

There is currently not enough data to support a recommendation for additional doses or boosters in individuals who received the Moderna or Johnson & Johnson COVID-19 vaccines. FDA and CDC are working to provide guidance to these individuals.

# Interchangeability

## COMIRNATY and Pfizer-BioNTech

- Interchangeable for any patient, per CDC
- Same formulation
- COMIRNATY is FDA-approved for individuals ages 16 years and older
- Pfizer-BioNTech is FDA-authorized for individuals ages 12-15 years old

## Pfizer-BioNTech and Moderna

- Interchangeable ONLY when a moderately or severely immunocompromised patient presents for an additional dose and the product given for the first two doses is not available, per CDC
- mRNA vaccines

# Discussion with Steve Foster & John Grabenstein

Discuss breaking updates and information to help you prepare to administer booster doses, including recommendations for use and considerations related to authority, documentation, and billing.

# Billing for COVID-19 Vaccine Boosters

| Dose | Prescription Billing Pathway (NCPDP): SCC Values | Medical Billing Pathway: CPT Codes | | |
|---|---|---|---|---|
| | All COVID-19 Vaccines | Pfizer-BioNTech | Moderna | Janssen (J&J) |
| **First Dose** | 2 | 0001A | 0011A | 0031A |
| **Second Dose** | 6 | 0002A | 0012A | |
| **Additional Dose*** | 7 | 0003A | 0013A | |
| **Booster Dose** | 10** | 0004A | 0064A | |

*For targeted populations
**Some PBMs may temporarily require SCC 7 and SCC 10 to be submitted together

# Open Forum Discussion: Share Your Questions & Thoughts

# Review of APhA's Ongoing Activities & What's Coming


- **PREP Act 9th amendment** - Authorization for pharmacists to order and administer select COVID-19 therapeutics, including monoclonal antibody therapy
- **Testing:** Expansion of testing to 10,000 additional "retail" pharmacies
- **Boosters:** Utilizing all pharmacies to administer millions of doses of the vaccine boosters once they are approved

Link to the Plan: [President Biden's COVID-19 Plan | The White House]

# PREP Act – 9th Amendment

| | Pharmacists | Pharmacy Technicians | Pharmacy Interns |
|---|---|---|---|
| **Active state license** | Licensed or registered per state requirements; must have CPhT from PTCB or NHA if no state requirements | Licensed or registered per state requirements or if inactive/expired/lapsed in good standing within 5 years; must be authorized if no state requirements | Licensed or registered per state requirements or if inactive/expired/lapsed in good standing within 5 years; must be authorized if no state requirements |
| **Authority** | Order and administer | Administer | |
| **Supervision Requirements** | None | A readily available qualified pharmacist | A trained health care professional |
| **COVID-19 Therapeutics Requirements** | Must be ordered and administered subcutaneously, intramuscularly, or orally in accordance with FDA approval, authorization, or licensing. | | |
| **Training Requirements** | Must complete an ACPE-approved practical training program that includes hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required by FDA approval, authorization, or licensing.<br>These requirements can be met by completing the following training programs:<br>• APhA's Certificate Training Program for Pharmacy-based Immunization Delivery meets the requirement for hands-on injection technique and general recognition and treatment of emergency reactions to COVID-19 therapeutics.<br>• APhA's Monoclonal Antibodies: Assessment and Administration of COVID-19 Therapy training program reviews the clinical evaluation of indications and contraindications for COVID-19 therapeutics, adverse events, as well as and product-specific requirements or considerations related to FDA approval, authorization, clearance or licensing of COVID-19 therapeutics. | | |
| **Basic CPR Requirements** | Must have a current certificate in basic CPR. An online basic CPR certification program accredited by ACPE, the American Nurses Credentialing Center, or the Accreditation Council for Continuing Medical Education satisfies this requirement. | | |
| **Recordkeeping Requirements** | Must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary care provider when available and complying with adverse-event reporting requirements. | The supervising qualified pharmacist must comply with recordkeeping and reporting requirements as described to the left. | Same as pharmacists. |
| **Additional Requirements** | Must comply with any relevant requirements or conditions of use that apply to the administration of COVID-19 therapeutics. | | |

# COVID-19 Therapeutics

APhA APhA COVID-19 RESOURCES: KNOW THE FACTS

## Authority to Provide COVID-19 Therapeutics

Pharmacists, Pharmacy Technicians, and Student Pharmacists and Interns

The federal government now allows eligible licensed pharmacists to order and administer COVID-19 therapeutics has approved, authorized, cleared, or licensed. The amendment also authorizes pharmacy interns and pharmacy therapeutics. This federal authority was made official when the U.S. Department of Health and Human Services ( Public Readiness and Emergency Preparedness (PREP) Act on September 9, 2021.

