

2024 Vaccination Program Administration Guidelines

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PLEASE NOTE:

The information provided herein is accurate as of the publication date. Please check available sources for any future updates issued subsequently to ensure you reference the most current vaccination information.



2024 HD Vaccine Administration Guideline

The purpose of this guide is to serve as a reference for general vaccine administration with a focus on preventing seasonal respiratory illness in the community care setting.

This reference includes specific information about the licensed vaccines available for influenza, COVID-19, respiratory syncytial virus, pneumococcal disease, and herpes zoster in the U.S. Market.

Recommendation summaries and vaccine information are updated with current ACIP / CDC recommendations, and vaccine product labeling as approved by the FDA from the manufacturer.

Section I: General Best Practices for Vaccine Administration

- An individual's medical record and immunization history should be compared to the current CDC Recommended Vaccination Schedule to determine which vaccine(s) are appropriate for the individual at time of encounter.
 - Child and Adolescent Immunization Schedule by Age
 - Adult Immunization Schedule by Age

Section I: Topic Listing

- 1. Adverse Reactions, Precautions & Contraindications to Vaccine Delivery
- 2. Intramuscular (IM) Vaccine Administration Recommendations
- 3. Maintaining Vaccination Records & State Registry Reporting Requirements
- 4. On Vaccine Administration Spacing and Timing

1. Adverse Reactions, Precautions & Contraindications to Vaccine Delivery:

- Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an undesirable side effect that may occur after a vaccination. Vaccine adverse reactions are classified as local, systemic, or allergic. Local reactions (e.g., redness) are usually the least severe and most frequent. Systemic reactions (e.g., fever) occur less frequently than local reactions, and severe allergic reactions (e.g., anaphylaxis) are exceedingly rare.
 - Vaccine providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be prepared and competent in treating these events at the time of vaccine administration.
 - Previous anaphylactic reaction to the vaccine being administered in most cases is an absolute contraindication and should not be attempted.
 - Systemic and Allergy type reactions should be reported to the HHS Vaccine Adverse Event Reporting System, <u>VAERS</u>.
- For all vaccines, if a person has an acute illness with or without fever, consider holding vaccine administration until after the person has fully recovered from their illness. This is a precaution for most vaccines, not an absolute contraindication.
- Severely immunocompromised persons generally should not receive live vaccines. Because
 of the theoretical risk to the fetus, pregnant women generally should not receive live,
 attenuated virus vaccines.
- + adapted from CDC General Best Practice Guidelines <u>Adverse Reactions</u>, Precautions & Contraindications



2. Intramuscular (IM) Vaccine Administration Recommendations:

- All of the vaccines covered in our guideline are recommended for intramuscular administration.
 PPSV23 can also be administered subcutaneously.
- Injectable immunobiologics (i.e. vaccines) should be administered where local, neural, vascular, or tissue injury is unlikely. Use of longer needles has been associated with less redness or swelling than occurs with shorter needles because of injection into deeper muscle mass. Appropriate needle length depends on age and body mass. Injection technique is the most important parameter to ensure efficient intramuscular vaccine delivery.
- Intramuscular injections are administered at a 90-degree angle to the skin, preferably into the deltoid muscle of the upper arm or the anterolateral aspect of the thigh, depending on the age of the patient. The correct needle gauge for intramuscular injection is 22-25 gauge.
- The below table and infographics define appropriate needle length and needle insertion for intramuscular (IM) injection.

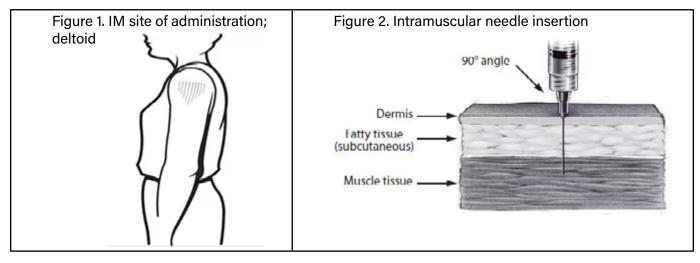
TABLE 1. Needle length and injection site of IM injections for children aged \leq 18 years (by age) and adults aged \geq 19 years (by sex and weight).

Age Group	Needle Length	Injection	
Children (birth-18 years)			
Neonates(a)	5/8 inch (16 mm)(b)	Anterolateral thigh	
Infants, 1-12 months	1 inch (25 mm)	Anterolateral thigh	
Toddlers, 1-2 years	1-1.25 inch (25-32 mm)	Anterolateral thigh(c)	
	5/8(b)-1 inch (16-25 mm)	Deltoid muscle of arm	
Children, 3-10 years	5/8(b)-1 inch (16-25 mm)	Deltoid muscle of arm(c)	
	1-1.25 inches (25-32 mm)	Anterolateral thigh	
Children, 11-18 years	5/8(b)-1 inch (16-25 mm)	Deltoid muscle of arm(c)	
	1-1.5 inches (25-38 mm)	Anterolateral thigh	

Adults (≥19 years)		
Men and women, <60 kg (130 lbs)	1 inch (25 mm)(d)	Deltoid muscle of arm
Men and women, 60-70 kg (130-152 lbs)	1 inch (25 mm)	
Men, 70-118 kg (152-260 lbs)	1-1.5 inches (25-38 mm)	
Women, 70-90 kg (152-200 lbs)		
Men, >118 kg (260 lbs)	1.5 inches (38 mm)	
Women, >90 kg (200 lbs)		
Men and women, any weight	1.5 inches (38 mm)(e)	Anterolateral thigh



Abbreviation: IM = intramuscular.



+ adapted from CDC General Best Practice Guidelines - Vaccine Administration

3. Maintaining Vaccination Records & State Registry Reporting Requirements:

- Appropriate and timely vaccination documentation helps ensure not only that persons in need of recommended vaccine doses receive them but also that adequately vaccinated patients do not receive excess doses.
- Health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program (VICP) are required under the National Childhood Vaccine Injury Act to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine.
 - This Act applies to any vaccine for which there is a routine recommendation for childhood vaccination, even if many or most doses of the vaccine are administered to adults (e.g., influenza vaccine).
 - In addition, vaccine providers are required to record the edition date of the VIS distributed and the date those materials were provided
 - The Act considers a health-care provider to be any licensed health care professional, organization, or institution, whether private or public (including federal, state, and local departments and agencies), under whose authority a specified vaccine is administered.
 - This information should be kept for all vaccines, not just for those required by the Act.
- Providers and staff members also should systematically update patients' permanent medical records
 to reflect any documented episodes of adverse events after vaccination and any serologic test results
 related to vaccine-preventable diseases (e.g., those for rubella screening and anti-HBs).
 - IISs (formerly referred to as immunization registries) are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health care providers within a geographic area.



