State Vaccine Toolkit

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Executive Summary

The Centers for Disease Control and Prevention (CDC) publishes recommendations for appropriate vaccine use, informed by recommendations from its Advisory Committee for Immunization Practice (ACIP). CDC's vaccine recommendations have ripple effects in many areas of federal and state law, and so play a role in vaccine coverage, access, and uptake.

Some states and other stakeholders perceive risk in automatic deference to CDC's vaccine recommendations in light of recent events, including ACIP's September vote to:

- Recommend shared clinical decision making for individuals 6 months and older for the COVID-19 vaccine; and
- Cease recommending the combination vaccine for measles, mumps, rubella, and varicella (MMRV) for children under age 4.

On October 6, 2025, the Department of Health and Human Services (HHS) announced that CDC had formally adopted ACIP's recommendations.[1]

As states and others respond to these developments and prepare for potential additional changes in the future, this toolkit provides an overview of key policy issue areas impacted by CDC/ACIP recommendations, as well as changes to the Food and Drug Administration's (FDA) approval and licensure, where relevant, with guidance to help states support continued vaccine access and maximize flexibility on the ground. These areas include:

A. **State approaches for defining appropriate vaccinations beyond CDC's recommendations.** Alongside CDC's recommendations, states could consider, for example, recommendations issued by professional organizations or academic institutions, as well as their own health officials' assessment of the medical evidence. Relevant policy questions include:

- Will the state develop uniform recommendations that apply across all policy areas outlined below? Or will the state assess appropriate vaccine use on a policy-by-policy basis (e.g., the Medicaid agency decides which vaccines are covered in Medicaid, while the pharmacy board decides which vaccines can be administered by pharmacists)?
- Will the state maintain its own comprehensive set of vaccine recommendations? Or will the state address vaccine recommendations on an ad hoc basis in response to federal developments?
- Will the state act alone or participate in a multi-state coalition?

In addition to setting a standard for state policy, these state-developed recommendations can guide healthcare providers as they decide which vaccines to stock and how to communicate with patients about vaccine recommendations.

B. **Health coverage for vaccines, including through Medicaid and the Children's Health Insurance Program (CHIP).** Federal law requires coverage of all ACIP-recommended vaccines without cost-sharing across Medicaid, CHIP, Medicare, and commercial coverage. Thus, changes to CDC/ACIP recommendations impact which vaccines must be covered under federal law.

- Impact of Recent Federal Changes. Following CDC/ACIP's revised recommendations, payers must continue covering COVID-19 vaccines. Payers are no longer required to cover the MMRV vaccine

for children under age 4, although they must continue covering separate vaccinations for MMR and varicella.

- State Opportunities. Federal law establishes a floor for coverage, not a ceiling. States can:
  - Cover additional vaccines through Medicaid and CHIP. This may or may not require a state plan amendment (SPA) depending on the current state plan language. However, it is likely no amendment is required for Medicaid-covered youth under age 21 due to the coverage standard for Early and Periodic Screening, Diagnostic, and Treatment (EPSDT).
  - Require state-regulated plans and state employee plans to cover additional vaccines and encourage other plans to follow suit.

C. Vaccine distribution programs like Vaccines for Children (VFC). Uninsured and underinsured children and adults receive CDC/ACIP-recommended vaccines through two CDC programs: VFC and the Section 317 Immunization Program. VFC also supplies vaccines for Medicaid-enrolled children and youth, with Medicaid covering the cost of vaccine administration. Changes to CDC/ACIP recommendations impact the vaccines that may be accessed through these programs.

- Impact of Recent Federal Changes. The MMRV vaccine will no longer be available to children under age 4 through VFC. Access to COVID-19 vaccines remains unchanged.
- State Opportunities. To support continued vaccine access, states can:
  - For Medicaid-enrolled children and youth, cover non-VFC vaccinations under Medicaid at the state's regular match rate.
  - Explore whether, under federal law, VFC practitioners may use VFC vaccines beyond CDC's recommendations if compliance would be "medically inappropriate."
  - Establish or expand state-funded programs to purchase and distribute vaccines beyond CDC's recommendations. Several states already have universal purchase programs that distribute vaccines for populations ineligible for VFC or 317 funds.

D. Vaccination authority for pharmacists (and other practitioners). In general, each state regulates "scope of practice" for healthcare practitioners, including which vaccines they are authorized to administer, whether they are limited to vaccinating patients in certain age ranges, and whether a prescription is required. For pharmacy personnel—including pharmacists, pharmacy technicians and interns—many states link vaccination authority to CDC/ACIP recommendations. A few states limit pharmacists to the "on-label" vaccine indications approved by the FDA. (Some states may have similar policies for other practitioners who lack independent prescription authority.)

Currently, under the Public Readiness and Emergency Preparedness (PREP) Act, HHS has authorized pharmacists nationwide to order and administer COVID-19 and adult flu vaccines, subject to compliance with CDC's recommendations and FDA's approved indications.

- Impact of Recent Federal Changes. Depending on the state, pharmacists may no longer be able to administer COVID-19 vaccines to certain populations without a prescription. CDC/ACIP's revised MMRV recommendation likely has minimal impact, as it is less common for states to authorize pharmacist vaccinations for babies and toddlers.

- State Opportunities. If a state currently links pharmacist vaccination authority to the CDC/ACIP recommendations and/or the FDA label, consider:
    - In the short term, exercising options under existing law (if any) to nimbly update pharmacist vaccination authority via executive action, such as updating a statewide standing order or issuing emergency regulations.
    - In the longer term, amending the regulations and (if necessary) the statutes defining pharmacist vaccination to either:
        - Allow flexibility for pharmacists to exercise their medical judgment such as by authorizing pharmacists to administer all vaccines approved by FDA and removing restrictions against off-label use; or
        - Clearly authorize the pharmacy board or state health officials to modify pharmacist vaccination authority through swift subregulatory action.

E. Vaccination requirements for daycares, schools, and healthcare workers. Like pharmacist scope of practice, vaccination requirements for school attendance, childcare, and healthcare workers are generally established at the state level and sometimes incorporate CDC recommendations. In addition to revising their reliance on CDC recommendations, states should be mindful of HHS' recent threat to cut VFC and Medicaid funding in states that do not comply with their own state laws on religious exemptions for vaccination requirements.

- Impact of Recent Federal Changes. CDC/ACIP's revised recommendation regarding MMRV likely has no impact, since vaccine requirements typically focus on the diseases immunized against rather than the particular vaccine formulation. With respect to COVID-19, CDC/ACIP's updated recommendation likely will not impact requirements for these settings or individuals.
- State Opportunities. In light of changing federal guidance, states can:
    - Confirm whether state health officials are able to supplement CDC/ACIP recommendations, if state vaccination requirements are currently linked to them. If not, consider amending regulations and (if necessary) statutes to ensure an independent role for state health officials.
    - Review state policies for vaccines required for school attendance and religious exemptions, bearing in mind recent attention to these exemptions from HHS.

