

**Background:****The PREP Act Declaration and Implications for COVID-19 Vaccine Policy in 2025–2026**

The [Public Readiness and Emergency Preparedness \(“PREP”\) Act Declaration for Medical Countermeasures Against COVID-19](#) (PREP Act Declaration)<sup>1</sup> provides liability immunity to covered individuals and entities involved in the manufacture, distribution, and administration of medical countermeasures against COVID-19. The PREP Act Declaration plays a critical role in enabling widespread access to vaccines and therapeutics by offering providers liability protection and expanding the scope of practice for certain health care professionals, including pharmacists, pharmacy technicians, and interns.

As the United States prepares for the 2025–2026 respiratory virus season, the status of the PREP Act Declaration will remain highly relevant—particularly if the federal government updates FDA approvals or CDC/ACIP recommendations for COVID-19 vaccines. Two key policy dimensions are at stake: **provider liability** and **scope of practice**, both of which directly affect vaccine access and administration across clinical settings.

**Provider Liability**

Liability protections under the PREP Act Declaration depend on whether a provider is authorized under state law, whether the product is used according to FDA approval or licensing, and whether the vaccine administration follows CDC/ACIP recommendations. If future COVID-19 vaccines are indicated only for specific high-risk groups—such as adults aged 65+ or individuals with underlying health conditions—off-label administration or use outside CDC guidance may fall outside the PREP Act’s protective scope. If PREP Act liability immunity does not apply, providers would be subject to the ordinary state laws of professional liability, which generally will not penalize a healthcare provider for providing the customary standard of care, even if something goes wrong.

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<sup>1</sup> The [Public Readiness and Emergency Preparedness Act](#) (PREP Act), enacted in 2005, authorizes the Secretary of the Department of Health and Human Services (HHS) to issue declarations that provide liability immunity for the use of medical countermeasures during public health emergencies. In this document, the term “PREP Act Declaration” refers specifically to the [12th Amendment to the Declaration for Medical Countermeasures Against COVID-19](#), issued by HHS and published on December 11, 2024 ([89 Fed. Reg. 99875](#)).

## Pharmacist Scope of Practice

The PREP Act Declaration expands pharmacists' authority to prescribe and administer COVID-19 vaccines, including by allowing pharmacy technicians and interns to administer vaccines under supervision, even if not permitted to do so under state law. This expansion was explicitly tied to CDC/ACIP recommendations. In the absence of an active PREP Act Declaration or if recommendations are not issued for certain populations, scope of practice reverts to state law. This creates a patchwork landscape in which access to vaccination—particularly in pharmacies—could vary widely based on the alignment (or lack thereof) between federal guidance and state regulations.

## Why This Matters for the 2025–2026 Season

This policy moment arrives at a time of uncertainty: COVID-19 vaccines may be licensed this year for a more limited subset of the population than they have been in the past. Coverage and liability protections are inextricably linked to both FDA labeling and ACIP recommendations, meaning providers could face more risk or more limitations in serving patients who fall outside narrowly defined high-risk groups.

To aid providers, policymakers, and payers in understanding the implications of these shifting dynamics, the following scenario planning tables explore how different federal actions could affect:

- **Provider liability under the PREP Act Declaration**
- **Insurance coverage under Medicare, Medicaid, and commercial plans**
- **Scope of practice for pharmacists and other vaccinators**

## Liability & Coverage Scenario Planning

**Assumption Across All Scenarios.** *FDA labels all 2025-2026 COVID-19 vaccines only for adults 65+ or other people with conditions that put them at high risk for severe COVID-19. Our assumption for this analysis is that this labeling is reflected in the approved Biologics License Application (BLA) for each vaccine, and any Emergency Use Authorizations (EUAs) expire. In each scenario, we assume CDC adopts in the immunization schedules any recommendation that ACIP makes.*

Below is a table outlining three scenarios that *can potentially* happen if the federal government chooses to update FDA and/or ACIP recommendations for the 2025-2026 COVID-19 vaccines, and how those scenarios impact provider liability and coverage.