- IISs are a critical tool that can increase and sustain vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices for each person, and providing official vaccination forms and vaccination coverage assessments.
 - Providers should be aware of state and/or regional IISs and follow requirements for reporting.
- + adapted from CDC General Best Practice Guidelines Vaccination Records

4. On Vaccine Administration Spacing and Timing:

- For most individuals and vaccines, multiple vaccines can be given at the same time. Per ACIP data, simultaneously administering vaccines together has produced seroconversion rates very similar to those administered separately.
- Simultaneous administration of vaccines is defined as administering more than one vaccine on the same clinic day, at different anatomic sites, and not combined in the same syringe.
- Simultaneously administering all vaccines for which a person is eligible at the time of a visit increases the probability that a child, adolescent, or adult will be vaccinated fully by the appropriate age.
- Consult the immunization schedule or CDC recommendation page for additional information, there are exceptions, and clinical decision-making should involve the patient's vaccination response history and personal preferences when vaccine providers are considering and scheduling simultaneous vaccine(s) administration.
 - NON-LIVE: There is no evidence that non-live vaccines interfere with the immune response of
 other non-live or live vaccines. Most non-live vaccines can be given simultaneously or given at any
 other time before or after another vaccine.
 - <u>LIVE</u>: Multiple live vaccines can be administered on the same day. If not administered on the same day, live vaccines should be separated by 4 weeks.
- When administering multiple vaccines at a single time, administer each preparation at a different anatomical site (i.e. each arm). At minimum, the injections sites should be separated by 1 inch or more.
 - This way, local site reactions can be differentiated.



TABLE 2. Vaccine Types

Vaccine Category	Vaccines	
Live	 Oral adenovirus vaccine 	
Live attenuated	 ACAM2000 smallpox vaccine Bacille Calmette Guerin (BCG) vaccine Dengue vaccine Ebola vector vaccine Live attenuated influenza vaccine (LAIV) Live oral typhoid vaccine (Ty21a) Measles-mumps-rubella-containing (MMR, MMRV) Oral cholera vaccine Rotavirus vaccines (RV1, RV5) Varicella (Var) vaccine Yellow Fever vaccine 	
Non-live	 Anthrax vaccine COVID-19 vaccines (Pfizer, Moderna, Novavax) Haemophilus influenza type b (Hib) vaccines Hepatitis A (HepA) vaccines Hepatitis B (HepB) vaccines Human papillomavirus (HPV) vaccines Inactivated poliovirus vaccine (IPV) Inactivated typhoid vaccine (Typhim Vi) Influenza vaccines (IIV4, RIV4) Japanese Encephalitis Vaccine (JEV) Meningococcal conjugate (MenACWY) vaccine Pneumococcal conjugate vaccines (PCV13, PCV15, PCV20, PCV21) Pneumococcal polysaccharide vaccine (PPSV23) Rabies vaccine Recombinant zoster vaccine (RZV) Respiratory syncytial virus vaccine (RSV) Serogroup B meningococcal (MenB) vaccines (MenB-FHbp, MenB-4C) Tetanus-toxoid, diphtheria-toxoid, or pertussis-containing vaccines (DTaP, Tdap, DT, Td, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV, DTaP-IPV-Hib-HepB) 	
Non-replicating	COVID-19 vaccine (Janssen) Jynneos smallpox/monkeypox vaccine	

⁺ adapted from CDC General Best Practice Guidelines - <u>Timing and Spacing of Immunobiologics</u>



Section II: Current CDC Recommended Vaccine Schedule, by Vaccine Type

- 1. Influenza
- 2. COVID-19
- 3. RSV
- 4. Pneumococcal
- 5. Herpes Zoster (RZV)

1. Influenza:

All preparations listed below are Inactivated Influenza Vaccines (IIV3s), trivalent, currently recommended by ACIP / CDC for the 2024-2025 flu vaccine season and provided by HealthDirect Pharmacy Services.

Flu vaccine is administered intramuscularly (IM). For adults and older children, the deltoid is the preferred site. For infants and younger children, the anterolateral thigh is the preferred site.

(see Section 1 - Intramuscular (IM) Vaccine Administration Recommendations for more details)

Approved Ages	Available 2024-2025 Vaccine Formulation	Comments
≥6 mos (IIV3: standard-dose, 15 µg HA per virus component in 0.5 mL; 7.5 µg in 0.25 mL)	1. Fluzone PFS (Sanofi Pasteur) NDC: 49281-0424-88	1. Either 0.25 or 0.5 mL approved for ages 6-35 months. Egg-based.
	 Flucelvax PFS (Seqirus) NDC: 70461-0654-03 Afluria (Seqirus) MDV 	2. Cell culture-based; ≥6 mos—0.5 mL; Egg-free.
	NDC: 33332-0124-10	3. 6 through 35 mos—0.25 mL; ≥3 yrs—0.5 mL; jet injector approved for 18-64 years only. Eggbased.
≥65 years old (HD-IIV3: High-dose, 60 µg hemagglutinin per virus component in 0.5 mL)	1. Fluzone High-Dose (Sanofi Pasteur) NDC: 49281-0124-88	1. One of 3 options preferred for ≥65 years. Egg-based.

Recommended Schedule: Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

Annual administration recommended September – October



1. Influenza continued:

Precautions to Influenza Vaccine Administration:

- Guillain-Barré syndrome (GBS) within 6 weeks after any type of influenza vaccine
- Moderate to severe acute illness, with/without fever

Contraindications to Influenza Vaccine Administration:

- Any severe allergic reaction to any component of the flu vaccine (except for egg):
 - Beginning on the 2023-2024 season, the ACIP voted that people with egg-allergy may receive any flu vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended for flu vaccination beyond those recommended for receipt of any vaccine. If there are any concerns regarding severe allergies, flu vaccination should be discussed with a healthcare provider.
 - Providers can also consider consulting with an allergist to help determine which vaccine component is responsible for an allergic reaction.