F. Frameworks for vaccine-related injuries. While state law generally dictates professional liability, three federal programs provide compensation for certain vaccine-related injuries and offer liability protections for vaccinating providers: the PREP Act, the COVID-19 Countermeasures Injury Compensation Program (CICP), and the Vaccine Injury Compensation Program (VICP). Changes to FDA approval and CDC/ACIP recommendations can impact some of these programs and may also factor into liability under state law.

- Impact of Recent Federal Changes. Narrowed FDA licensure and CDC recommendations for COVID-19 will narrow certain protections under the PREP Act and CICP. However, VICP continues to cover MMRV-related injuries. Once a vaccine is added to the VICP list, compensation is available even for vaccinations that do not follow CDC's recommendations.

- State Opportunities. To help providers navigate these implications and support continued vaccine access, states can:
    - Update state laws on malpractice to confirm that practitioners will not be liable for administering vaccines in accordance with the state's own vaccine recommendations, even if those recommendations differ from CDC's or pertain to "off-label" clinical scenarios.
    - Partner with state medical, pharmacy, and hospital associations to communicate clearly about appropriate vaccinations, including off-label vaccinations in accordance with the state's own recommendations (if applicable).

These steps and considerations will be crucial as states, providers, and others examine how to support continued access to vaccines amid a rapidly changing federal landscape.

I. Background: Federal Vaccine Recommendations and Recent Federal Vaccine Developments

A. Vaccine Licensure by the Food and Drug Administration

Before a vaccine may be marketed and distributed in the U.S., it must be approved ("licensed") by the FDA. The FDA approves specific indications (i.e., target patient populations) and precautions based on product safety, efficacy, and manufacturing quality, based on studies conducted in accordance with FDA regulations. Those indications and precautions appear on the FDA-approved vaccine label. As with other types of pharmaceuticals, however, physicians are generally able to prescribe vaccines for "off-label" uses beyond those listed on the FDA label. For other practitioner types, the ability to prescribe or administer off-label depends on their scope of practice as defined under state law. FDA decisions related to approval/authorization and label indications can shape payer policies, provider standing orders, and school/occupational vaccination requirements.[2]

B. The Centers for Disease Control and Prevention's Vaccine Recommendations

CDC publishes recommendations about appropriate vaccine use.[3] To inform this work, the CDC Director has for decades relied on the expert opinions and recommendations of the Advisory Committee on Immunization Practices (ACIP). ACIP is composed of up to 19 voting members selected by the HHS Secretary who serve up to four-year terms.[4] ACIP generally issues recommendations after the FDA approves or authorizes a new vaccine (or a new indication for an existing vaccine) but can also reconsider existing recommendations or develop new ones at any time.[5] CDC occasionally recommends off-label vaccinations beyond those listed on the FDA-approved vaccine label based on, for example, medical evidence that was not available at the time of FDA licensure, or that does not meet FDA's standards but nonetheless provides robust support of appropriate use.

ACIP structures its guidance by specifying: (1) the age and other population groups (e.g., by sex or occupation) for whom vaccination is recommended; (2) the timing, dose schedule, and intervals for multidose products; and (3) relevant precautions and contraindications. Recommendations for "routine use" apply universally to an entire age cohort, while others are risk-based or targeted to particular circumstances (e.g., travel immunizations). ACIP issues recommendations in two categories:

- Standard Recommendation: CDC recommends vaccination for all individuals in a defined age or risk group.
- Shared clinical decision-making: Vaccination should be based on a patient-provider discussion tailored to individual risks and preferences.[6]

CDC's recommendations have ripple effects in many areas of health policy, as described below. Importantly, for some areas, ACIP recommendations do not become official federal policy automatically; the CDC Director reviews and decides whether to adopt them.[7]

C. Recent Federal Actions Regarding Vaccines

Recent federal actions have put the CDC and ACIP's roles in recommending how vaccines should be used under the spotlight, including comments from HHS Secretary Robert F. Kennedy Jr. expressing skepticism over previously recommended vaccines, changing guidelines from CDC, and the Secretary's decision to dismiss and replace all 17 sitting members of ACIP.[8] Following its reconstitution, ACIP met on June 25-26 and September 18-19, 2025, leading to revised recommendations issued by the committee.

As of October 6, 2025, all recommendations had been formally adopted by CDC.[9] These revised recommendations from the September and June meetings included:

- COVID-19 (Sept): ACIP continued to recommend vaccination for everyone 6 months old and over but shifted all populations to shared clinical decision-making.[10]
    - Separately, in August, FDA narrowed its COVID-19 approval for the 2025–26 season. Unlike prior COVID-19 vaccines, this vaccine is licensed only for adults 65 and older and other high-risk individuals.
- MMRV (Sept): For children less than 4 years old, ACIP recommended use of separate MMR and varicella doses, and to reserve MMRV for those 4 years or older receiving follow-on or initial doses. ACIP recommended aligning the VFC product list.
- Hepatitis B (Sept): ACIP reaffirmed universal prenatal testing. ACIP considered but tabled a proposal to delay the infant birth dose to 1 month old or older babies born to hepatitis B surface antigen (HBsAg)-negative mothers (with earlier vaccination via shared clinical decision-making). If adopted in the future, this would be a significant departure from the longstanding practice of administering the hepatitis B dose at birth unless declined.
- Influenza (June): ACIP reaffirmed annual vaccination for everyone 6 months old or older. ACIP specified exclusive use of formulations free of thimerosal, a preservative used only in some multi-dose vials (approximately three-to-four percent of flu doses) for children, pregnant individuals, and adults.
- RSV (June): No vaccine-related votes. ACIP recommended monoclonal antibody Clesrovimab for infants less than 8 months old not protected by maternal vaccination.

While ACIP's revised recommendations are relatively modest, continued confusion and uncertainty may limit vaccine uptake and the revisions may signal future changes to come. For example, in the days between ACIP's revised recommendations in September and CDC's formal adoption, HHS paused states' ability to order COVID-19 vaccines for children through the VFC program, temporarily disrupting access for Medicaid-eligible and uninsured children.[11] Broadly, these events signal that the federal government may issue additional changes to vaccine recommendations in the future, which could generate uncertainty and limit vaccine access and uptake. In light of this, states, health providers, payors, and other stakeholders may wish to consider how to support continued access to vaccines going forward.

II. Considerations for States and Healthcare Providers

CDC/ACIP's vaccine recommendations have implications throughout the healthcare system, including for federal health coverage, vaccine distribution programs, provider liability protections, and, depending on state laws, pharmacist scope of practice and vaccine requirements for schools, childcare settings, or healthcare workers.

The direct impact of these and potential future changes will vary by state and by issue. In some cases, CDC's recommendations are baked into federal law, while in others, states have chosen to rely on CDC's recommendations. Across the board, confusion over the impact of changing CDC/ACIP recommendations could also decrease vaccine uptake.

States have opportunities to support continued access to vaccines, notwithstanding potential changes at the federal level. Below, we describe the current legal landscape for each policy area, the impact of

recent and potential future changes from CDC/ACIP and FDA, and state policy opportunities to preserve vaccine access.

