



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

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For Every Pharmacist. For All of Pharmacy.

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Sandra Leal, PharmD, MPH, FAPhA, CDCES

Executive Vice President

SinfoniaRx a TRHC Solution

President

American Pharmacists Association

Host and Moderator

Today's Webinar

Discuss available evidence and recommendations for COVID-19 vaccines as well as what we know about the impact of COVID-19 disease in patients who are pregnant, breastfeeding, or contemplating pregnancy.

Conducted in collaboration with the American College of Obstetricians and Gynecologists





Jen Villavicencio, MD, MPP

Darney/Landy Fellow, Strategies for Health Equity
American College of Obstetricians and Gynecologists
(ACOG)

Guest Speaker



Veronica Vernon, PharmD, BCPS, BCACP, NCMP

Associate Professor of Pharmacy Practice
Butler College of Pharmacy and Health Sciences

Guest Speaker



Mitch Rothholz, RPh, MBA

Chief of Governance & State Affiliates
American Pharmacists Association

Executive Director
American Pharmacists Association Foundation

Subject Matter Expert: Q&A



Dan Zlott, PharmD, BCOP

Senior Vice President

Education and Business Development

American Pharmacists Association

Subject Matter Expert: Q&A



Ilisa G. Bernstein, PharmD, JD, FAPhA

Senior Vice President

Pharmacy Practice and Government Affairs

American Pharmacists Association

Subject Matter Expert: Q&A

Format for Today's Webinar

1:00pm: **Introductions**

1:05pm: **Discussion with Jen Villavicencio and Veronica Vernon**

1:25pm: **Open Forum Discussion: Share Your Questions & Thoughts**

1:50pm: **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.
- This webinar recording will be available in 24 hours.

Discussion with Jen Villavicencio and Veronica Vernon

Discuss available evidence and recommendations for COVID-19 vaccines as well as what we know about the impact of COVID-19 disease in patients who are pregnant, breastfeeding, or contemplating pregnancy.

COVID-19 Infection Risk in Pregnancy

Symptomatic pregnant women with COVID-19 are at **increased risk** of **more severe illness** compared with nonpregnant peers.

- ICU admission
- Need for mechanical ventilation
- ECMO
- Death

Safety of COVID-19 Vaccines

- Despite ACOG's persistent advocacy for the inclusion of pregnant individuals in COVID-19 vaccine trials, **none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals.** However, studies in pregnant women have begun.
- Based on the **mechanism of action of these vaccines** and the demonstrated safety and efficacy in Phase II and Phase III clinical trials, **it is expected that the safety and efficacy profile of the vaccine for pregnant individuals would be similar to that observed in non-pregnant individuals.**
- There is data demonstrating COVID-19 vaccine mediated **immunity** can be **passed through breast milk**

CDC “V-Safe Pregnancy Registry Data”

- CDC is currently enrolling pregnant individuals in a v-safe pregnancy registry and as of April 19, 2021 over 4,478 pregnant individuals were enrolled.
- Data collected through February 16th from the “**v-safe pregnancy registry**” indicate that the reactogenicity profile and adverse events observed among pregnant individuals in v-safe **did not indicate any safety concerns**. Additionally, side effects were similar in pregnant and non-pregnant populations.

Discussion with Jen Villavicencio and Veronica Vernon

Discuss available evidence and recommendations for COVID-19 vaccines as well as what we know about the impact of COVID-19 disease in patients who are pregnant, breastfeeding, or contemplating pregnancy.