Additional notes:

- If a person has tested positive for influenza and/or is currently ill, wait until they have fully recovered from illness before administering the influenza vaccine.
- For additional information on flu vaccines for the 2024-2025 influenza season, see the ACIP / CDC recommendation summary page available at:

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm



2. COVID-19:

2024-2025 mRNA COVID-19 Vaccine Composition

The 2024–2025 formulations for COVID-19 vaccines approved or authorized in the United States have been updated to a monovalent vaccine based on the Omicron JN.1-lineage of SARS-CoV-2, as follows:

- Moderna and Pfizer-BioNTech: KP.2 strain
- Novavax: JN.1 strain

Groups Recommended for Vaccination

- COVID-19 vaccination is recommended for everyone ages 6 months and older in the United States for the prevention of COVID-19. There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children younger than age 6 months.
- CDC recommends that people receive all recommended COVID-19 vaccine doses to stay up to date.
- Vaccination is especially important for people at highest risk of severe COVID-19, including people ages 65 years and older; people with <u>underlying medical conditions</u>, including immune compromise; people living in long-term care facilities; and pregnant people to protect themselves and their infants.
- People ages 65 years and older: Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months (minimum interval 2 months) apart.

COVID-19 Vaccine Dosage and Administration (2024-2025 Formulas)

COVID-19 vaccine doses should be administered by the intramuscular (IM) route to the deltoid muscle in upper arm, or the anterolateral thigh for 6 months – 2 years of age.

Vaccine Name	Туре	Approved Age Groups	Dose / Presentation
SPIKEVAX (2024-2025), Moderna	mRNA	FDA Approved ≥12 Years	0.5 mL/50 μg; PFS
Moderna COVID-19 Vaccine (2024-2025 Formula)		EUA 6 months – 11 years	0.25 mL/25 μg; PFS
COMIRNATY (2024- 2025), Pfizer-BioNTech		FDA Approved ≥12 Years	0.3 mL/30 μg; PFS
Pfizer-BioNTech COVID-19 Vaccine (2024-		EUA 5 years – 11 years	0.3 mL/10 μg; SDV - blue cap and blue label
2025 Formula)		EUA 6 months – 4 years	0.3 mL/3 μg; 3-dose MDV with diluent - yellow cap and yellow label
Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula)	Protein Subunit	EUA ≥12 Years	0.5 mL/5 μg (rS) - 50 μg Matrix-M adjuvant, PFS



2. COVID-19 continued:

Recommended COVID-19 vaccine schedule including dosage and interval for subsequent administration is dependent on the person's age, risk factors (i.e. immunocompromised status) and known COVID-19 vaccination history.

- Recommendations vary based on if the patient is considered immunocompetent (<u>Table 1</u>) or immunocompromised (<u>Table 2</u>).
- For most people the minimum interval between their last 2023–2024 COVID-19 vaccine dose and their 2024–2025 COVID-19 vaccine dose is 8 weeks.
 - There are exceptions for people who are completing a multi-dose initial vaccination series (i.e., children ages 6 months–4 years; people ages 6 months and older who are moderately or severely immunocompromised; and people ages 12 years and older who receive Novavax).
- An overview of the 2024–2025 COVID-19 vaccination schedule is summarized below.

i. People who are not moderately or severely immunocompromised

Routine COVID-19 vaccination

- Children ages 6 months-4 years:
 - Unvaccinated: Should receive a multidose initial series with a 2024–2025 mRNA vaccine
 - Previously completed an initial series: Should receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series*
- People ages 5–64 years:
 - Should receive 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine
 - People ages 12–64 years who are unvaccinated and receive the 2024–2025 Novavax COVID-19
 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 Vaccine.
- People ages 65 years and older:
 - Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months (minimum interval 2 months) apart
 - People ages 65 years and older who are unvaccinated and receive Novavax COVID-19 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 Vaccine followed by a third dose of any 2024–2025 COVID-19 vaccine dose 6 months (minimum interval 2 months) after the second dose



2. COVID-19 continued:

Table 1. People who are not moderately or severely immunocompromised: Recommended COVID-19 vaccination schedule by COVID-19 vaccination history, October 31, 2024

Ages 12 years - 64 years [2024-2025 COVID-19 vaccines]

COVID-19 vaccination history before 2024–2025 vaccine*†	Number of 2024-2025 doses indicated	Recommended 2024-2025 vaccine [‡] and interval between doses
Unvaccinated:		
Initiate vaccination with	2024-2025 vaccine	
Unvaccinated	1	2024–2025 Dose 1 (Moderna or Pfizer-BioNTech): Day 0
	OR	
	2	2024–2025 Dose 1 (Novavax): Day 0 2024–2025 Dose 2 (Novavax): 3–8
		weeks after Dose 1 [§]
Previously vaccinated before 2024–2025 vaccine:		
Receive 1 dose of 2024–	2025 vaccine	
1 or more doses mRNA (Moderna or Pfizer-BioNTech) vaccine	1	2024–2025 Dose 1 (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose
1 dose Novavax	1	2024–2025 Dose 1 (Novavax): 3–8 weeks after last dose ^{§¶}
2 or more doses Novavax	1	2024–2025 Dose 1 (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose

Ages 65 years and older [2024-2025 COVID-19 vaccines]

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024-2025 doses indicated	Recommended 2024-2025 vaccine [‡] and interval between doses
Unvaccinated:		
 Initiate vaccination with 	2024-2025 vaccine	
Unvaccinated	2	2024-2025 Dose 1 (Moderna or Pfizer-BioNTech): Day 0 2024-2025 Dose 2 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 1
	OR	
	3	2024-2025 Dose 1 (Novavax): Day 0 2024-2025 Dose 2 (Novavax): 3-8 weeks after Dose 1 [§] 2024-2025 Dose 3 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 2



2. COVID-19 continued:

COVID-19 vaccination history before 2024–2025 vaccine*†	Number of 2024-2025 doses indicated	Recommended 2024-2025 vaccine* and interval between doses
Previously vaccinated before 202	24-2025 vaccine:	
 Receive 2 doses of 2024 	1–2025 vaccine	
1 or more doses mRNA vaccine (Moderna or Pfizer-BioNTech)	2	2024–2025 Dose 1 (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose 2024–2025 Dose 2 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1
1 dose Novavax	2	2024-2025 Dose 1 (Novavax): 3-8 weeks after last dose ^{§1} 2024-2025 Dose 2 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024-2025 Dose 1
2 or more doses Novavax	2	2024-2025 Dose 1 (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose 2024-2025 Dose 2 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024-2025 Dose 1

^{*}COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

[†]People ages 18-64 years who received 1 or more doses of Janssen COVID-19 Vaccine should receive 1 dose of any 2024–2025 COVID vaccine.

