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FAQ COVID-19 Vaccines – Off-Label Use

This FAQ is intended to summarize some of the legal implications of the changes in federal COVID-19 vaccination policy and provide suggestions to respond to those changes. The content is current as of September 18, 2025.[i]

What has the Food and Drug Administration (FDA) done in relation to COVID vaccines?

- The FDA restricted approvals for the 2025-2026 COVID-19 vaccinations to individuals who are 65 years of age or older and for individuals who are under 65 to only those individuals who have an underlying condition that puts them at high risk for severe outcomes from COVID-19 (immunocompromised).[1] In other words, the FDA has not approved COVID vaccines for healthy individuals who are under the age of 65.

- The Centers for Disease Control and Prevention (CDC) released a revised routine vaccination schedule, which removed COVID-19 vaccines from the recommended routine vaccinations schedule for individuals who are between the ages of 6 months to18 years who are not immunocompromised.[2] The CDC recommends that parents who would like their children to be vaccinated engage their healthcare provider in shared-clinical decision-making.[3]
- At its September 18-19 meeting, the CDC Advisory Committee on Immunization Practices (ACIP) may revise their recommendation and limit COVID-19 vaccinations to only those individuals who are age 65 and older and individuals with immunocompromise.

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[1] Novavax, NUVAXOVID, COVID-19 Vaccine (approved for ≥ age 65 and ages 12-64 with at least 1 high risk condition); Moderna, MNEXSPIKE COVID-19 Vaccine (approved for ≥ age 65 and ages 12-64 with at least 1 high risk condition), and Moderna, SPIKEVAX COVID-19 Vaccine (approved for ≥ age 65 and ages 6 months-64 years with at least 1 high risk condition; Pfizer-BioNTech, COMIRNATY COVID-19 Vaccine (approved for ≥ age 65 and ages 5-64 with at least 1 high risk condition)

[2] Child and Adolescent Immunization Schedule by Age (Addendum updated Aug. 7, 2025)

[3] ACIP Shared Clinical Decision-Making Recommendations

What are the impacts of the FDA denying approval of COVID-19 vaccines for healthy individuals under age 65?

- The decision to deny approval means that COVID-19 vaccines for healthy individuals under age 65 is an off-label use.

- For this population, COVID-19 vaccines change from being FDA "authorized" to "unapproved" and off-label.

- For practitioners and provider organizations, the change increases legal risks, decreases legal protection, and creates a need for internal processes to ensure documented informed consent for off-label use.

Does the FDA regulate patient care?

- The FDA regulates drugs, vaccines and other health products, but it does not regulate patient care. For vaccines, FDA regulates vaccine approval, product labeling and marketing. In approving a drug or a vaccine, the FDA determines what the manufacturer is required to put on a label and the content of any marketing information for healthcare providers and the general public. The FDA approval only relates to the conditions that were included in the manufacturer's application. Once a product is approved, the FDA does not determine how a practitioner may use an approved product for an individual patient.

What are the impacts of the CDC/ACIP changing its recommendations for COVID-19 vaccines?

- The State has and may continue to be able to limit the negative impacts of the CDC/ACIP recommendations as it has with the September 17 Standing Order, which will allow pharmacies to continue to provide vaccines to all individuals age 5 and over.

    - But, paragraph 4 of the Standing Order states that pharmacies are required to "refer persons with medical questions, with potential contraindications or health conditions" to primary care providers.

    - Practitioners will need to understand their role in relation to individuals who pharmacies are not able to serve.

How will the current and anticipated HHS changes affect practitioners when they prescribe or order a COVID-19 vaccine for an off-label use?

- The HHS policy changes and removes certain legal protections for the use of COVID-19 vaccines but otherwise does not affect a practitioner's professional judgment regarding off-label use.

- Practitioners may prescribe off-label drugs and vaccines for any use that the prescriber believes is medically appropriate and consistent with the standard of care.[4]

- In determining the standard of care for an off-label use for a particular patient, a practitioner may consider FDA approval including any warnings and contraindications, but in exercising their medical judgment they would also consider guidance from authoritative sources such as the Vermont Department of Health[5], and evidence-based recommendations[6] in relation to a decision about an individual patient.