### What is a COVID-19 therapeutic?

To be considered a COVID-19 therapeutic, the therapy must be approved, authorized, or licensed by FDA. License administer a COVID-19 therapeutic only when it is administered by subcutaneous, intramuscular, or oral route.

At this time, there is only one COVID-19 therapeutic that can be given subcutaneously. REGEN-COV (casirivimab/ with an emergency use authorization (EUA) for the treatment of COVID-19 infection and for post-exposure proph

While other COVID-19 monoclonal antibody therapies and COVID-19 therapeutics are authorized or approved, the infusion. Under the PREP Act, pharmacists do not have the authority to order and administer these intravenously

Oral COVID-19 therapeutics are being studied; if authorized, approved, or licensed, pharmacists would have the a treatment of COVID-19, likely with proof of a positive COVID-19 test.

### What if my state scope of practice does not allow me to order and/or administer COV therapeutics?

During the public health emergency, the federal authority to order and/or administer COVID-19 therapeutics woul apply even when a state law otherwise prohibits a qualified person from ordering, dispensing, or administering c COVID-19 therapeutics.

### What if my state scope of practice is more permissive than this federal authority?

When state scope of practice allows pharmacists, pharmacy technicians, or pharmacy interns greater authority t and/or administer therapeutics, this more permissive state authority would remain. Individuals practicing in such should continue to follow their state scope of practice.



APhA APhA COVID-19 RESOURCES: KNOW THE FACTS

## Monoclonal Antibody Therapies

Considerations for Therapy and the Pharmacists' Role

**Quick Links**

- HHS's Monoclonal Antibody Resources for Clinicians
- NIH's COVID-19 Treatment Guidelines for Anti-SARS-CoV-2 Monoclonal Antibodies

### What is the benefit of monoclonal antibody therapy?

Monoclonal antibody therapies use exogenously generated antibodies that neutralize the SARS-CoV-2 virus's ability to infect cells. This can reduce the severity of COVID-19 symptoms in patients at high risk for developing COVID-19 disease.

Food and Drug Administration (FDA) has authorized monoclonal antibody therapies to treat individuals with mild to moderate COVID-19 disease who are at risk of developing severe disease. Casirivimab/imdevimab (REGEN-COV) is also authorized for prophylaxis in high-risk individuals who have been exposed to COVID-19.

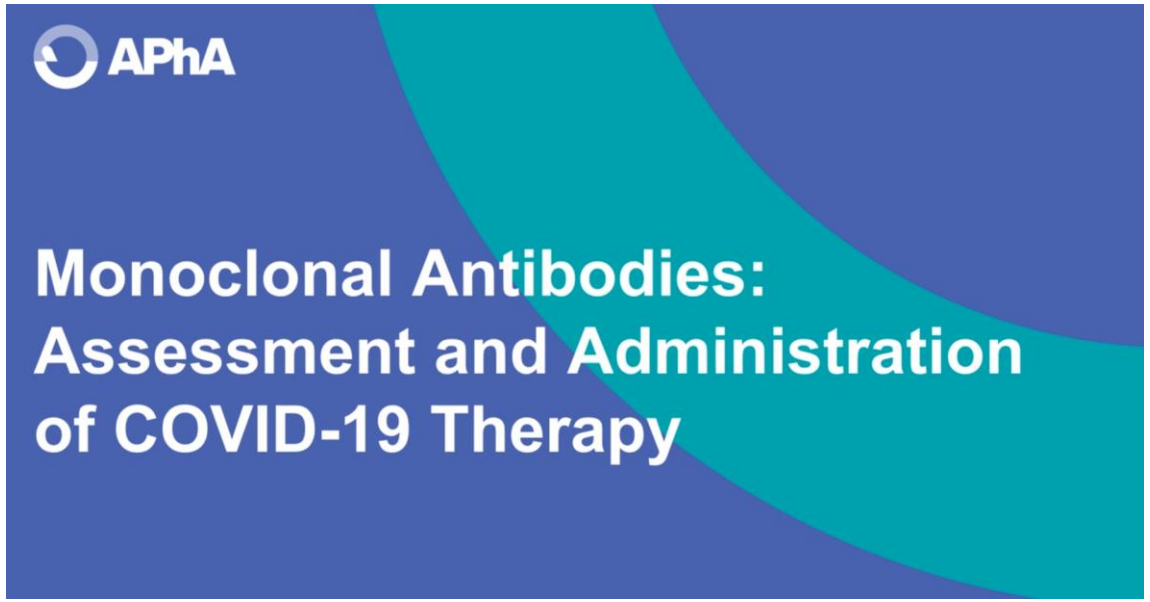
These therapies should not be considered a substitute for vaccination or be used for pre-exposure prophylaxis, i.e., to prevent COVID-19 infection.