§An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, Pfizer-BioNTech) doses might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

¹If more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.

For recommended COVID-19 vaccine doses and intervals for age groups 6 months – 11 years of age, consult the CDC website (Table 1); or contact your HealthDirect Pharmacist Team for consultation and guidance.



2. COVID-19 continued:

ii. People who are moderately or severely immunocompromised

- Unvaccinated: Should receive a multidose initial series with an age-appropriate 2024–2025 COVID-19 vaccine and 1 dose of a 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after completing the initial series.
- Previously completed an initial series: Should receive 2 doses of an age-appropriate 2024–2025
 COVID-19 vaccine, spaced 6 months (minimum interval 2 months) apart*
- May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under <u>shared clinical</u> <u>decision-making</u>[†]
- In all age groups, COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended; see <u>Interchangeability of COVID-19 vaccines</u> for circumstances in which doses from different manufacturers may be considered.

*For people ages 6 months and older who are moderately or severely immunocompromised who initiated but did not complete an initial series, consult <u>Table 2</u>.

[†]Additional doses may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

Table 2. People who are moderately or severely immunocompromised: Recommended COVID-19 vaccination schedule by COVID-19 vaccination history, October 31, 2024

Ages 12 years and older [2024-2025 COVID-19 vaccines]

COVID-19 vaccination history before 2024–2025 vaccine ^{1‡}	Number of 2024–2025 doses indicated	Recommended 2024-2025 vaccines and interval between doses
Unvaccinated:		
Receive an initial series	with 2024–2025 vaccine	
 Receive 1 dose of 2024– initial series 	2025 vaccine 6 months (min	imum interval 2 months) after completing
 May receive additional of 	doses of 2024–2025 vaccine	under shared clinical decision-making¶
Unvaccinated	4	2024-2025 Dose 1 (Moderna): Day 0 2024-2025 Dose 2 (Moderna): 4 weeks after Dose 1 2024-2025 Dose 3 (Moderna): At least 4 weeks after Dose 2 2024-2025 Dose 4 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 Additional doses (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024-2025 vaccine [¶]
	OR	



2. COVID-19 continued:

COVID-19 vaccination history before 2024–2025 vaccine ¹¹	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine ^s and interval between doses
Unvaccinated	3	2024-2025 Dose 1 (Novavax): Day 0 2024-2025 Dose 2 (Novavax): 3 weeks after Dose 1 2024-2025 Dose 3 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 2 Additional doses: (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024-2025 vaccine [¶]
	OR	
	4	2024–2025 Dose 1 (Pfizer-BioNTech): Day 0 2024–2025 Dose 2 (Pfizer-BioNTech): 3 weeks after Dose 1 2024–2025 Dose 3 (Pfizer-BioNTech): At least 4 weeks after Dose 2 2024–2025 Dose 4 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 Additional doses (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine [¶]
Initiated but did not complete th		-2025 vaccine:
 Receive 1 dose of 2024- initial series 	·	imum interval 2 months) after completing under shared clinical decision-making ¹
1 dose Moderna	3	2024-2025 Dose 1 (Moderna): 4 weeks after last dose 2024-2025 Dose 2 (Moderna): At least 4 weeks after 2024-2025 Dose 1 2024-2025 Dose 3 (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024-2025 Dose 2 Additional doses (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024-2025 vaccine [¶]



2. COVID-19 continued:

COVID-19 vaccination history before 2024–2025 vaccine ^{†‡}	Number of 2024-2025 doses indicated	Recommended 2024-2025 vaccines and interval between doses
2 doses Moderna	2	2024-2025 Dose 1 (Moderna): At least 4 weeks after last dose 2024-2025 Dose 2 (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024-2025 Dose 1 Additional doses (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024-2025 vaccine [¶]
1 dose Pfizer-BioNTech	3	2024–2025 Dose 1 (Pfizer-BioNTech): 3 weeks after last dose 2024–2025 Dose 2 (Pfizer-BioNTech): At least 4 weeks after 2024–2025 Dose 1 2024–2025 Dose 3 (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 Additional doses (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine¶
2 doses Pfizer-BioNTech	2	2024-2025 Dose 1 (Pfizer-BioNTech): At least 4 weeks after last dose 2024-2025 Dose 2 (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024-2025 Dose 1 Additional doses (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024-2025 vaccine [®]
1 dose Novavax	2	2024-2025 Dose 1 (Novavax): At least 3 weeks after last dose 2024-2025 Dose 2 (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024-2025 Dose 1 Additional doses (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024-2025 vaccine [¶]



2. COVID-19 continued:

COVID-19 vaccination history before 2024–2025 vaccine ^{†‡}	Number of 2024-2025 doses indicated	Recommended 2024-2025 vaccine [§] and interval between doses						
Completed the initial series befo	Completed the initial series before 2024–2025 vaccine:							
Receive 2 doses of 2024	 Receive 2 doses of 2024–2025 vaccine spaced 6 months (minimum interval 2 months) apart 							
 May receive additional c 	doses of 2024–2025 vaccine	under shared clinical decision-making¶						
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech#								
2 or more doses Novavax#	2	2024–2025 Dose 1 (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose 2024–2025 Dose 2 (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 Additional doses (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine [¶]						

[†]COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

[‡]People ages 18 years and older who received 1 or more doses of Janssen COVID-19 Vaccine should receive 1 dose of any 2024–2025 COVID-19 followed by a second dose of any 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after the first dose. Additional doses of any 2024–2025 COVID-19 vaccine may be administered under shared clinical decision-making at least 2 months after last dose of any 2024–2025 vaccine.

¹Additional doses may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

*This COVID-19 vaccine history refers to previous receipt of 3 doses of mRNA vaccine from the same manufacturer (i.e., Moderna or Pfizer-BioNTech) for initial vaccination or 2 doses of Novavax for initial vaccination followed by 1 or more additional doses of any COVID-19 vaccine.