Does FDA regulate off-label use?

- The FDA regulates off-label marketing and promotion. It does not regulate off-label use.

    - The FDA regulates what information manufacturers may provide to health care providers regarding off-label use such as scientific studies of the effectiveness of off-label use for particular conditions.[7] Manufacturers may not promote off-label use to the general public.

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[4] In Vermont, the standard of care is defined as the degree of knowledge or skill possessed or the degree of care ordinarily exercised by a reasonably skillful, careful, and prudent health care professional engaged in a similar practice under the same or similar circumstances. 12 V.S.A. § 1908(1)(medical malpractice).

Under the Vermont Medical Practice Act, unprofessional conduct includes the gross failure to exercise the degree of care, skill, and proficiency that is commonly exercised by the ordinary skillful, careful, and prudent physician engaged in similar practice under the same and similar conditions, and the failure to practice competently includes failing to conform to the essential standards of acceptable and prevailing practice. 26 V.S.A. § 1354.

[5] VDH Updated Respiratory Virus Vaccine Guidance, (Sept. 18, 2025)

[6] American Academy of Pediatrics, 2025 Recommended Child and Adolescent Immunization Schedule for Ages 18; American Academy of Family Physicians, Fall Immunization Recommendations; AAFP, Adults 19 and Older Immunization Schedule

[7] FDA, Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products, (Jan. 2025)

- The off-label use of a vaccine would be treated as any other medical services performed or delegated by physicians and other practitioners in that prescribing, ordering, and administering vaccines for off-label use is regulated through a physician or other practitioner's license under the State Medical Practice Act, the Nursing Practice Act, and the Pharmacy Practice Act. Medical services may also be subject to medical malpractice and other legal claims.

How do the restrictions on FDA approval affect health care provider's legal risks?

- The restrictions on FDA approval limits the protections provided by the Public Readiness and Emergency Preparedness Act (PREP Act). The PREP Act does not extend liability immunity to off-label uses of COVID-19 vaccines. Therefore, practitioners are not shielded from malpractice and other civil claims as they have been since 2020.

- The PREP Act provides immunity from liability related to the administration of covered countermeasures for diseases associated with a public health emergency. The Secretary of the Department of Health and Human Services' declaration for the authorization of the PREP Act for COVID-19 has been in place since March 17, 2020.

- The PREP Act has covered COVID-19 vaccinations that are subject to FDA emergency use authorization and currently the COVID-19 and seasonal influenza vaccine declaration are scheduled to stay in effect through December 31, 2029, but for only approved uses.[8]

Who is covered by PREP Act Immunity for COVID-19 countermeasures?

- The PREP Act declaration applies to "qualified persons," which includes a wide variety of licensed health professionals and students, licensed pharmacists, pharmacy interns, and qualified pharmacy technicians. The PREP Act preempts state law that would prohibit qualified persons from prescribing, dispensing, or administering approved COVID-19 and influenza vaccines.

[8] HHS, 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875 (Dec. 11, 2024). COVID-19 vaccinations are not covered by the National Vaccine Injury Compensation Program (VICP).

How do the limitations on the PREP Act affect the administration of vaccines?

- Pharmacies and provider organizations may be hesitant to provide to COVID-19 vaccines for off-label uses because the previously applicable PREP Act liability protection will not apply to off-label use of COVID-19 vaccines.

- There is also a risk of increased litigation because the vaccine injury compensation funds do not apply to off-label uses. The PREP Act authorizes compensation to individuals who sustain serious injuries that are a direct result of a covered counter measure. The compensation is provided though the Countermeasures Injury Compensation Program (CICP). The compensation fund reduces legal risks to providers because it offers a no-fault alternative to litigation for injured individuals. With the limitations the only recourse for an individual who seeks compensation for an injury associated with an off-label use of a COVID-19 vaccine would be a malpractice or other legal claim.

Are there things that healthcare providers can do to manage legal risks for providing COVID-19 vaccines

- Organize authoritative medical and scientific literature including clinical guidelines to use for staff and patient education materials, as well as policies and protocols.