ACOG Resources

- Practice Advisory: [Vaccinating Pregnant and Lactating Patients Against COVID-19](#)
- COVID-19 Vaccines and Pregnancy: [Conversation Guide for Clinicians](#)
- Resource: [Eight Key Recommendations for COVID-19 Vaccination Sites](#)
- Joint Statement: [Maternal Immunization Task Force and Partners Urge That COVID-19 Vaccine be Available to Pregnant Individuals](#)
- Joint Statement: [Medical Experts Continue to Assert that COVID Vaccines Do Not Impact Fertility](#)
- ACOG Statement on the [Johnson & Johnson COVID-19 Vaccine](#)
- Patient Resources:
 - <https://www.acog.org/womens-health/faqs/coronavirus-covid-19-pregnancy-and-breastfeeding>
 - <https://www.acog.org/womens-health/faqs/coronavirus-covid-19-and-womens-health-care>

Additional Resources

- Academy of Breastfeeding Medicine (ABM): [Considerations for COVID-19 Vaccination in Lactation](#)
- Organization of Teratology Information Specialists Resources: [MotherToBaby](#)
- American Society for Reproductive Medicine (ASRM): [Statement from the ASRM COVID-19 Task Force](#)
 - [ASRM COVID-19 Updates and Resources](#)

Open Forum Discussion: Share Your Questions & Thoughts

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

Congressional legislation reintroduced to reimburse pharmacists for their services

- The *Pharmacy and Medically Underserved Areas Enhancement Act* was reintroduced in Congress today
- Lead sponsors include Reps. G.K. Butterfield (D-NC) & David McKinley (R-WV) Sens. Charles Grassley (R-IA) & Bob Casey (D-PA)
- The bill would do the following:
 - allow pharmacists in medically underserved areas to bill Medicare Part B for patient care services
 - pharmacists would be reimbursed at 85% of the physician fee schedule
 - services are limited to pharmacists' state scope of practice laws



- **In a big win for pharmacists and immunizers across the country**, HRSA [announced](#) the withdrawal of its final rule that would have removed federal liability protections for vaccination shoulder injuries and syncope.
- APhA – joined by NASPA – have submitted numerous letters opposing HRSA's harmful proposal.
- In its rationale for withdrawal of the final rule, HRSA specifically cited APhA's and NASPA's [joint comments](#).
- **Important point:** Shoulder injuries and syncope will remain on the Vaccine Injury Table, thus precluding state lawsuits against immunizers for these injuries.



- APhA recently met with UnitedHealthcare (UHC) to discuss billing problems for COVID-19 vaccines for uninsured patients
- Key points:
 - Vaccines (and COVID-19 tests) are paid in the medical benefit
 - Need a medical intermediary to submit claims
 - Claims can be submitted for services *within last 12 months* once enrolled
 - Enrollment process can be expedited by setting up Optum Pay ACH and completing provider roster *concurrently*
 - Provider roster – choose *hospital_ancillary_clinic* tab and fill in *pharmacy* info
 - UHC is expanding pharmacy resources and updating call center scripts
- For More Information Visit: [HRSA's Frequently Asked Questions](#) webpage.

Know the Facts (Practice Resources)

Visit the COVID-19 Practice Resource Library

APHA COVID-19 RESOURCES: KNOW THE FACTS

COVID-19 Vaccine Summary Chart

Find the following information in this quick reference for pharmacy:

Quick Links

• Quick links and guidance

• Dosing and administration

• Storage

• Dose preparation

• Efficacy and safety information

• Clinical considerations

• Special populations

• Ingredients

Quick Links

• CDC: [Frequently Asked Questions about COVID-19 Vaccination](#)

• CDC: [Understanding and Explaining Viral Vector COVID-19 Vaccines](#)

• FDA: [COVID-19 Vaccines](#)

• CDC: [V-safe After Vaccination Health Checker](#)

• CDC: [VaxTextSM COVID-19 Vaccination Second-Dose Reminder](#)

• USP: [COVID-19 Vaccine Handling: Operational Considerations for Healthcare Practitioners](#)

Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.5)
EUA	Issued December 11, 2020	Issued December 18, 2020	Issued February 27, 2021
Fact sheet	<div><div>• Health care providers</div><div>• Recipients/caregivers</div></div>	<div><div>• Health care providers</div><div>• Recipients/caregivers</div></div>	<div><div>• Health care providers</div><div>• Recipients/caregivers</div></div>
ACIP	Interim recommendation for use: Persons aged ≥16 years for prevention of COVID-19	Interim recommendation for use: Persons aged ≥18 years for prevention of COVID-19	Interim recommendation for use: Persons aged ≥18 years for prevention of COVID-19
CDC resources	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen COVID-19 Vaccine
CDC clinical considerations	Interim Clinical Considerations		

Continues.