2. COVID-19 continued:

Considerations for extended intervals (>8 weeks) for COVID-19 vaccine doses

- An 8-week interval between the first and second mRNA COVID-19 vaccine (Moderna, Pfizer-BioNTech) doses and between the first and second doses of Novavax COVID-19 Vaccine might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these COVID-19 vaccines.
- While absolute risk remains small, an elevated risk for myocarditis and pericarditis has been observed among mRNA COVID-19 vaccine recipients, particularly in males ages 12–39 years (see <u>COVID-19</u> vaccination and myocarditis and pericarditis for additional information).
- Cases of myocarditis and pericarditis were identified in clinical trials of Novavax COVID-19 Vaccine and through passive surveillance during post-authorization use outside the United States.

Under the current COVID-19 vaccination schedule (<u>Table 1</u>), the **extended interval (8 weeks)** consideration applies only to the following people who are not moderately or severely immunocompromised:

- Ages 6 months-4 years, depending on their vaccination history
- Ages 12 years -64 years and receiving a 2-dose Novavax series

The minimum interval (3-4 weeks) between the first and second doses continues to be recommended for:

- People who are moderately or severely immunocompromised
- People ages 65 years and older receiving Novavax vaccine
- Situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual's higher risk for severe disease)

Description of moderate and severe immunocompromising conditions for vaccination

Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)



2. COVID-19 continued:

<u>Factors to consider</u> in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

For additional information about the degree of immune suppression associated with different medical conditions and treatments, providers can consult ACIP's <u>General Best Practice Guidelines for Immunizations</u>, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

Self-attestation of immunocompromised status

✓ People can self-attest to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

For additional information from the CDC on COVID-19 vaccine use in the United States, see their provider recommendation page at the web address below, or scan the QR code with your smartphone.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html



CDC considers the conditions listed in Table 3 to be COVID-19 vaccination contraindications and precautions

Table 3. Contraindications and precautions to COVID-19 vaccination

Medical Condition or History	Guidance	Recommended Action
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a	Contraindication	Do not vaccinate with the same COVID-19 vaccine type.
component of the COVID-19 vaccine [‡]		May administer the alternate COVID-19 vaccine type.
		See <u>Considerations for people</u> with a history of allergies and allergic reactions for additional information.



2. COVID-19 continued:

Medical Condition or History	Guidance	Recommended Action		
History of a diagnosed non- severe allergy* to a component of the COVID-19 vaccine [‡]	Precaution	May administer the alternate COVID-19 vaccine type.		
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	For additional information, see Considerations for people with a history of allergies and allergic reactions.		
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.		
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.		
History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and		
		myocarditis and pericarditis		

Abbreviations: MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

Allergic reactions described in Table 3. Contraindications and precautions to COVID-19 vaccination are defined as follows:

Severe allergic reactions include: known or possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria (hives) but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure; angioedema (visible swelling) affecting the airway (i.e., tongue, uvula, or larynx); diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome).

Non-severe allergic reactions include but are not limited to: urticaria beyond the injection site; angioedema involving lips, facial skin, or skin in other locations.

NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) is considered a <u>severe allergic</u> reaction.

- ✓ Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines (estimated incidence: 5 per million doses of mRNA COVID-19 vaccines administered).
- ✓ For more information on the assessment and potential management of anaphylaxis, see Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.
- ✓ See <u>package inserts and EUA fact sheets</u> for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).



2. COVID-19 continued:

Additional notes:

- If someone recently had COVID-19, they may consider delaying their next dose by 3 months (90 days), due to perceived natural immunity from infection recovery.
- If a person has tested positive or currently has COVID-19, wait until they have fully recovered from illness before administering COVID-19 vaccine or discuss with a healthcare provider if delaying vaccination 3 months (90 days) is appropriate.



3. Respiratory Syncytial Virus (RSV):

CDC recommends a single dose of any FDA-licensed RSV vaccine for all adults ages 75 and older and adults ages 60–74 at increased risk of severe RSV.

Available 2024-2025 FDA Approved RSV Vaccines for Older Adults 60+

Vaccine Name	Manufacturer	Dose/Administration
Arexvy	GSK	0.5 mL, intramuscular injection
Abrysvo	Pfizer	0.5 mL, intramuscular injection
mResvia (PFS)	Moderna	0.5 ml, intramuscular injection

Recommended Schedule: All adults ages 75 years and older are recommended to receive a single dose of RSV Vaccine. Adults Ages ≥ 60 years old can receive 1 dose of RSV vaccine based on shared clinical decision-making assessing the patient's risk factors, desired healthcare outcomes and provider's preference for preventing severe RSV infection and comorbidity for that individual.

Administration Timing: CDC recommends RSV vaccination in late Summer to Early Fall, before RSV usually starts to spread in the community.

The population most likely to benefit from RSV vaccination are those who have risk factors for developing severe RSV disease after becoming infected with the virus.

Risk Factors for Developing Severe RSV Disease:

Chronic lung disease (COPD, asthma, etc.)	Chronic hematologic disorders
Chronic CVD (CAD, CHF, etc.)	Diabetes mellitus
Neurologic or neuromuscular conditions	Moderately/severely immunocompromised
Chronic kidney disease	Frailty/advanced age
Chronic liver disease	Residence in a nursing home/long-term care

[per the CDC]

Precautions to RSV Vaccine Administration:

Moderate to severe acute illness with/without fever

Contraindications to RSV Vaccine Administration:

Severe allergic component to any RSV vaccine component

Additional notes:

- The RSV is not currently an annual vaccine. Only one dose of RSV vaccine is currently recommended for those ≥60 years old through shared clinical decision-making.
- An RSV vaccine can be given to an adult with a minor acute illness (common cold), but vaccination should be deferred if a person has a moderate/severe acute illness.
- For additional information, see the CDC webpage on RSV Vaccine Guidance for Older Adults
 - https://www.cdc.gov/rsv/vaccines/older-adults.html



4. Pneumococcal (PNA) Vaccination:

- CDC recommends pneumococcal vaccination for children younger than 5 years and adults 50 years or older.
- CDC also recommends pneumococcal vaccination for children and adults at increased risk for pneumococcal disease.

About Pneumococcal Infection and Disease:

Pneumococcal disease is common in young children, but older adults are at greatest risk of serious illness and death. Pneumococcal vaccines help protect against pneumococcal infections, including invasive disease.

