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American Academy of Pediatrics
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Hot Topics on Respiratory Vaccines: Clearing the Air on Liability and Practice Considerations

October 21, 2025

5:00 – 6:00 pm ET

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Common Health Coalition

Faculty Disclosure Information

Nivedita (Nita) Mohanty

I have no relevant financial relationship with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this activity.

I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation

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Our time together today

5:00 - 5:05 pm **Welcome**

Nivedita (Nita) Mohanty, MD, MS, FAAP; *American Academy of Pediatrics*

5:05 - 5:10 pm **Situational Update**

Chelsea Cipriano, MPH; *Common Health Coalition*
Brigid Groves, PharmD, MS; *American Pharmacists Association*

5:10 - 5:45 pm **Shared Clinical Decision-Making, Liability & Informed Consent**

Charlene Wong, MD, MPH; *Common Health Coalition*
Steve Bondi, JD, MD, FAAP; *AAP Committee on Medical Liability and Risk Management*
Paul Rodriguez, JD; *Common Health Coalition*

5:45 - 6:00 pm **Q&A**

Liability Considerations and Practice

- The information in this webinar does not constitute legal advice. The purpose of this webinar is to share legal principles.
- Our focus today is on Respiratory Virus Season and most significantly around considerations for COVID-19

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Situational Update

Faculty Disclosure Information

Chelsea Cipriano

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2025-2026 Combined Respiratory Vaccine Recommendations

	Influenza Vaccine	RSV Immunization	COVID-19 Vaccine
Infants and Children	**All children 6 months and older** Some children 6 months to 8 years may need multiple doses AAP, AAFP, CDC	**All infants <8 months + children 8-19 months with risk factors** (nirsevimab, clesrovimab), typically Oct-Mar, if no maternal RSV vaccine AAP, AAFP, CDC	**All children 6-23 months + children 2-18 years with risk factors or if parent desires vaccine** AAP, AAFP
Pregnancy	**All** At any point in pregnancy ACOG, AAFP, CDC	OR **32-36 weeks gestation** (Pfizer, Abrysvo only) Typically Sept-Jan ACOG, AAFP, CDC	**All** At any point in pregnancy ACOG, AAFP
Adults 18-50	**All** AAFP, CDC	**See Pregnancy** AAFP, CDC	**All** *Especially important for people with risk factors or who have never received a vaccine* AAFP, IDSA
Adults 50+	**All** High-dose, recombinant or adjuvanted flu vaccine preferred for 65+, if available AAFP, CDC	**All 75+ and adults 50-74 with risk factors** One lifetime dose of RSV vaccine AAFP, CDC	**All** *Especially important for people with risk factors or who have never received a vaccine* AAFP, IDSA