	<b>Scenario 1</b> CDC/ACIP recommendations align with the (potential) forthcoming FDA label for the 2025-2026 COVID vaccine	<b>Scenario 2</b> ACIP does not make a recommendation for the 2025-2026 COVID vaccine.	<b>Scenario 3</b> CDC/ACIP recommends routine universal vaccination except for pregnant people, for which there is no recommendation, and recommends shared clinical decision-making for children.
<b>Adult (65+)</b>  <i>On-Label</i>	<b>Liability:</b> <a href="#">PREP Act immunity</a> can apply  <b>Coverage:</b> Covered by Medicare, Medicaid and commercial coverage	<b>Liability:</b> PREP Act immunity can apply  <b>Coverage:</b> Covered by Medicare; Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity can apply  <b>Coverage:</b> Covered by Medicare, Medicaid and commercial coverage
<b>Pregnant People</b> (assuming pregnancy is a high-risk condition) <i>On-Label</i>	<b>Liability:</b> PREP Act immunity can apply  <b>Coverage:</b> Covered by Medicare, Medicaid and commercial coverage	<b>Liability:</b> PREP Act immunity can apply  <b>Coverage:</b> Covered by Medicare; Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity can apply  <b>Coverage:</b> Covered by Medicare; Medicaid and commercial plans may elect to cover

	<b>Scenario 1</b> CDC/ACIP recommendations align with the (potential) forthcoming FDA label for the 2025-2026 COVID vaccine	<b>Scenario 2</b> ACIP does not make a recommendation for the 2025-2026 COVID vaccine.	<b>Scenario 3</b> CDC/ACIP recommends routine universal vaccination except for pregnant people, for which there is no recommendation, and recommends shared clinical decision-making for children.
<b>Nonpregnant adult (19-64) with a high-risk condition</b> <i>On-Label</i>	<b>Liability:</b> PREP Act immunity can apply <b>Coverage:</b> Covered by Medicare, Medicaid and commercial coverage	<b>Liability:</b> PREP Act immunity can apply <b>Coverage:</b> Covered by Medicare; Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity can apply <b>Coverage:</b> Covered by Medicare, Medicaid and commercial coverage
<b>Nonpregnant adult (19-64) without a high-risk condition</b> <i>Off-Label</i>	<b>Liability:</b> PREP Act immunity may not apply <sup>‡</sup> <b>Coverage:</b> Covered by Medicare; Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity may not apply <sup>‡</sup> <b>Coverage:</b> Covered by Medicare; Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity may not apply <sup>‡</sup> <b>Coverage:</b> Covered by Medicare, Medicaid and commercial coverage.
<b>Child (6 months-18) with a high-risk condition</b> <i>On-Label</i>	<b>Liability:</b> PREP Act immunity can apply <b>Coverage:</b> Covered by Medicaid and commercial coverage	<b>Liability:</b> PREP Act immunity can apply for providers authorized to administer or prescribe under state law <b>Coverage:</b> Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity can apply <b>Coverage:</b> Covered by Medicaid and commercial coverage

<sup>‡</sup> † The PREP Act declaration requires that, for liability immunity to apply, the person must “manufacture, test, develop, distribute, administer, or use” the Covid vaccine “pursuant to the FDA license, clearance, or approval.” It is unclear whether off-label prescribing or administration would be considered “pursuant to the FDA license.” 89 Fed. Reg. 99875, 99881 (Dec. 11, 2024). In this situation, providers have the same options as when they typically provide health care (1) they can be subject to state medical malpractice litigation, which generally means they will be liable only if they deviated from customary standards of practice, and (2) medical malpractice insurance is available.