A. Developing State Vaccine Recommendations

As states weigh how to navigate the road ahead, a key threshold question that cuts across the issue areas is how the state will define appropriate vaccines. As described throughout this toolkit, many states reference CDC/ACIP recommendations in their laws and policies, and healthcare providers, schools, and others often look to CDC/ACIP recommendations in determining appropriate practices and requirements.

States could consider supplementing CDC/ACIP recommendations with state-level recommendations. States can look to recommendations issued by professional organizations, academic institutions, and other credible bodies, such as the immunization schedule developed the American Academy of Pediatrics (AAP), which differs from the CDC's schedule with respect to COVID-19 and MMRV vaccinations.[12]

Relevant policy questions for states to consider will include:

- Will the state develop uniform recommendations that apply across some or all policy areas outlined below? Or will the state assess appropriate vaccine use on a policy-by-policy basis (e.g., the Medicaid agency decides which vaccines are covered in Medicaid, while the pharmacy board decides which vaccines can be administered by pharmacists)?
    - An important first step is to review a state's vaccine policies and determine which policies incorporate CDC/ACIP and/or FDA standards, and whether those existing policies leave room for state discretion.
- Will the state maintain its own comprehensive set of vaccine recommendations? Or will the state address vaccine recommendations on an ad hoc basis in response to federal developments? As examples:
    - The Oregon Health Authority maintains a comprehensive set of Model Immunization Protocols for vaccines that are "routinely recommended in the state of Oregon."[13] These protocols incorporated both CDC and state-level recommendations.
    - Most states have implemented policy changes specifically addressing COVID-19 vaccines, including a mix of emergency changes responding to new developments as well as permanent amendments to statutes and regulations.[14]
- Will the state act alone or participate in a multi-state coalition? As examples, in response to changing federal guidance, two groups of states recently formed regional public health coalitions to issue independent vaccine recommendations grounded in evidence-based research:
    - The West Coast Health Alliance formed by the governors of California, Oregon, and Washington;[15] and
    - The Northeast Public Health Collaborative, a voluntary coalition of public health agencies and leaders from Connecticut, Maine, Massachusetts, New Jersey, New York State (and New York City), Pennsylvania, and Rhode Island.[16] Leveraging recommendations from the AAP, the American College of Obstetrics and Gynecology,

and the American Academy of Family Physicians, the Collaborative recently issued its first set of recommendations for the 2025-2026 COVID-19 vaccine.[17]

B. Health Coverage for Vaccines

1. Legal Background

Under federal law, CDC/ACIP-recommended vaccines must be covered without cost-sharing across all major payors, including Medicaid, CHIP, Medicare, and commercial plans. Although the precise legal standard varies by program (as described below), the Centers for Medicare & Medicaid Services (CMS) generally focuses on the CDC's Immunization Schedules for routine use, including standard and risk-based recommendations, as well as recommendations for shared clinical decision-making.[18] Federal law establishes a floor for vaccine coverage, but not a ceiling; and states and other payers can choose to cover additional vaccines beyond those recommended by CDC/ACIP.

Medicaid provides coverage for all CDC/ACIP-recommended vaccines to children and adults without cost-sharing, with children additionally entitled to any vaccine that is medically necessary.[19,20]

- Children and youth under 21 are entitled to all medically necessary vaccines, including and not limited to those recommended by ACIP, through Medicaid's comprehensive health benefit for children, the EPSDT benefit.[21]
    - EPSDT coverage includes, at a minimum, all ACIP-recommended pediatric vaccines according to the "periodicity, dosage, and contraindications" as recommended by ACIP on CDC's Immunization Schedule for pediatric vaccines.[22]
    - In addition, EPSDT requires that states provide all medically necessary services that could be covered under the state plan, regardless of whether those services are covered for older adults or expressly listed in the state's Medicaid plan.[23] Under the Biden Administration, CMS confirmed that children are entitled to any medically necessary vaccine, even if a vaccine is not recommended by ACIP.[24]
    - Cost-sharing is prohibited for all Medicaid-enrolled children under age 18, and for ACIP-recommended adult vaccinations provided to youths ages 19 and 20.[25]
- For Medicaid-enrolled adults, states must cover all vaccines recommended on CDC's Immunization Schedules. Since the Affordable Care Act (ACA), states have been required to provide coverage without cost-sharing to adults enrolled through Medicaid expansion for vaccines recommended "for routine use" by ACIP, consistent with the standard for commercial plans.[26] Following the Inflation Reduction Act, federal law has required coverage without cost-sharing for "approved vaccines recommended by" ACIP for adults enrolled through non-expansion pathways since 2023.[27]

States with separate CHIP programs must cover, without cost-sharing, all vaccines recommended by CDC/ACIP for children and pregnant individuals enrolled in the program. For children under 19, states must cover "age-appropriate immunizations," which CMS has defined as vaccines in accordance with ACIP recommendations.[28] For pregnant individuals covered by CHIP, states must cover "approved vaccines recommended by" ACIP for adults.[29] Cost-sharing is prohibited for all vaccines that fall under the minimum coverage standard.[30]

With respect to private coverage, federal law also requires commercial plans to cover, without cost-sharing, all vaccines recommended by CDC/ACIP. Under the ACA, commercial plans must cover, without

cost-sharing, all "immunizations that have in effect a recommendation from" ACIP.[31] States also have the authority to require state-regulated health insurers to provide certain vaccines at no cost to enrollees; however, this regulatory power does not extend to self-insured private-employer health plans.[32]

Medicare Part D must cover, without cost-sharing, ACIP-recommended vaccines, and Medicare Part B must cover the COVID-19 vaccine without cost-sharing. For Medicare Part D enrollees, CMS requires Part D plans to cover all commercially available vaccines, unless the vaccine is specifically covered under Part B. Adult vaccines recommended by ACIP are covered without cost-sharing.[33] Plans may impose coinsurance or copayments for vaccines not on the CDC schedule, and may use drug utilization management tools to facilitate use of vaccines in line with ACIP recommendations.[34] Medicare Part B, including Medicare Advantage plans, are required by statute to cover influenza, pneumococcal, hepatitis B (for at-risk individuals), and COVID-19 vaccines (without cost-sharing).[35]

2. Impact of Recent Federal Changes

Following CDC/ACIP's revised recommendations:

- There should be no impact on coverage for COVID-19 vaccines due to CDC/ACIP's revised recommendation that vaccines for individuals 6 months and older include shared clinical decision-making[36] (nor from FDA's changes to the licensure of the COVID-19 vaccine for specific populations).
- Federal law would no longer require no-cost MMRV coverage for children under 4 years old, except that Medicaid would be required to cover it if deemed medically necessary for a specific child. Federal law would continue to require coverage of the separate MMR and varicella vaccines.

3. State Policy Opportunities

States can consider the following strategies to promote coverage of vaccines recommended by the state, beyond those recommended by CDC.