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Last updated 10/20/25

Recommendations Table

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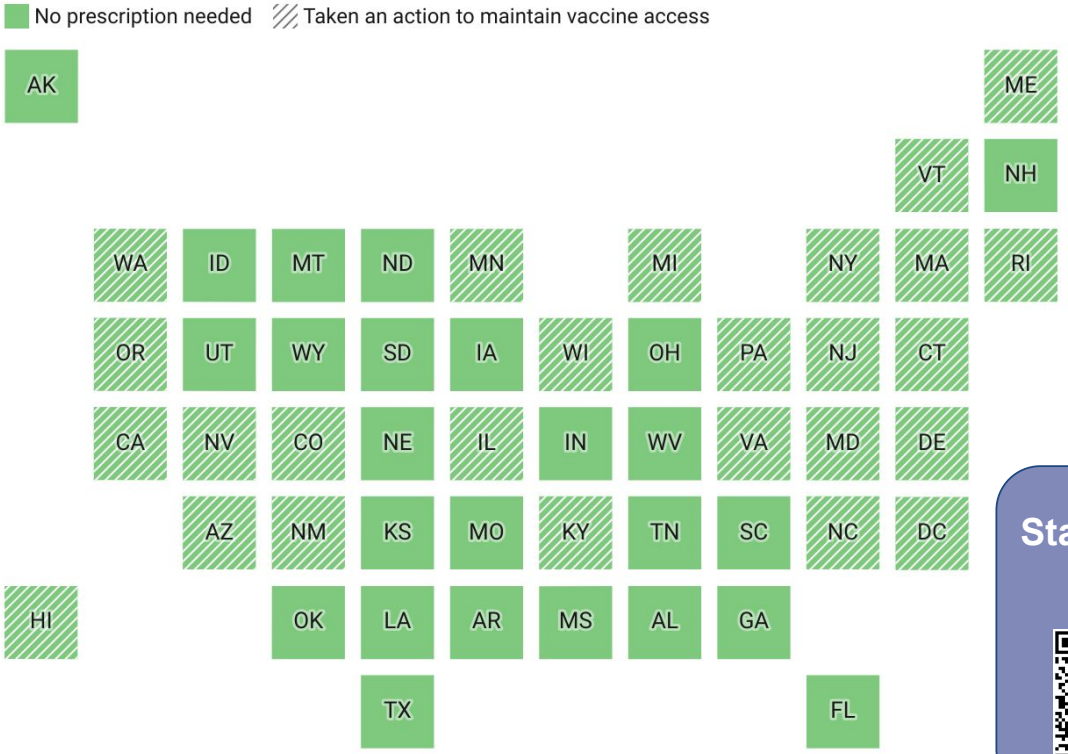
On September 19, 2025, ACIP recommended that vaccination for COVID-19 be determined by individuals – in consultation with a health care provider – **for everyone aged 6 months and older.**

ACIP explicitly voted **against** requiring prescriptions.

CHC ACIP Explainer

COVID-19 Vaccine Availability for Adults, by State

As of October 20, 2025



Map: Your Local Epidemiologist • Source: Common Health Coalition Tracker • Created with Datawrapper

State Action map

“4 Facts on COVID-19 Vaccines This Fall”

High Risk list

MOST AMERICANS ARE CONSIDERED “HIGH RISK”

More than 75% of Americans have a condition that qualifies them as “high risk.”

Risk factors for severe COVID-19 illness:

- Adults over the age of 65
- Children with certain conditions
- Underlying medical conditions
- Living or working in high risk setting

Other conditions that increase risk:

- Cancer
- Cerebrovascular disease
- Chronic kidney disease
- Chronic liver disease
- Chronic lung disease
- Cystic fibrosis
- Dementia or other neurological conditions
- Diabetes (type 1 or type 2)
- Disabilities
- Heart conditions
- Hemoglobin blood disorders
- HIV infection
- Immunocompromised condition or weakened immune system
- Mental health conditions
- Overweight and obesity
- Physical inactivity
- Pregnancy
- Smoking – current or former
- Solid organ or blood stem cell transplants
- Substance use disorders
- Tuberculosis