Invasive disease means the bacteria invade parts of the body, such as blood, that are normally free from germs. Invasive disease is usually very serious and can sometimes result in death.

Available 2024-2025 FDA Approved Pneumococcal Vaccines

Vaccine Name	Vaccine Type	Dose/Administration
Capvaxive (PCV21)	Pneumococcal 21-valent conjugate vaccine	0.5 mL, intramuscular injection
Prevnar 20 (PCV20)	Pneumococcal 20-valent conjugate vaccine	0.5 mL, intramuscular injection
Vaxneuvance (PCV15)	Pneumococcal 15-valent conjugate vaccine	0.5 mL, intramuscular injection
Pneumovax 23 (PPSV23)	Pneumococcal polysaccharide vaccine	0.5 mL, intramuscular or subcutaneous injection

CDC Recommendation Webpage: https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/

Recommended Schedule:

Children:

- All children younger than 5 years old
- Children 5 through 18 years old with certain risk conditions

Adults:

- All adults 50 years or older
- Adults ages 19 through 49 years old with certain risk conditions

CDC recommends PCV15, PCV20, or PCV21 for adults who never received a PCV and are

- Ages 50 years or older
- Ages 19 through 49 years with certain risk conditions

Please note: If PCV15 is used, it should be followed by a dose of PPSV23 one year later, if needed.



4. Pneumococcal (PNA) continued:

For Older Adults who may have already received PCV13 or PPSV23

Adults 65 years or older have the option to get PCV20 or PCV21, or to not get additional pneumococcal vaccines. They can get PCV20 or PCV21 if they've already received one or both of the following:

- PCV13 (but not PCV15 or PCV20) at any age
- PPSV23 at or after the age of 65 years

These adults can talk with a vaccine provider and decide, together, whether to get vaccinated (i.e., receive PCV20 or PCV21).

Certain age groups, race and ethnicity groups, children in group care settings, and the following medical conditions have been identified by the CDC as risk factors for developing severe Pneumococcal disease:

Heightened Risk Factors - Pneumococcal Disease

Alcoholism	HIV infection
Cerebrospinal fluid (CSF) leak	Hodgkin disease
Chronic heart, liver, or lung disease (i.e. COPD, asthma, emphysema)	latrogenic immunosuppression
Chronic renal failure	Leukemia
Cigarette smoking	Lymphoma
Cochlear implant	Multiple myeloma
Congenital or acquired asplenia	Nephrotic syndrome
Congenital or acquired immunodeficiencies	Sickle cell disease or other hemoglobinopathies
Diabetes mellitus	Solid organ transplant
Generalized malignancy	

For more information regarding pneumococcal infection and how risk factors for developing severe pneumococcal disease, please visit:

https://www.cdc.gov/pneumococcal/causes/index.html#cdc causes risk-risk-factors

Precautions to Pneumococcal Vaccine Administration:

Moderate to severe acute illness with/without fever

Contraindications to Pneumococcal Vaccine Administration:

Severe allergic reaction to any vaccine component

Additional notes:

The guidelines and vaccine products for pneumococcal vaccines have been changing over the years and it is very common for eligible persons to not have completed the current recommended schedule. If a person has had pneumococcal vaccines in the past, it is important to assess their history and determine if they need additional vaccines to complete their pneumococcal vaccinations.



4. Pneumococcal (PNA) continued:

- These determinations can be made by utilizing the CDC PneumoRecs VaxAdvisor app/website. This tool can be used to determine the need for additional vaccinations based on information regarding age, vaccine history and pertinent medical conditions.
- To access this tool, please visit: https://www2a.cdc.gov/vaccines/m/pneumo/pneumo.html or
- Download "PneumoRecs VaxAdvisor" free for iOS and Android devices.







5. Herpes Zoster (RZV):

Vaccine Name	Vaccine Type	Dose/Administration			
Zoster vaccine (SHINGRIX)	Recombinant Zoster Vaccine (RZV), adjuvanted	0.5 mL, two dose series separated by 2 – 6 months. Intramuscular injection.			

Recommended schedule: Adults \geq 50 years old are recommended to receive two dose series of the Shingrix vaccine separated by 2 – 6 months for the prevention of herpes zoster (shingles) and related complications.

Precautions to RZV Vaccine Administration:

Moderate to severe acute illness with/without fever

Contraindications to RZV Vaccination Administration:

Severe allergic reaction to vaccine component

Additional notes:

- There is no specific amount of time you need to wait before giving Shingrix to eligible patients who have had herpes zoster. However, you should <u>not</u> administer Shingrix to a person experiencing an acute episode of herpes zoster. Shingrix is not a treatment for herpes zoster or postherpetic neuralgia and should only be given after the person has recovered from the acute episode.
- Zostavax vaccine was previously used in the United States for herpes zoster but has now been removed from the market since November 2020 due to ineffectiveness and complications. This vaccine is no longer recommended and for those who have received it, they should still receive Shingrix. Studies have displayed safety in waiting 5 years after Zostavax to receive Shingrix, but there is no data to support that a shorter interval would be less safe or effective.



Section III: Consent & Screening Forms

Form	QR Code
COVID-19 Vaccine CS (2 pages)	
Flu Vaccine CS (2 pages)	
PNEUMO Vaccine CS (2 pages)	
RSV Vaccine CS (2 pages)	
RZV Shingles Vaccine CS (2 pages)	
Universal Vaccine CS (2 pages)	

Vaccine Informed Consent & Screening Form



Section 1: Personal Information

Care Level SNF AL PC IL Employee Room Number (if applicable)

Name DOB Age Social Security #

Gender Male Female

Street City State Zip

Insurance Information

Complete section below and/or provide copies of your insurance identification card