### Which monoclonal antibody therapies have received FDA authorization?

| Therapy | Manufacturer | Authorized Use | Dosage Form | Emergency Use Authorization Fact Sheets |
|---|---|---|---|---|
| **Casirivimab/ imdevimab (REGEN-COV)** | Regeneron | • Treatment of mild to moderate COVID-19 infection<br>• Post-exposure prophylaxis | I.V. or Sub-Q | • Fact Sheet for Health Care Providers<br>• Fact Sheet for Patients, Parents, and Caregivers |
| **Sotrovimab** | GSK | • Treatment of mild to moderate COVID-19 infection | I.V. | • Fact Sheet for Health Care Providers<br>• Fact Sheet for Patients, Parents, and Caregivers |
| **Bamlanivimab/ etesevimab** | Lilly | • Treatment of mild to moderate COVID-19 infection<br>• Post-exposure prophylaxis | I.V. | • Fact Sheet for Health Care Providers<br>• Fact Sheet for Patients, Parents, and Caregivers |



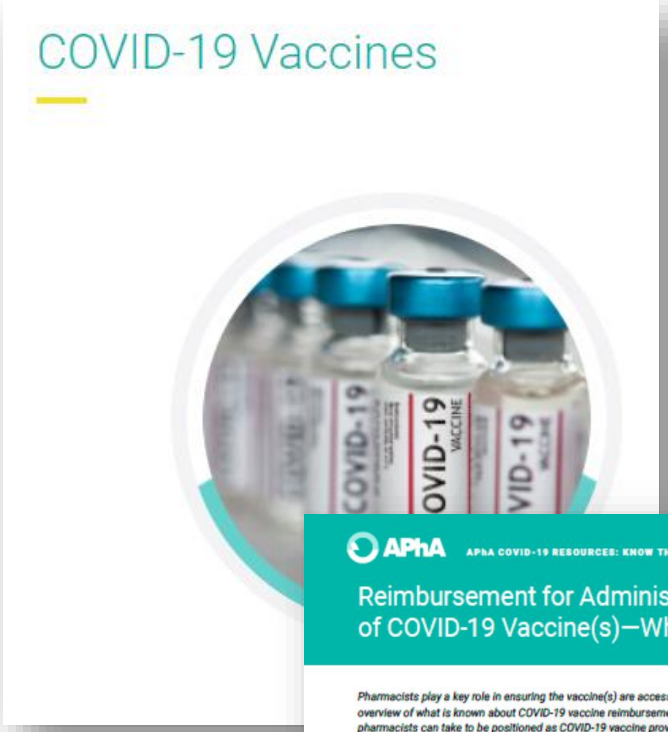
Visit the NEW APhA COVID-19 Therapeutics page to access our resources and training!