Faculty Disclosure Information

Brigid Groves

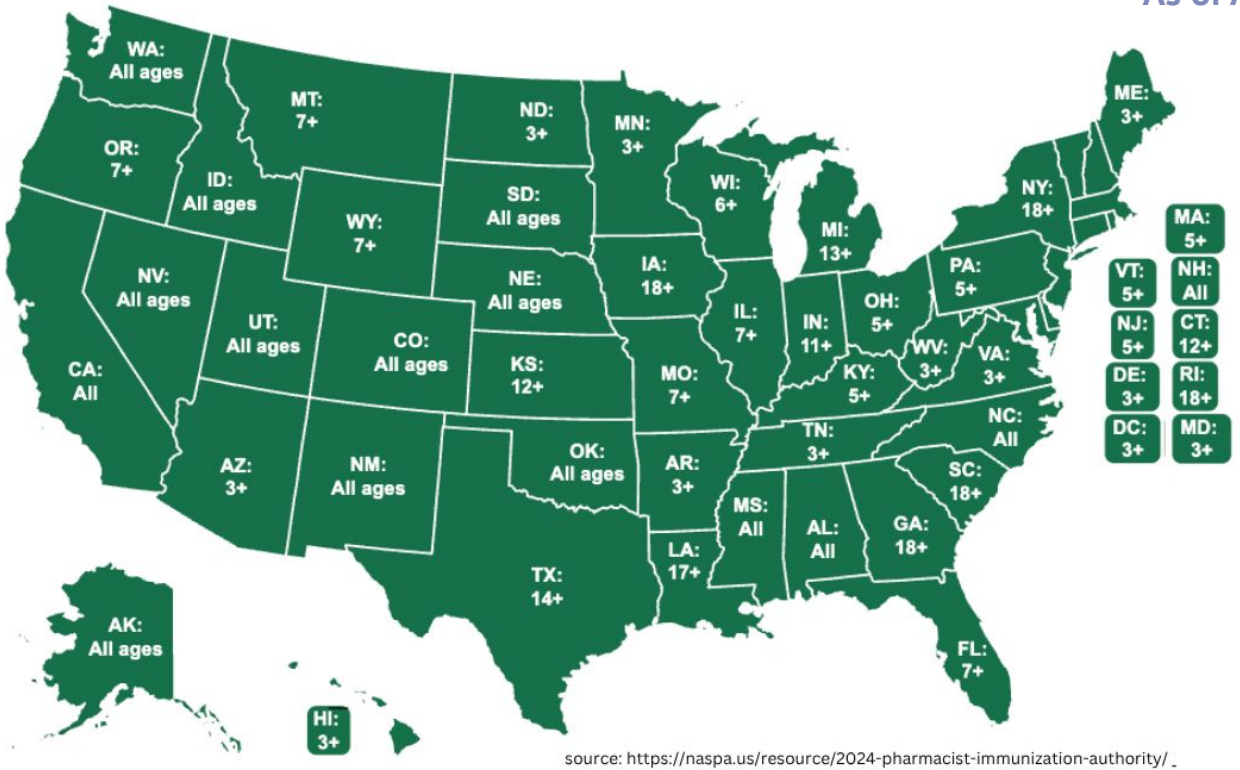
I have disclosed a consulting relationship with Pfizer for an educational speaking engagement that did not involve Pfizer commercial products.

I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this activity.

I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Pharmacists' Authority to Vaccinate Against COVID-19 by Age

As of August 2024



source: https://naspa.us/resource/2024-pharmacist-immunization-authority/

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Shared Clinical Decision-Making, Liability & Informed Consent

Faculty Disclosure Information

Charlene Wong

I have disclosed a past advisory relationship with Sanofi for future adolescent vaccines.

I have no relevant financial relationships with the manufacturer(s) of commercial product(s) and/or provider(s) of commercial services discussed in this activity.

I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Shared Clinical Decision-Making

- **What?** Clinicians talk with a patient about the benefits and risks of vaccination for them. This type of counseling already occurs often.

- **Who?** Primary care physicians, specialist physicians, physician assistants, nurse practitioners, registered nurses, and pharmacists can practice shared clinical decision making in all 50 states

See Common Health Coalition's SCDM Guide

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Shared Clinical Decision-Making

Can be conducted in many ways - and you're probably already doing it!

I recommend you (your child) get the updated COVID-19 vaccine today. The vaccine information sheets you have explain the vaccine's benefits and potential risks.

Do you have any questions about the vaccines that you want to talk about?

Sample EHR Documentation (e.g., dot phrase):

The patient/caregiver & I engaged in shared clinical decision-making about the benefits and risks of the 2025-2026 COVID-19 vaccine. This discussion included an opportunity for them to ask questions. No contraindication to vaccination was identified, & the patient/caregiver and I collaboratively determined the patient would benefit from vaccination. A COVID-19 vaccine was ordered in the context of shared clinical decision making & educational materials were provided.