Drug Ins. Co. ID# PH#

Group # BIN# PCN#

Primary Care Provider Name PCP Phone

Street City State

Section 2: Consent Vaccine(s) Requested: Flu COVID-19 RSV PNA RZV Other

I certify that I am: (a) the patient and at least 18 years of age; or (b) the legal guardian of the patient. Further, I hereby give my consent to the licensed health care professional of KPH Healthcare Services, Inc., as applicable, to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and had explained to me the Vaccine Information Statements on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering healthcare provider. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless KPH Healthcare Services, Inc., as applicable, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration and/or effects of the vaccine(s) listed above. I acknowledge that the administration of an immunization or vaccine does not substitute for an annual check-up with my primary care physician. I acknowledge receipt of KPH Healthcare Services, Inc.'s privacy notice for Protected Health Information. I acknowledge that (a) I understand the purposes/benefits of my state's immunization registry ("State Registry") and my state's health information exchange ("State HIE"); and (b) KPH Healthcare Services, Inc., as applicable, may disclose my immunization information to the State Registry, to the State HIE, or through the State HIE, to the State register, for purposes of public health reporting or to my health care providers enrolled in the State Registry and/or State HIE for purposes of care coordination. I acknowledge that, depending upon my state's law, I may prevent such disclosure, by using a state-approved opt-out form. Unless I provide KPH Healthcare Services, Inc. with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to KPH Health Services, Inc. and/or my State HIE, as applicable. I understand that even if I do not consent or if I withdraw my consent, my state's laws may permit certain disclosures of my immunization information to or through the State HIE and/or my primary care provider listed above as required or permitted by law. I further authorize KPH Healthcare Services, Inc. to (a) release my medical or other information, including my communicable disease (including HIV), mental health and drug/alcohol abuse information, to, or through, the State HIE to my healthcare professions, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment, (b) submit a claim to my insurer for the above requested items and services, and (c) request payment of authorized benefits be made on my behalf to KPH Healthcare Services, Inc., as applicable, with respect to the above requested items and services. I have been informed of the total cost of the immunization, subtracting any health insurance subsidization. I agree to be fully financially responsible for any co-sharing amounts, including copays, co-insurance and deductibles, for the requested items and services as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if HealthDirect Pharmacy Services, Inc. invoices me after the time of service, upon receipt of such invoice. The FDA has made the 2024-25 COVID-19 vaccine(s) available to the pediatric population 6 months to 11 years under an emergency use authorization (EUA). The EUA is used when circumstances exist to justify the emergency use of drugs and biological products. This vaccine(s) has not undergone the same type of review as an FDA-approved product.

I have reviewed the vaccine recipient's medical record and current CDC immunization schedule to determine the intended vaccine(s) is appropriate at this time, including the State registry IIS (immunization information system) if available. Initials: Date:

I GIVE CONSENT to the

NAME OF ORGANIZATION CONDUCTING CLINIC and its staff

for my person named at the top of this form to be vaccinated with this vaccine(s). If this consent form is not signed, then this person will not be vaccinated.

I DO NOT GIVE CONSENT to the

NAME OF ORGANIZATION CONDUCTING CLINIC and

its staff for my person named at the top of this form to be vaccinated with this vaccine(s). If this consent form is not signed, then this person will not be vaccinated.

Signature Date

Name

Relationship to Patient

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Eligibility Screening & Administration Record Section 1: Personal Information



Care Level	SNF	AL	PC	IL	Employe	е	Room Nur	mber (if applicable	e)		
Name					DOB		Age	Social Securi	ty#		
Section 2: S 1. Are you feeling sic 2. Have you ever felt today?	k today? Do	you have	a fever?	after a s	shot? Are you fe	eeling anxi	ous about rece	eiving your vaccine	Yes Yes	No No	Don't Knov Don't Knov
3. Have you received4. Do you have allerglatex? Can you describe	jies or have	you had a	n allergic re	action t	o medications,	food, a va	ccine or vaccir	ne component, or	Yes Yes	No No	Don't Knov Don't Knov
5. Do you have any ottes), asthma, a blood	of the follow	ing: a long	term health	problei					Yes	No	Don't Knov
6. Do you have cance 7. In the past 6 month or anticancer drugs; contreatments?	er, leukemia ns, have yo	a, HIV/AIDS u taken me	S, or any oth edications th	ner heal nat affec	th conditions that t your immune	at weaken system, su	the immune such as prednis	ystem? sone, other steroids,	Yes Yes	No No	Don't Knov Don't Knov
8. Have you ever had syndrome or other ne			r which you	are on	seizure medicat	tions, a bra	ain disorder or	injury, Guillain-Barre	Yes	No	Don't Knov
9. In the past year, h ma)globulin (IgG), or	ave you red any antivira	ceived a tra I drug(s)?				_		called immune(gam-	Yes	No	Don't Knov
10. For Women: Are 11. [COVID-19] Do yo lining of the heart), or	ou have a h	istory of m	yocarditis (i	nflamm	ation of the hea			nflammation of the	Yes Yes	No No	Don't Knov Don't Knov
12. [COVID-19] In the convalescent plasma	e past 6 mo	nths, have	you recove	red fron		nfection, o	r received an a	antibody therapy or	Yes	No	Don't Know
13. [FLU] Do you hav 14. [RZV] Do you cur	e a severe	egg allerg	y that result	ed in sy	mptoms beyond ny localized pair	d hives, an n, itching,	d required me or tingling that	dical intervention? may indicate an	Yes Yes	No No	Don't Knov Don't Knov
active herpes zoster (15. [MMR] Do you ha			r sister with	an imm	nune deficiency	problem?			Yes	No	Don't Knov
precautions to the			administ	ered to	oday. Immui w to be co	nizer Init mplete	ials:	patient for potentia			
	enza (Flu	٦)				RSV			pes Zo	ster (F	RZV)
Manufacturer				Manufacturer			Manufacturer				
Brand Name				Brand N	lame			Brand Name			
Lot#				Lot#				Lot#			
Expiration Date				Expiration	on Date			Expiration Date			
Dose	Route	IM Other		Dose			IM Other	Dose			IM Other
Site Left Deltoid	Right Delto			Site	Left Deltoid F	Right Deltoi		Site Left Delt	oid Ri	ght Deltoi	
Date on VIS	Date VIS	S Given		Date on	VIS	Date VIS	Given	Date on VIS		Date VIS	Given
CC	VID-19				Pneumoc	coccal (I	PNA)	Other Vacc	ine:		
Manufacturer				Manufa	cturer			Manufacturer			
Brand Name				Brand Name			Brand Name	Brand Name			
Lot#				Lot#				Lot#			
Expiration Date				Expiration Date			Expiration Date	Expiration Date			
Dose	Route	IM Other		Dose		Route	IM Other	Dose			IM Other
Site Left Deltoid	Right Delto			Site	Left Deltoid F	 Right Deltoi		Site Left Delt	oid Ri	 ght Deltoi	