- **Cover additional vaccines through Medicaid and CHIP.** Federal law establishes minimum coverage requirements across various benefit categories, but states are generally permitted to cover additional medically necessary services absent an express federal prohibition. Thus, unless CMS issues guidance to the contrary, states can cover vaccinations beyond those recommended by CDC.[37]

  For Medicaid-covered children and youth under 21, states are required to cover all medically necessary services under EPSDT, as described above. States could issue guidance confirming that any state-recommended vaccines are considered medically necessary will therefore be covered.

  For other Medicaid and CHIP populations, states should consult their Medicaid state plan to assess the limits of their current vaccine coverage.

  - In their state plan,[38] states often define vaccine coverage for some or all populations under the preventive services benefit. States may have a closed definition of vaccine coverage (i.e., the state covers the vaccines required under federal law), or an open-ended definition (e.g., the state covers vaccines "including" the required CDC-recommended vaccines).
  - The state plan may also include relevant language under the benefits for services by physicians, nurse practitioners, certified nurse midwives, and "other licensed practitioners" (often including pharmacists), and sometimes also federally qualified health centers. In

addition to vaccine-specific language, these provider benefit definitions may reserve authority for the state to modify the list of covered services by updating the relevant fee schedule or provider manual.

If a state plan expressly limits coverage for non-CDC vaccinations (in general, or for a particular provider type), the state could consider submitting a SPA to define vaccine coverage as an open-ended list. For example, the state could cover vaccines "as determined by the state Medicaid agency, including" CDC-recommended vaccines in accordance with federal law.

- **Require state-regulated plans to cover additional vaccines and encourage other plans to follow suit.** States may directly require plans that they regulate —including Marketplace plans, small group employer plans, and state employee health coverage —to cover vaccines beyond those recommended by CDC/ACIP, such as vaccines recommended by the state. To that end, a growing number of states have encouraged or required state-regulated insurers to cover vaccines based on the recommendations of independent medical associations, professional groups, or the state-lead coalitions described above.[39] As examples:

    - The Massachusetts Division of Insurance recently issued a bulletin requiring state-regulated health plans to cover all vaccines recommended by the Department of Public Health (DPH) at no cost. The bulletin also "encourage[d]" non-insured, employment sponsored, health benefit plans to adopt the same approach.[40]

    - Colorado enacted a law in May 2025 allowing the state insurance commissioner to adopt coverage guidelines based on ACIP recommendations as they existed in January 2025, or to follow recommendations from the Nurse-Physician Advisory Task Force for Colorado Healthcare.[41]

    - The New York legislature introduced a bill that would allow the state's two existing immunization policy bodies to recommend immunizations in addition to those recommended by ACIP. The bill requires that insurers cover vaccines in accordance with these state-led recommendations.[42]

States could also encourage plans not regulated by the state, such as private employer self-insured plans to cover additional vaccines. While Medicare Part D plans must cover all commercially available vaccines under current federal policy, states could encourage Part D plans to provide no cost-sharing for vaccines beyond ACIP recommendations.

C. Vaccine Distribution Programs

1. Legal Background

The VFC program provides millions of children with access to ACIP-recommended vaccines. VFC-eligible children include children under 19 years of age who are eligible for Medicaid (but not CHIP), uninsured, underinsured, or American Indian or Alaska Native (AI/AN). Under this program, CDC purchases and distributes vaccines to states and territories, which then distribute vaccines to participating providers. States are required to establish programs under VFC in order to participate in Medicaid.[43] For Medicaid-eligible children, the VFC program funds the cost of the vaccine, and Medicaid covers the cost of vaccine administration.

By statute, VFC is directly tied to CDC/ACIP recommendations in two key respects:

- VFC must supply vaccines on a "list established (and periodically reviewed and as appropriate revised) by" ACIP.[44] ACIP votes on resolutions specific to VFC.[45] Although ACIP has historically aligned its VFC resolutions with its recommendations on routine use, ACIP could theoretically recommend a narrower or broader list for VFC.[46] Indeed, in its September meeting, ACIP considered maintaining the prior MMRV recommendation for VFC despite the narrower recommendation for routine use, but ultimately voted to align.

- Participating providers must generally comply with CDC/ACIP's periodicity schedule for pediatric vaccines—i.e., the recommendations listed in the VFC resolutions.[47] However, providers may diverge from the CDC/ACIP immunization schedule under two circumstances:

    - Where an ACIP recommendation contradicts applicable state law, including those related to religious or other exemptions or school attendance; or

    - If a provider determines in their medical judgement that compliance with the recommendation is medically inappropriate, "subject to accepted medical practice." [48]

Notably, HHS has recently emphasized the importance of VFC participants following these state religious exemptions, as discussed further in Section II.E.3.[49]

Adults receive access to "recommended" vaccines through the Section 317 Immunization Program. Under this program, states receive CDC grants to purchase vaccines "recommended for routine use" for uninsured and underinsured adults, and also to fund vaccination infrastructure.[50]

2. Impact of Recent Federal Changes

Following CDC/ACIP's revised recommendations: The MMRV vaccine for children under age 4 will no longer be available through VFC, though the separate MMR and varicella vaccines will continue to be available. For the COVID-19 vaccine, CDC/ACIP's revision related to shared clinical decision making will likely not impact access through the VFC or 317 programs (though as noted above, states experienced disruptions in the immediate days following ACIP's revised recommendations before CDC formally adopted the new recommendations).[51]

3. State Policy Opportunities

States can take steps to bolster access to vaccines beyond those federal programs. States can:

- **Cover non-VFC vaccinations under Medicaid, for Medicaid-enrolled children and youth.** The state would share in the cost of the vaccine product but would receive federal funding at the state's regular match rate. States can likely cover non-VFC vaccinations under EPSDT without any need for a SPA, as described above in Section II.B.3.

- **Explore whether, under federal law, VFC practitioners may use VFC vaccines beyond CDC's recommendations if compliance would be "medically inappropriate."** While CDC has historically interpreted this law as authorizing VFC practitioners to decline to give a recommended vaccination based on their own clinical judgment, the statute arguably also authorizes providers to use VFC vaccinations in scenarios beyond CDC's recommendations based on "the provider's medical judgment subject to accepted medical practice."[52] CDC's view of this approach is not clear. To guide providers generally, states could consider pointing to state-recommended vaccines or other published recommendations.

- **Establish or expand state-funded programs to purchase and distribute vaccines beyond the CDC's recommendations.** Some states operate their own "universal purchase" programs funded by state

revenues.[53] These programs may complement VFC by furnishing vaccines to children regardless of coverage status and may also provide vaccines to adults. States could establish small "wraparound" programs that fill gaps in the VFC and 317 programs for the individuals served by those federal programs or could support vaccine distribution for other populations as well, such as individuals with commercial coverage.