- Develop or review policies on vaccine ordering, storage, preparation, and handling of vaccines.

- Consider developing evidence-based vaccine protocols that balance efficiency, safety, and legal risk for ordering, administering, and documenting vaccines that includes off-label use.

- Carefully screen individuals for contraindications

- Evaluate screening process to ensure the accurate identification underlying conditions or risk factors that potentially increase severe COVID-19 outcomes.
    - Evaluate question design to limit health risk under reporting
        - Consider adding a statement at the beginning of the screening tool to assure patients that screening questions are intended to promote access to the vaccine and not exclude people.
            - "**Note: The following list of underlying conditions is not used to exclude people from recommended measures for prevention**."[9]
                - Obesity (BMI≥30): Height:_____ Weight:_____
                - Risk factor: "**Smoking, current and former**.
                - Inaccurate question: "Are you a smoker?"
- Accurate question: Have you ever smoked cigarettes or other tobacco products?
- Consider utilizing alternative informed consent workflows for approved and off-label vaccines.
    - An informed consent process must ensure that patients or parents are informed of the risk and benefits and have an opportunity to ask a qualified clinician questions about the vaccine particularly for off-label use.[10]
        - Informing a patient that a vaccine is off-label may not help them make an informed decision because they would need to understand the FDA approval process and how the lack of approval does not mean that the vaccine is unsafe or ineffective for them.

[9] CDC, COVID-19 Underlying Conditions and Higher Risk for Severe COVID-19

[10] 12 VSA 1909 (medical malpractice for lack of informed consent). The lack of informed consent means the failure of the person providing the professional treatment to disclose to the patient the reasonably foreseeable risks and benefits involved, or the failure to provide reasonable answers to specific questions about foreseeable risks and benefits, as a reasonable medical practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.

- Consider supplementing the required CDC Vaccine Information Statement (VIS) with informative evidence-based information. The VIS represents the legal minimum information that needs to be communicated. Supplemental information may be helpful in fully informing patients about the risks and benefits.

    - AAP Childhood Immunization Discussion Guides.

    - AAFP Vaccine Resources

- Document the discussions with patients and parents regarding the risks and benefits of the vaccines and the provision of vaccine information.

    - For off-label use, confirm that obtaining and documenting informed consent is within the scope of practice of each licensed clinician who is assigned to have the conversation with the patient or parent. APRNs, RNs, and Physician Assistants should be able to obtain informed consent for COVID-19 vaccines when it is within their individual scope of practice.[11] Obtaining informed consent for an off-label vaccine may not be within the scope of practice of other licensed clinical staff such as LPNs and LNAs,[12] and may not be a reasonably delegated task for unlicensed clinical staff such as medical assistants.[13]

[11] Administrative Rules of the Board Nursing, § 11-6 (May 11, 2023).

[12] Id. at § 6.3 and § 10.

[13] Unprofessional conduct includes the delegation of professional responsibilities to a person whom the licensed professional knows or has reason to know, is not qualified by training, experience, education, or licensing credentials. 26 V.S.A. § 1354(29). A physician may delegate to a medical technician or other assistant or employee certain activities related to medical care and treatment that the individual is qualified to perform by training, education, experience, or a combination of these when the activities are under the control of the physician. The physician delegating the activities to the individual shall be legally liable for the individual's performance of those activities, and in this relationship, the individual shall be the physician's agent. 26 V.S.A. § 1444.

- It the context of a malpractice claim, it may not be difficult to establish that providing a vaccine to an individual patient was consistent with the standard of care. However, if the vaccine process for off-label use does not include a qualified, licensed healthcare professional, it may be more difficult to establish the patient had a reasonable opportunity to ask questions about the foreseeable risk and benefits and have them answered as a reasonable medical practitioner would under similar circumstances.[14]

[i] The recommendations suggested here are for informational purposes only and do not constitute legal advice. Decisions regarding the provision of healthcare must be made by each healthcare professional considering based on the circumstances of the individual situation.

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[14] See footnote 10, medical malpractice for lack of informed consent.