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APHA COVID-19 RESOURCES: KNOW THE FACTS

Reimbursement for Administration of COVID-19 Vaccine(s)—What We Know

Pharmacists play a key role in ensuring the vaccine(s) are accessible to the public. This resource provides an overview of what is known about COVID-19 vaccine reimbursement and outlines steps that pharmacists can take to be positioned as COVID-19 vaccine administrators.

Summary of CMS's Plan for COVID-19 Vaccine Reimbursement

The Centers for Medicare and Medicaid (CMS) is leading COVID-19 vaccine reimbursement efforts by setting a standard for reimbursement rates and working with state and private health insurers to lay the groundwork for reasonable reimbursement nationwide. CMS's [COVID-19 webpage](#) outlines information and action that health care providers can take to ensure coverage and reimbursement for COVID-19 vaccine administration.

What should pharmacists know about vaccine reimbursement as outlined by CMS?

CMS addresses reimbursement for the vaccine product(s) approved or authorized by the Food and Drug Administration (FDA) under an [Emergency Use Authorization \(EUA\)](#) and reimbursement to the provider for their administration. The federal government has

will be distributed through federal public health emergency (PHE), and private health insurers to cover network, with no cost sharing. Patients do not incur out-of-pocket costs to receive a COVID-19 vaccine.

Pharmacists administer COVID-19 vaccine to Medicare and Medicaid patients. The care provider needed to bill COVID-19 patients. Today for Medicaid

Note: HHS's CPR requirement for the Council for

APHA COVID-19 RESOURCES: KNOW THE FACTS

Authority to Provide Childhood Immunizations

Pharmacists, Pharmacy Technicians, and Pharmacy Interns

The U.S. Department of Health and Human Services (HHS) expanded [childhood](#) vaccination authority under the Public Readiness and Emergency Preparedness (PREP) Act for pharmacists, [pharmacy technicians](#), and [student pharmacists](#) and interns. To optimize these opportunities and increase access for the communities you serve, it is important to know what is expected and prepare for your expanded role as an immunizer.

Note: HHS's CPR requirement for the Council for

APHA COVID-19 RESOURCES: KNOW THE FACTS

Authority to Immunize Against COVID-19

Pharmacists, Pharmacy Technicians, Student Pharmacists and Interns (Active, Retired, or Inactive)

The U.S. Department of Health and Human Services (HHS) expanded COVID-19 vaccination authority under the [Public Readiness and Emergency Preparedness \(PREP\)](#) Act for [pharmacists](#), [pharmacy technicians](#), [student pharmacists](#) and [interns](#), and [retired or inactive pharmacists and interns](#) nationwide during the public health emergency. To optimize these opportunities and increase access for the communities you serve, it is important to know what is expected and prepare for your expanded role as an immunizer.

	Pharmacists	Pharmacy Technicians	Student Pharmacists/Interns	Retired/Inactive Pharmacists and Pharmacy Interns
Licensure Requirements	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	Active license or certification within the last 5 years has expired or lapsed; in good standing*
Authority	Order and administer	Administer	Administer	See applicable column to the left
Supervision Requirements	None	A readily available qualified pharmacist	A trained health care professional	See applicable column to the left
Age Requirements	Authorized to vaccinate patients 3 years or older; currently, Pfizer-BioNTech COVID-19 vaccine recommended for patients 16 years and older; Moderna and Janssen COVID-19 vaccines recommended for patients 18 years and older; refer to ACIP COVID-19 vaccine recommendations below			
Vaccine Requirements	FDA-authorized or FDA-licensed			
ACIP Guidelines/Recommendations	ACIP's COVID-19 vaccine recommendations ; reference CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States and the "COVID-19 Vaccine Summary Chart" in APHA's COVID-19 Resources: Know the Facts library.			