D. Vaccination Authority for Pharmacists (and Other Practitioners)

1. Legal Background

As a general matter, states regulate the practice of medicine, including providers' authority to administer vaccines (i.e., their "scope of practice"), which vaccines they can administer, and who they can vaccinate. Physicians are typically able to administer any vaccine they deem medically appropriate, subject to overarching standards of medical malpractice. However, many states impose limits on vaccination for pharmacists (as well as pharmacy technicians and pharmacy interns), who have provided a growing share of vaccines since COVID-19. Some states may impose similar limitations on other non-prescribing practitioners, such as registered nurses and licensed practical nurses. For example, with respect to pharmacists, states may:

- Authorize pharmacists to administer vaccines approved by FDA and/or recommended by ACIP/CDC.[54]
    - State laws vary as to whether they incorporate ACIP's recommendations, CDC's recommendations, or the recommendations in the CDC's Immunization Schedules (which may not be updated immediately following a new/updated recommendation).
    - States also vary in their treatment of CDC/ACIP recommendations for shared clinical decision-making. Some states have limited pharmacists' ability to offer such vaccines without a prescription. That said, CDC expressly acknowledges that pharmacists can provide the recommended clinical consultation,[55] and pharmacist scope of practice generally includes counseling patients about appropriate medication use.
    - Some states expressly grant state health officials or pharmacy boards the power to authorize additional vaccines beyond those codified in state scope of practice laws and regulations.
- Prohibit pharmacists from administering vaccines off-label or administering vaccines to children below a certain age, regardless of any recommendations from CDC or state health officials.
- Authorize pharmacists to order vaccines on their own or pursuant to a statewide standing order or limit pharmacists to administering vaccines under a prescriber protocol or, in some circumstances, a patient-specific prescription.

Where state policies on vaccination authority are ambiguous, pharmacies have sometimes defaulted to the most conservative interpretation, which restricts access to pharmacy-based vaccines until the state provides clarifying guidance. In addition to scope of practice, pharmacy vaccination policies are also informed by payer policies on vaccine coverage as well as overarching standards for professional misconduct and medical malpractice.

HHS has authorized pharmacists nationwide to order and administer COVID-19 and adult flu vaccines, subject to compliance with CDC recommendations and the FDA's approved indications. HHS took this action during the COVID-19 pandemic under the PREP Act, asserting the authority to preempt state laws

on scope of practice in addition to the PREP Act's more common application of creating liability protections for providers and others during emergencies (discussed more below in Section II.F).

Under HHS' current declaration (which extends through 2029 unless terminated sooner), pharmacists may order and administer COVID-19 vaccines to individuals ages 3 and up, as well as adult flu vaccines—and pharmacy technicians and interns may administer them, under pharmacist supervision—in accordance with CDC/ACIP COVID-19 vaccine recommendations and "pursuant to the FDA license, clearance, or approval."[56] Although HHS has not expressly weighed in, this standard arguably limits the PREP Act authorization to on-label vaccinations in accordance with the FDA-approved label.

2. Impact of Recent Federal Changes

With respect to MMRV vaccines for individuals under age 4, the impact on pharmacists' vaccination authority will depend on state law. In states that limit these providers' scope of practice to CDC/ACIP-recommended vaccines, pharmacists would not be able to administer the combined MMRV vaccine to children under age 4, or may require a prescription to do so, but would continue to have that authority for separate MMR and varicella vaccinations.

For COVID-19 vaccines, the impact of CDC/ACIP and FDA's updates will also hinge on state requirements. As noted above, the PREP Act generally requires pharmacists to follow FDA approval and CDC/ACIP recommendations for its expanded authority to apply; where pharmacists do not follow those requirements, state law applies. Thus:

- To the extent state laws restrict off-label vaccination for pharmacists or any other health provider, those providers will not be able to administer the COVID-19 vaccine to individuals other than those who are high risk or 65 years or older, consistent with FDA's updated licensure. Otherwise, in states that permit off-label use, pharmacists could continue to be able to provide the COVID-19 vaccine, depending on other state requirements.
- To the extent state laws require pharmacists to comply with CDC/ACIP recommendations, pharmacists could continue to provide the COVID-19 vaccine under a prescription or by providing this clinical consultation in states that allow it. In states that do not limit pharmacists' vaccination authority to CDC/ACIP recommendations, pharmacists' vaccination authority would not be impacted by the revised recommendation.

3. State Policy Opportunities

States can take steps to support pharmacists and other providers' flexibility to continue administering vaccines. States can:

- **In the short term, exercise options under existing law (if any) to nimbly update pharmacist vaccination authority via executive action, such as updating a statewide standing order or issuing emergency regulations.** For example, several states have issued statewide standing orders broadly authorizing pharmacy-based COVID-19 vaccinations, notwithstanding recent changes in federal policy.[57]
- **In the longer term, amend regulations and (if necessary) statutes defining pharmacist vaccination to either:**
  - **Allow flexibility for pharmacists to exercise their medical judgment such as by authorizing pharmacists to administer all vaccines approved by the FDA and removing restrictions against off-label use.** Pharmacists would still be subject to payer-defined vaccine coverage as

well as overarching standards for professional misconduct and medical malpractice. In states where pharmacists are otherwise required to act under physician supervision, pharmacists would remain subject to these limitations unless states took additional action to remove requirements for third party orders. For instance, 26 states have made changes to state laws and regulations that would allow pharmacists to administer COVID-19 vaccines without a prescription even in instances no longer recommended by the CDC.[58] Even more broadly, some states, such as Missouri, permit pharmacists to administer any FDA-approved vaccine to any adult without any third-party order.[59]

- **Alternatively, clearly authorize the pharmacy board or state health officials to modify pharmacist vaccination authority through swift subregulatory action.** This would give the state swifter control over pharmacists' vaccination authority in the event of changes at the federal level. Some states permit state health officials to recommend additional vaccines in the event of an outbreak or public health emergency. For example, in New York, an executive official may authorize pharmacists to administer any vaccine via a non-patient specific statewide standing order in the event of an outbreak, or a threatened outbreak, of disease – a flexibility that the New York Commissioner of Health used to authorize pharmacist administration of RSV vaccine to certain populations via executive action.[60]

E. Vaccination Requirements for Schools, Daycares, and Healthcare Workers

1. Legal Background

Each state establishes vaccination requirements for schools and day cares. Many of these laws reference CDC/ACIP recommendations and schedules. To date, all states have some vaccination requirement for entering school.[61] Some states directly reference ACIP recommendations in their school vaccine requirements, whereas others also point to recommendations from provider organizations such as AAP.[62] All states allow medical exemptions to these requirements, and nearly all (47) states allow exemptions for religious and/or personal beliefs.[63] For childcare settings, as of 2022, all states required children from birth through age 5 to be vaccinated against certain diseases as a condition of attending certain childcare settings. State approaches vary, with most expressly specifying the required vaccines, two states (Delaware and Pennsylvania) tying requirements to CDC recommendations, and three states requiring certain vaccines while giving additional flexibility to the state department of health.[64]

For healthcare workers, state laws vary in their requirements; there is currently no federal law requiring vaccination.[65] Many states and organizations look to CDC/ACIP guidance when designing policies for healthcare workers, but the specifics of what vaccines are required, who is covered, how exemptions are handled, and how compliance is documented vary by state, care setting (e.g., hospitals, long-term care, ambulatory, home health), and job role.[66] Some states also recommend, but do not necessarily require, healthcare workers to receive vaccinations.[67]

The federal government has recently emphasized its interest in enforcing state religious exceptions to vaccine requirements. As noted above, the VFC program requires participating providers to comply with CDC/ACIP recommendations, unless (in part) excepted by state law, such as for a religious exemption. In September, HHS issued a letter to all state, local, and territorial VFC awardees emphasizing their obligation to ensure that providers comply with state religious exemptions.[68] The letter followed a separate letter to West Virginia threatening the state's continued receipt of federal VFC and Medicaid funding until it enacted a state religious exemption statute following related litigation in the state.[69] While questions remain, the letters underscore HHS' current focus on religious exemptions for vaccinations.