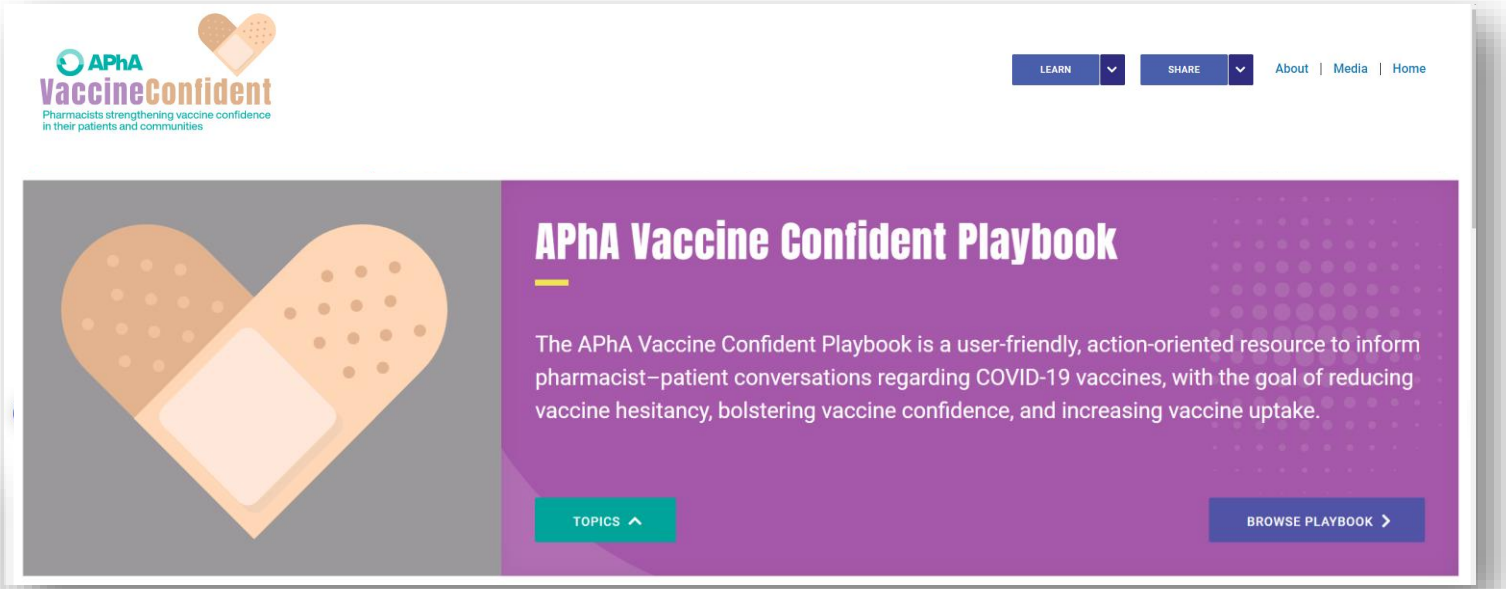



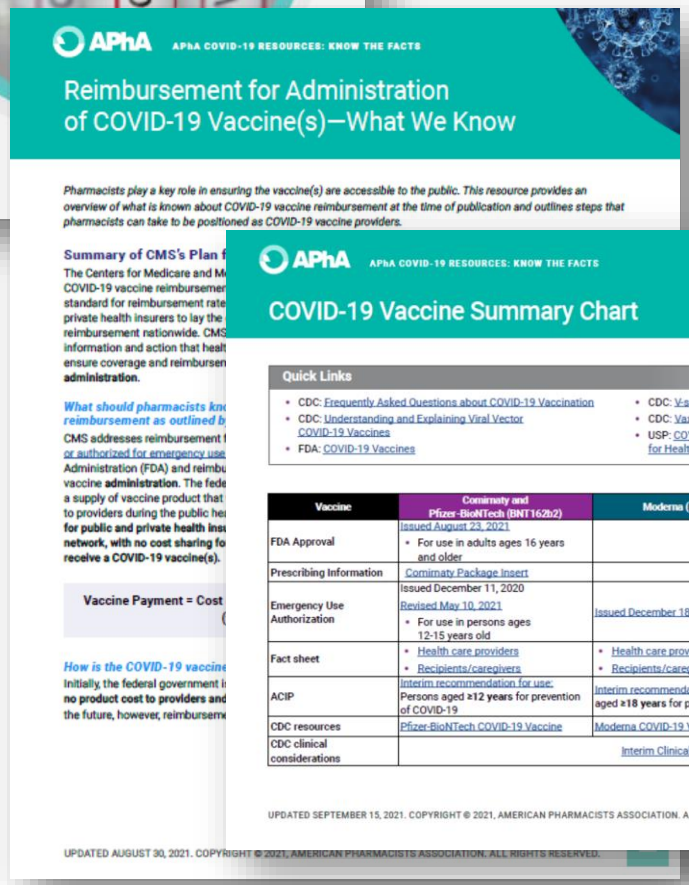

## *NEW CPE!*

Free training program designed to fully satisfy the requirements of the PREP Act by supplementing the Pharmacy-based Immunization Delivery certificate training programs.