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Education During COVID-19(CPE Videos)



COVID-19 Myth vs. Fact: Vaccine Hesitancy

1 hour CPE home study

A CDC representative shares his expertise in addressing vaccine hesitancy and messages pharmacists should know in order to build vaccine confidence in the patients they serve.

[Access APhA's Library of COVID-19 Education \(CPE\)](#)

Post on ENGAGE

Pharmacy's Response to COVID-19

POST your questions
SHARE your lessons learned
SUPPORT your colleagues
ACCESS the latest information

What are the top concerns you're hearing about COVID-19 vaccines?



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What resources have you shared with patients?

Join Us!

Thursday, May 13, 1:00-2:00 pm ET

CPE Available & Registration Coming Soon!

Today's webinar will be available within 24 hours

<https://aphanet.pharmacist.com/coronavirus/weekly-webinars>

COVID-19 Developmental and Reproductive Toxicity (DART) Studies

- **Pfizer-BioNtech COVID-19 vaccine:** Animal studies using the Pfizer/BioNtech COVID-19 vaccine do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development ([EMA](#)).
- **Moderna COVID-19 Vaccine:** mRNA1273 given to rats prior to mating and during gestation periods at dose of 100 µg did not have any adverse effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention ([FDA](#)).
- **Janssen COVID-19 Vaccine:** No vaccine related adverse effects on female fertility, embryo-fetal or postnatal development up to Postnatal Day 28 were observed ([FDA 2021](#)). Further, based on data from ongoing and completed clinical trials of Ad26-vectored vaccines including COVID-19, HIV, and Ebola administered to pregnant individuals, overall, the Ad26-based vaccines have an acceptable safety and reactogenicity profile, without significant safety issues identified to date. In addition, the review of the available pregnancy data is not suggestive of a pregnancy-related safety concern ([FDA 2021](#)).

These DART studies provided the first safety data to help inform the use of the vaccine in pregnancy until there are more data in this population.

CDC v-safe Pregnancy Registry Data

- Specific pregnancy outcome data for 275 completed pregnancies were presented at the February 18, 2021 ACIP meeting.
- As demonstrated in this table, no differences have been seen when comparing pregnant women participating in the v-safe pregnancy registry with the background rates of adverse pregnancy outcomes.

Pregnancy Outcomes	Background Rate	V-safe Pregnancy Registry Overall
Miscarriage (<20 weeks)	26%	15%
Stillbirth (≥20 weeks)	0.6%	1%
Pregnancy Complications	Background Rate	V-safe Pregnancy Registry Overall
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal	Background Rate	V-safe Pregnancy Registry Overall
Preterm birth	10.10%	10%
Congenital anomalies	3%	4%
Small for gestational age	3-7%	4%
Neonatal death	0.38%	0%

ACOG Recommendations

Pregnancy

- COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
- In the interest of patient autonomy, pregnant individuals should be free to make their own decision regarding COVID-19 vaccination.
- While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

Lactation

- COVID-19 vaccines be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
- Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine.
- There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine.

Individuals Contemplating Pregnancy

- **ACOG recommends** vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization recommendations.
- Given the mechanism of action and the safety profile of the vaccine in non-pregnant individuals, COVID-19 mRNA vaccines are not thought to cause an increased risk of infertility. It is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.
- ACOG, SMFM, and ASRM issued a statement asserting that these vaccines do not impact fertility.
- If an individual becomes pregnant after the first dose of a COVID-19 requiring two doses, the second dose should be administered as indicated.
- Pregnancy testing should not be a requirement prior to receiving any COVID-19 vaccine.