2. Impact of Recent Federal Changes

CDC/ACIP's revised recommendation on MMRV likely has no meaningful impact, since vaccine requirements typically focus on the diseases immunized against rather than the particular vaccine formulation. With respect to COVID-19, CDC/ACIP's updated recommendation would likely not impact any of these settings.[70] As is true across issue areas, confusion over the impact of changing CDC/ACIP recommendations could also decrease vaccine uptake.

3. State Policy Opportunities

- **If a state currently links vaccination requirements to CDC/ACIP recommendations, confirm whether state health officials are able to supplement those recommendations.** If not, consider amending regulations and (if necessary) statutes to ensure an independent role for state health officials or supplemental recommendations. For example, earlier this year, Colorado passed legislation directing the state board of health to take into consideration ACIP recommendations as well as recommendations issued by AAP, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians when establishing vaccine requirements for schools.[71]
- **Review state policies related to religious exemptions, bearing in mind recent attention to these exemptions from HHS.** While HHS' recent letter on religious exemptions does not require specific action, states should be mindful of HHS' likely close attention to states' religious exemptions, including states' enforcement of their own requirements.

F. Frameworks for Vaccine-Related Injuries

1. Legal Background

Federal programs provide compensation and liability protections for many vaccine-related injuries, with important links to recommendations from the CDC. These federal programs include the PREP Act, the CICP, and the VICP.

For COVID-19 vaccines, liability protections and compensation regimes are linked to—but not solely based on—the FDA label and CDC recommendations. In general, the PREP Act authorizes HHS to prohibit claims for liability related to "covered countermeasures" in an emergency scenario, except in cases of death or serious physical injury caused by "willful misconduct."[72] Today, under HHS' active PREP Act declaration for COVID-19, the following providers are shielded from liability with respect to administering COVID-19 vaccines, so long as the vaccines is administered "pursuant to the FDA license, clearance, or approval":

- Licensed health professionals who are authorized to prescribe, administer, or dispense COVID-19 vaccines under state law.
- Licensed pharmacists (and pharmacy interns and qualified technicians, under the supervision of a pharmacist), if the vaccine is ordered and administered to an individual age 3 or above according to CDC/ACIP COVID-19 vaccine recommendations.[73]

The CICP is available for injuries directly caused by a "covered countermeasure" used "pursuant to the terms of a declaration" under the PREP Act, or "in a good faith belief that it was administered or used pursuant to the terms of a declaration."[74] Thus, for compensation to be available for COVID-19 vaccine-related events, the vaccine must be administered pursuant to the FDA license and, if by a pharmacist,

consistent with CDC/ACIP recommendations, or under the good faith belief that its administration was consistent with these federal requirements.

Where the PREP Act and CICP don't apply, providers remain subject to state laws on malpractice and professional misconduct related to COVID-19 vaccinations. When the PREP Act declaration expires at the end of 2029 (or if HHS terminates it sooner), the federal government may add COVID-19 to the VICP, as described below, depending on ACIP's future recommendations.

For vaccines other than COVID-19, VICP provides liability protections and compensation for injuries related to certain vaccines, including those recommended by CDC for children and pregnant women.[75] Individuals who accept no-fault compensation through VICP are barred from filing civil claims for the same injury (e.g., for malpractice). Vaccines covered under the VICP include those related to tetanus and/or pertussis (e.g., DTaP); measles, mumps, and/or rubella (e.g., MMR, MMRV); and polio (both the advance and inactive virus), as well as any vaccines recommended by CDC for routine administration to children and pregnant individuals.[76] New vaccines recommended for children or pregnant individuals by the CDC must be added to the table by the HHS Secretary, which federal regulations indicate can be done through the publication of a notice.[77] Additionally, for a vaccine to be covered under VICP, the vaccine must be subject to a tax that funds the compensation program; new vaccines will be included as covered vaccines in the Vaccine Injury Table as of the effective date of the tax.[78] Thus, both administrative and congressional actions are needed for a vaccine to be covered under VICP. Notably, while covered vaccines include those recommended for children or pregnant individuals by CDC, there are no requirements that the vaccine be administered consistent with CDC guidelines or the FDA label for compensation to be available (suggesting adults who are not pregnant may be able to seek compensation).[79]

Where these federal programs do not apply, state law will apply through laws related to malpractice and professional misconduct (as well as products liability). For malpractice and professional misconduct, liability will generally hinge on the applicable standard of care and/or standards of professional conduct, which often takes into account published guidelines and recommendations from federal and state governments, as well as professional medical societies.

2. Impact of Recent Federal Changes

Following FDA's recent changes to its licensure of the COVID-19 vaccine, providers who administer the vaccine "off-label" (that is, to individuals who are not high risk or 65 and older) may be subject to state professional liability laws. CDC/ACIP's updated recommendation that this vaccine be administered under shared decision making will not impact the PREP Act's application, so long as pharmacists engage in the required consultation (or satisfy this requirement in another manner consistent with state law).

With respect to VICP, it appears that injuries related to MMRV could continue to be available. As currently constructed, the Vaccine Injury Table includes, in part, "[v]accines containing the rubella virus (e.g., MMR, MMRV)" or "containing the measles virus (e.g., MMR, MM, MMRV)" – both broad categories which include MMRV as well as other vaccines unaffected by ACIP's latest recommendation.[80] Additionally, while the HHS Secretary is required to add vaccines to the Vaccine Injury Table that are recommended by CDC, there is no requirement or process associated with removing a vaccine that loses its recommendation. As compensation can be available even if a vaccine is administered outside of CDC's recommendation, it is possible compensation could continue to be available for MMRV.

3. State Policy Opportunities

To help providers navigate these implications and support continued vaccine access, states can:

- **Update state laws on malpractice to confirm that practitioners will not be liable for administering vaccines in accordance with the state's own vaccine recommendations**, even if those recommendations differ from CDC's or pertain to "off-label" clinical scenarios. This update would ensure that, even if federal protections or flexibilities do not apply, providers are not penalized under state law for complying with the state's own vaccine recommendations. Note that, even without an express update to state malpractice laws, state guidance on appropriate vaccinations would likely be offered as evidence in a malpractice dispute.

- **Partner with state medical, pharmacy, and hospital associations to communicate clearly about appropriate vaccinations**, including off-label vaccinations in accordance with the state's own recommendations (if applicable). Changing federal recommendations will generate questions and confusion on the ground among providers, particularly if federal guidance conflicts with state vaccine recommendations. Working with provider associations to address these questions will be important to ensure continued access to vaccination services and compliance with state law.