Where applicable for patients with underlying conditions add: The patient has _____(indicate underlying condition).

Shared Clinical Decision-Making

Can be conducted in many ways - and you're probably already doing it! For example:

Now is when I recommend the updated COVID-19 and flu vaccines for you (your child).

I'm worried about what if my son has a bad reaction

I understand that you're worried about COVID-19 vaccine side effects, and that's perfectly normal. Most people have minor side effects - like a sore or red arm - or no side effects. What's your main concern?

I heard there is a risk of heart problems

Heart inflammation after a COVID-19 vaccine is rare, especially in your son's age group. The risk of this kind of heart inflammation is much higher after getting COVID-19 infection than after vaccination itself.

Faculty Disclosure Information

Paul Rodriguez

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I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Faculty Disclosure Information

Steven Bondi

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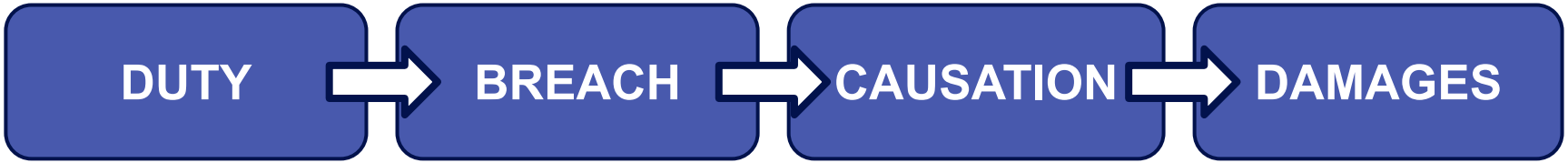
Clinician Liability

- Standard negligence framework:



- Standard of care informed by:
  - Evidence & Published studies
  - Reflected in:
    - FDA labeling
    - ACIP recommendations
    - Professional society guidance
- Determined by “trier of fact” = judge or jury

Clinician Liability: Federal Vaccine Protections

Vaccine Injury Compensation Program (VICP)

National Childhood Vaccine Injury Act of 1986

- No-fault compensation for covered vaccines
- Paid through trust fund
- Providers not initially involved
- Patients must exhaust process before suing a provider
- Coverage depends on published Vaccine Injury Table
  - Routine childhood, including Flu
  - Not COVID-19 and RSV

Countermeasures Injury Compensation Program (CICP)

Public Readiness and Emergency Preparedness (PREP) Act of 2005

- No-fault compensation for covered vaccines
- Paid through separate trust fund
- Providers not involved
- Coverage depends on PREP Act
  - Includes COVID-19
  - For pharmacists (+ interns and techs):
    - ACIP rec vaccines (ages 3-18)
    - Seasonal influenza vaccines (ages 19+)
    - COVID-19 vaccines (ages 3+)

Clinician Liability: Practical Legal Implications

- FDA label change ≠ withdrawal of ACIP recommendation
  - **Off-Label use**:
    - Common, legally permissible if aligned with standard of care
    - If no PREP Act protection → standard rules still apply, like RSV/travel vaccines
- Shift from "routine use" to "**Shared Clinical Decision-Making**" for COVID
  - Reflects individualized risk-benefit assessment, not withdrawal of support
  - Heightened emphasis on documenting individualized assessment
  - ACIP recommendation remains in place → no coverage change under ACA

Informed Consent (and Informed Refusal)

Overview:

- Risks
- Benefits
- Alternatives

Important to note:

- Generally uses negligence standard for adequacy
- Generally uses a “reasonable person” standard in absence

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Q&A

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CHC Resources

- Toolkits
- Regulatory/legal briefs
- Scenario planning tools
- Explainers
- Recommendations
- FAQs

AAP Resources

COVID-19 Vaccine FAQs

Pediatric COVID-19 Vaccine Dosing Guide

Share your liability-related concerns/administration issues here