Learn more.







Visit APhA's **Vaccine Confident** website to access resources, talking points, and other information to empower pharmacists to build vaccine confidence. https://vaccineconfident.pharmacist.com/

Visit APhA's COVID-19 Vaccines page.


# Post on ENGAGE

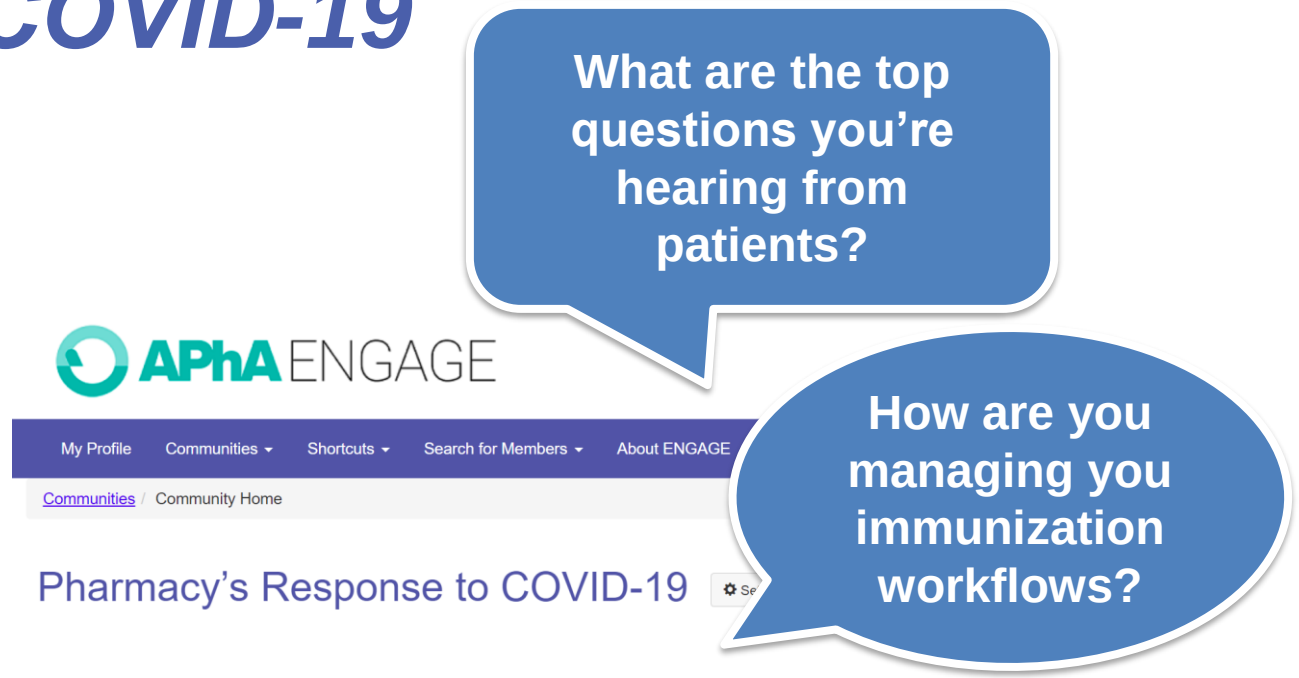
## *Pharmacy's Response to COVID-19*

**POST** your questions

**SHARE** your lessons learned

**SUPPORT** your colleagues

**ACCESS** the latest information

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# Join Us!

## Thursday, October 14, 1:00-2:00 pm ET

## CE Available

Registration coming soon!

Today's webinar will be available at
https://www.pharmacist.com/Practice/COVID-19/Open-Forum-Webinars


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