III. Conclusion

CDC's recommendations on the use of vaccines have ripple effects across the healthcare sector, with direct consequences for federal as well as state programs and requirements, to the extent states reference CDC guidelines in their laws and policies. Beyond these effects, continued uncertainty and volatility around these recommendations may fuel confusion on the ground, leading fewer people to receive available and recommended vaccines. In light of these challenges, now is a key opportunity for states to consider how they can support and strengthen access to vaccines for the future.

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This toolkit was prepared by Julian Polaris, Elizabeth Dervan, Mandy Cohen, Patti Boozang, Krusheeta Patel, Catherine Kuchel, and Rawan Latif. Manatt Health, a division of Manatt, Phelps & Phillips, LLP, is an integrated legal and consulting practice with over 160 professionals in nine locations across the country. Manatt Health supports states, providers, and insurers with understanding and navigating the complex and rapidly evolving healthcare policy and regulatory landscape. Manatt Health brings deep subject matter expertise to its clients, helping them expand coverage, increase access, and create new ways of organizing, paying for, and delivering care. For more information, visit https://www.manatt.com/health.

ENDNOTES

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[1] Department of Health and Human Services (HHS), CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers
[2] Congressional Research Service (CRS), Off-Label Use of Prescription Drugs.
[3] Centers for Disease Control and Prevention (CDC), Immunization Schedules.
[4] For more on ACIP's history and structure, *see* Kaiser Family Foundation (KFF), Federal Vaccine Advisory Committees: Roles and Current Issues.
[5] CRS, The Advisory Committee on Immunization Practices.
[6] CDC, ACIP Shared Clinical Decision-making Recommendations.
[7] When the CDC lacks an appointed Director, the HHS Secretary may approve ACIP recommendations as the official federal guidance.
[8] HHS, HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP; The New York Times, What Kennedy Has Said About the Polio Vaccine in Recent Years; Secretary Kennedy Post on X.
[9] Department of Health and Human Services (HHS), CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers. Notably, in May, HHS announced—without an ACIP vote—that CDC was no longer recommending the COVID-19 vaccine for pregnant individuals. Following CDC's adoption of ACIP's latest recommendations, CDC now recommends the COVID-19 vaccine to all individuals 6 months and older, including pregnant individuals, with shared clinical decision making.
[10] HHS, ACIP Recommends COVID-19 Immunization Based on Individual Decision-making.
[11] STAT News, Low-income children lack access to Covid vaccines because of approval delay.
[12] American Academy of Pediatrics (AAP), Recommended Child and Adolescent Immunization Schedule.
[13] Oregon Health Authority, Model Immunization Protocols.
[14] KFF, Tracking State Actions on Vaccine Policy and Access.
[15] Office of California Governor Gavin Newsom, California, Oregon, and Washington to Launch New West Coast Health Alliance to Uphold Scientific Integrity in Public Health as Trump Destroys CDC's Credibility.
[16] Massachusetts Department of Public Health, Several Northeastern States and America's Largest City Announce the Northeast Public Health Collaborative.
[17] Northeast Public Health Collaborative, Recommendations for the 2025-2026 Covid-19 Vaccine.
[18] *See e.g.*, CMS, Response to Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act.
[19] Note that vaccines are excluded from the definition of a "Covered outpatient drug" under the Medicaid Drug Rebate Program (MDRP) under the Social Security Act (SSA) 1927(k)(2)(B). As a result, they are not subject to MDRP coverage requirements, nor are they eligible for MDRP federal rebates (although states may negotiate rebates).
[20] Please refer to the following links for citations referencing the Social Security Act (Medicaid, CHIP) and the U.S. Code.
[21] SSA §§ 1904 (a)(4)(b), 1905(r). This requirement applies to children enrolled in Medicaid-expansion CHIPs who are eligible for EPSDT. See HHS, Response to Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act.
[22] SSA § 1905(r)(1)(A)(i) (requiring coverage of "immunizations under subparagraph (B)(iii), in accordance with the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines"); 1928(c)(2)(B)(i) (requiring, for participation in the Vaccines for Children Program, providers to "comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised by" the ACIP).
[23] SSA § 1905(a); CMS, Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements.
[24] See CMS, Best Practices for Adhering to EPSDT Requirements. CMS has confirmed that EPSDT coverage includes "non-ACIP-recommended vaccines and vaccine administration … if the service is determined to be medically necessary." CMS, Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act.

[25] SSA §§ 1916(a)(2)(A), 1916A(b)(3)(B)(ii), 1916(a)(2)(J) (prohibiting cost-sharing for adult vaccines recommended by ACIP).
[26] For Medicaid expansion beneficiaries, state Medicaid programs must cover the same preventive services as Marketplace plans' essential health benefits (EHB). SSA § 1937(b)(5), 42 C.F.R. § 440.347(a). EHB includes preventive services, defined in regulations as including vaccines for "routine use" that "have in effect a recommendation" from ACIP, which has been adopted by the Director of the CDC. 45 C.F.R. §§ 156.115(a)(4), 147.130(a)(1)(ii). *See also* CMS, Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act. ("Vaccination recommendations for shared clinical decision-making that are listed on the CDC/ACIP immunization schedules are considered to be for routine use.").
[27] SSA §§ 1902(a)(10)(A) & (C)(iv), 1916(a)(2) & (b)(2), 1916A(b)(3)(B). CMS has expressly interpreted that standard to include "any category of ACIP recommendations," not just vaccines recommended under CDC's routine Immunization Schedule, such as risk-based indications. CMS, Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act ("The IRA coverage requirement is therefore not limited to vaccines that ACIP includes on the immunization schedules or recommends for routine use").
[28] Federal statute requires coverage of "age-appropriate immunizations," which CMS has interpreted in regulations as "age-appropriate immunizations in accordance with the recommendations of [ACIP]." SSA § 2103(c)(1)(D), 42 C.F.R. § 457.410(b)(2); *see also* 42 C.F.R. §§ 457.520(b)(4), 447.56(a)(i)-(ii) & (a)(2)(iii). There is little CMS guidance interpreting this provision. However, it is likely that states must cover vaccines with CDC recommendations for shared clinical decision-making or risk-based special circumstances, consistent with the vaccine coverage requirements for other Medicaid and CHIP populations.
[29] SSA § 2103(c)(12), requiring coverage of vaccines described in § 1905(a)(13)(B). CMS, SHO# 23-003: Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act.
[30] SSA § 2103(e)(2), prohibiting cost-sharing for vaccines described in § 2103(c)(1)(D) (relating to children) and § 2103(c)(12) (relating to pregnant individuals).
[31] 42 U.S.C. § 300gg-13(a)(2). Regulations specify that immunizations are required to be covered under section 2713 if an ACIP recommendation is approved by the CDC director and reflected in the CDC immunization schedules. 29 C.F.R. § 2590.715-2713(a)(1)(ii), 45 C.F.R. § 147.130(a). A recommendation for "shared clinical decision making" meets this definition and is required to be covered without cost-sharing. CDC, ACIP Shared Clinical Decision-Making Recommendations (2025). *See also* MS, SHO# 23-003: Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act, at 5 ("Vaccination recommendations for shared clinical decision-making that are listed on the CDC/ACIP immunization schedules are considered to be for routine use.").
[32] KFF, Tracking State Actions on Vaccine Policy and Access.
[33] See CMS, Medicare Prescription Drug Benefit Manual ch. 6 § 30.2.7. SSA § 1860D-2(b)(8). Part D plans must not apply cost-sharing for vaccines administered on or after the day a new ACIP recommendation is adopted by the CDC Director, as reflected on the CDC website.
[34] CMS, Medicare Prescription Drug Benefit Manual ch. 6 § 30.2.7 (2016)).
[35] SSA § 1861(s)(10)(A); 42 C.F.R. § 410.57.
[36] As described above, CMS has generally interpreted vaccines recommended by ACIP "for routine use" to include those with shared clinical decision-making recommendations.
[37] Historically, CMS has deferred to states to define "medical necessity" and, thus, the outer limits of each covered benefit, except in cases where federal law expressly defines coverage exclusions.
[38] For expansion adults, coverage is defined under an alternative benefit plan (ABP). Many states have chosen to align their ABP with the Medicaid state plan as to some or all covered benefits. Similarly, for separate CHIP programs, many states have chosen to align some or all benefits with the Medicaid state plan.
[39] KFF, Tracking State Actions on Vaccine Policy and Access.
[40] Massachusetts Division of Insurance, Bulletin 2025-03 re: Coverage for Vaccines. Massachusetts Governor Maura Healey recently filed a bill that would codify DPH's independent authority to set vaccine recommendations for the state. Mass.gov, Governor Healey Files $2.45 Billion Supplemental Budget to Close Fiscal Year 2025.
[41] Colorado First Regular Session of the Seventy-Fifth General Assembly, Senate Bill No. 196.
[42] New York Two Hundred Forty-Eighth Legislative Session, Assembly Bill No. 9060.