	<b>Scenario 1</b> CDC/ACIP recommendations align with the (potential) forthcoming FDA label for the 2025-2026 COVID vaccine	<b>Scenario 2</b> ACIP does not make a recommendation for the 2025-2026 COVID vaccine.	<b>Scenario 3</b> CDC/ACIP recommends routine universal vaccination except for pregnant people, for which there is no recommendation, and recommends shared clinical decision-making for children.
<b>Child (6 months-18) without a high-risk condition</b>  <i>Off-Label</i>	<b>Liability:</b> PREP Act immunity may not apply†  <b>Coverage:</b> Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity may not apply†  <b>Coverage:</b> Medicaid and commercial plans may elect to cover	<b>Liability:</b> PREP Act immunity may not apply†  <b>Coverage:</b> Covered by Medicaid and commercial coverage

## Scope of Practice Scenario Planning

Below is a table outlining three scenarios that *can potentially* happen if the federal government chooses to update FDA and/or ACIP recommendations for the 2025-2026 COVID-19 vaccines, and how those scenarios impact provider scope of practice.

### Upshot for Providers:

- Physicians' and nurses' scope of practice will be defined by state law; the PREP Act Declaration will generally not establish broader scope of practice for physicians and nurses than state law. The PREP Act Declaration can provide liability immunity for physicians and nurses as detailed in the table above.
- Scope of practice for pharmacist vaccine administration may be limited under state law, but was expanded by the PREP Act Declaration to allow prescribing (pharmacist only) and administering (pharmacists, interns, and techs) of vaccines. The PREP Act Declaration ties this expansion of pharmacy scope of practice to the CDC/ACIP recommendation.
- In the absence of the PREP Act, scope of practice for pharmacists, interns and techs related to vaccines is [defined in state law](#).

**Assumption Across All Scenarios.** *FDA labels all 2025-2026 COVID-19 vaccines only for adults 65+ or other people with conditions that put them at high risk for severe COVID-19. Our assumption for this analysis is that this labeling is reflected in the approved Biologics License Application (BLA) for each vaccine, and any Emergency Use Authorizations (EUAs) expire. In each scenario, we assume CDC adopts in the immunization schedules any recommendation that ACIP makes.*

**Pharmacist Scope of Practice Governed by:**

*Pharmacists (prescribe and administer), Pharmacist techs and Interns (administer only)*









**Key:**

**PREP Act Declaration Applies;**



**State Law Applies**

	<b>Scenario 1</b> CDC/ACIP recommendations align with the FDA label for the 2025- 2026 COVID vaccine	<b>Scenario 2</b> ACIP does not make a recommendation for the 2025-2026 COVID vaccine.	<b>Scenario 3</b> CDC/ACIP recommends routine universal vaccination except for pregnant people, for which there is no recommendation, and recommends shared clinical decision-making for children.
<b>Adult (65+)</b>  <i>On-Label</i>			
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Nonpregnant adult (19-64) with a high-risk condition  <i>On-Label</i>			
Adult (19-64) without a high- risk condition  <i>Off-Label</i>			
Child (6 months-18) with a high-risk condition  <i>On-Label</i>			
Child (6 months-18) without a high-risk condition  <i>Off-Label</i>			

**Scenario Planning Notes:**

- Medicare and Medicaid for children will cover COVID-19 vaccine for all populations
  - Commercial plans and other Medicaid coverage is required to cover ACIP/CDC recommended vaccines (including shared clinical decision-making)
  - Pharmacists not authorized to prescribe or administer, or pharmacy interns or techs not authorized to administer, under state law may do so under PREP Act (and receive liability immunity) only if pursuant to ACIP/CDC recommendation
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### **About the Common Health Coalition (CHC)**

Founded in 2023, the Common Health Coalition (CHC) brings together leading health organizations in pursuit of a reimagined health system, one in which the nation's healthcare and public health systems no longer work in parallel, but hand in hand, with better health for all as the common goal. The Coalition's founding members are the Alliance of Community Health Plans, AHIP, American Hospital Association, American Medical Association, and Kaiser Permanente. It has since grown to 300+ members. CHC is working with providers, payers, public health agencies, and other key actors to develop and implement a coordinated strategy for the continued coverage, access, and uptake of COVID-19, flu, and RSV vaccines. Focusing on the fall respiratory season, CHC is building consensus on industry best practices for vaccine access, analyzing and navigating the evolving coverage and regulatory landscape, and developing tools that promote a shared understanding of key issues and impacts across all stakeholders.

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