[43] SSA § 1902(a)(62).
[44] SSA §§ 1928(e).
[45] CDC, Vaccines Provided by the VFC Program.
[46] Per the VFC Operations Guide: July 1, 2024 – June 30, 2025 (p. 17), when recommending a new vaccine or a change in vaccine use, the ACIP votes on a resolution to include the vaccine change in the VFC program.
[47] SSA §§ 1928(e); 1928(c)(2)(B)(i).
[48] SSA § 1928(c)(2)(B) ("(i) Subject to clause (ii), the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised by the advisory committee referred to in subsection (e), except in such cases as, in the provider's medical judgment subject to accepted medical practice, such compliance is medically inappropriate. (ii) The provider will provide pediatric vaccines in compliance with applicable State law, including any such law relating to any religious or other exemption."). *See also* CDC, VFC Operations Guide: July 1, 2024 – June 30, 2025.
[49] HHS Office for Civil Rights, Response to Vaccines for Children Program.
[50] 42 U.S.C. § 247b(a), (j)(2). Although the statute does not expressly reference recommendations from ACIP/CDC, that has been the common historical understanding. Institute of Medicine (US) Committee on Immunization Finance Policies and Practices. Calling the Shots: Immunization Finance Policies and Practices. Appendix A, Public Health Services Act, Section 317.
[51] STAT News, Low-income children lack access to Covid vaccines because of approval delay.
[52] SSA 1928(c)(2)(B)(i).
[53] National Academy for State Health Policy, Recovering Routing Immunization Rates – State Strategies to Move Beyond COVID-19.
[54] National Alliance of State Pharmacy Associations, Pharmacist and Pharmacy Technician Vaccination Authority.
[55] CDC, ACIP Shared Clinical Decision-making Recommendations.
[56] HHS, 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.
[57] KFF, Tracking State Actions on Vaccine Policy and Access.
[58] Ibid.
[59] 20 Missouri Code of State Regs. 2220-6.050.
[60] NYEL § 6802(22)(a); New York Department of Health, Current New York State Standing Orders for Pharmacists.
[61] KFF, State Vaccine Requirements for Children.
[62] *See* Association of State and Territorial Health Officials, Impact of the Advisory Committee on Immunization Practices Recommendations on State Law. For example, in Hawaii, the health department "may adopt, amend, or repeal as rules, the immunization recommendations of [ACIP]." HI Rev Stat § 302A-1162 (2024). Missouri permits school enrollment when a child "has been adequately immunized against vaccine-preventable childhood illnesses specified by [CDC/ACIP]." MO Rev Stat § 210.003 (2024). New Mexio requires that "[t]he immunizations required and the manner and frequency of their administration shall conform to recommendations of [ACIP] and [AAP]." NM Stat § 24-5-1 (2024).
[63] KFF, A Look at Recent Changes to State Vaccine Requirements for School Children.
[64] *See* Health Affairs, A Comprehensive Assessment of Child Care Vaccination Laws Across the U.S. ("Forty-three states and Washington, D.C. (86 percent of all jurisdictions), expressly identified in the law which vaccines were required for child care; two states (4 percent) required all CDC recommended vaccines without expressly detailing the specific vaccines required (Delaware and Pennsylvania); two states (4 percent) indicated that the required vaccines would be published by the department of health (Florida and South Carolina); and three states (6 percent) used a mixed system whereby some vaccinations were required and others could be identified by the department of health (Indiana, Massachusetts, and Montana).")
[65] CMS withdrew its requirement that personnel in certain healthcare facilities receive the COVID-19 vaccine in 2023. *See* 88 F.R. 36485.
[66] CDC, State Healthcare Worker and Patient Vaccination Laws.
[67] California Department of Public Health, Immunization Recommendations for California Healthcare Personnel.
[68] HHS Office for Civil Rights, Response to Vaccines for Children Program.
[69] HHS Office for Civil Rights, Letter to West Virginia Health Departments Participating in the Vaccines for Children Program.

[70] Although comprehensive data does not exist, we are not aware of state vaccination requirements for these settings that restrict vaccines provided under shared clinical decision-making.
[71] 2025 CO HB 1027.
[72] 42 U.S.C. §247d–6d.
[73] HHS, 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.
[74] 42 C.F.R. 110.20.
[75] 42 U.S.C. §§ 300aa-10 et seq.
[76] 42 U.S.C. § 300aa-14. See also 42 CFR 100.3.
[77] 42 U.S.C. § 300aa-14(e); 42 C.F.R. § 100.3.
[78] *See* 26 U.S.C. § 4132, providing a list of vaccines subject to such tax. 42 C.F.R. § 100.3(c)(8).
[79] Health Resources & Services Administration, National Vaccine Injury Compensation Program Covered Vaccines. (specifying that compensation under VICP is available even if a covered vaccine is administered contrary to CDC/ACIP guidelines or contrary to FDA-approved uses (i.e., "off-label")).
[80] 42 C.F.R. § 100.3. The excise tax that currently applies is similarly broad, applying to any vaccine against rubella, mumps, or measles by statute. *See* 26 U.S.C. §4132.