Signature of Immunizer License Number

Date VIS Given

Date of Immunization(s)

Date on VIS

Date VIS Given

Date on VIS

Date on VIS

Date VIS Given



Section IV: Declination Forms

Form	QR Code
COVID-19 Declination (1 page)	
Flu & Pneumococcal Declination Form (1 page)	
Universal Vaccine Declination Form (1 page)	

Adult Immunization(s) Declination Form



I,[Resident's Full Name], hereby acknowledge that the following
denoted vaccines have been recommended to me by my [community] healthcare provider and in accordance with the CDC Adult Immunization Schedule, and I have been offered the opportunity to ask questions and to receive education through the CDC's Vaccine Information Statements (VIS).
Vaccine (check all that apply)
Influenza
Pneumococcal (PCV15, PCV20, PPSV23, and PCV21)
COVID-19
Respiratory Syncytial Virus (RSV)
Zoster recombinant (RZV)
Hepatitis A (HepA)
Hepatitis B (HepB)
Haemophilus Influenza type b (Hib)
Measles, Mumps, Rubella (MMR)
Meningococcal A,C,W,Y (MenACWY)
Meningococcal B (MenB)
Tetanus, Diphtheria, Pertussis (Tdap or Td)
Varicella (VAR)
MPOX
Other:
I am choosing to decline the recommended and offered vaccination(s) noted above.
I understand that these vaccines are recommended to reduce the health risks associated with my contracting their targeted infectious diseases.
I understand that by declining the vaccination(s), I may be at risk of contracting otherwise preventable or mitigatable infectious diseases and experiencing associated health consequences.
I acknowledge that I have made this decision voluntarily and based on my own understanding of the risks and benefits associated with these vaccines.
I also understand that I can change my decision at any time and request to receive the vaccine in the future, subject to its availability and my healthcare provider's recommendations at that time.
By signing this document, I affirm that I am providing an informed declination of the noted vaccine(s) after receiving education and having my questions answered to my satisfaction.
Resident Signature or POA Signature
Full Name (Print)
Witness Name (Print)
Date

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Section V: HealthDirect Standing Order Protocol Listing

Standing Order Protocols authorize HealthDirect Pharmacists and other aptly trained healthcare personnel, where allowed by State Law, such as nursing staff, pharmacy technicians and licensed pharmacist interns, to assess a patient's immunization status and administer vaccinations according to non-patient specific protocol authorized by a Physician in your State of community care practice.

Our standing order protocols allow us to directly support your community's vaccination efforts to help better protect your residents from preventable illness and disease.

The below table summarizes 2024-2025 vaccine offerings under our KPH / HealthDirect Standing Order Vaccination Protocol in accordance with CDC and ACIP recommendations:

Protocol	Population
Cover Page	Medical Authorization
Vaccine Reaction Management	Children and Adults 18+
Hepatitis A Vaccine	Adults 18+
Hepatitis B Vaccine	Adults 18+
Haemophilus influenzae type b (Hib) Vaccine	Adults 18+
Measles, Mumps and Rubella Vaccine	Adults 18+
Tetanus, Diphtheria and Pertussis (TDP) Vaccine	Adults 18+
Varicella (chickenpox) Vaccine	Adults 18+
Herpes Zoster (shingles) Vaccine	Adults 18+
Influenza (flu) Vaccine	Children and Adults
Respiratory Syncytial Virus (RSV) Vaccine	Adults 60 +
COVID-19 Vaccine	Children and Adults
Pneumococcal Vaccines	Children and Adults
MPOX Vaccine	Adults 18+

Contact your HealthDirect Pharmacy representative for more information on how our vaccination program and highly trained personnel can assist your vaccination efforts. For more information on developing standing order protocols, including blank templates, visit: https://www.immunize.org/



Section VI: Non-Patient Specific Order for the Management of Vaccine Reactions

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Signs and Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site.
	injection site	Consider recommending an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright,	Fright before injection is given	Have patient sit or lie down for the vaccination.
presyncope, and Syncope (fainting)	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck. Keep patient under close observation until recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient.
		Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient.
		Place patient flat on back with feet elevated.
		Call 911 if patient does not recover immediately
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse,	See "Emergency Treatment Protocol" on the next page for detailed steps to follow in treating anaphylaxis



Section VI: Non-Patient Specific Order for the Management of Vaccine Reactions

First Line Medication

Epinephrine, aqueous 1:1000 (i.e. 1mg/ml) dilution, in ampule, vials or prefilled syringe, including epinephrine autoinjectors. If autoinjectors are stocked, at least 3 should be available (both pediatric and adult formulations).

Optional Medication: H1 Antihistamines

 Diphenhydramine oral (12.5mg/5ml liquid or 25-50mg capsules/tablets. These relieve itching and hives only; they DO NOT relieve upper or lower airway obstruction, hypotension or shock.

Equipment

- Epinephrine autoinjectors (e.g., EpiPen) at least three pediatric and adult doses should be available.
- Syringes: 1 and 3 cc, 22-25g, 1", 1 ½", and 2" needles for epinephrine and diphenhydramine
- Wristwatch with a second hand or time piece able to count seconds
- Sphygmomanometer (pediatric, adult and extra-large cuffs) and stethoscope
- Light with extra batteries (for examination of mouth and throat)
- Adult and child size pocket mask with one-way valve
- Alcohol swabs
- Cell phone or access to an on-site phone

Recognition of Anaphylactic Reaction:

- Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.
- Swelling of the lips, face, or throat (angioedema)
- Bronchospasm or shock

Emergency Treatment Protocol:

- 1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911). This should be done by a second person, while the immunizing pharmacist assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously. Stay on the line until EMS arrives.
 - a. The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis. Administer EpiPen according to the package insert instructions and dosed based on body weight, intramuscularly. Site of administration can be the anterior thigh or deltoid area. Alternatively, administer aqueous epinephrine 1:1000 dilution (1.0mg/mL) intramuscularly, 0.01ml/kg/dose, with a maximum single dose of 0.5 mg (children) or 0.5ml (adults). Administer in the anterolateral thigh.



Section VI: Non-Patient Specific Order for the Management of Vaccine Reactions

- b. Optional treatment: H1 antihistamines relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving diphenhydramine (e.g., Benadryl) for relief of itching or hives. Administer diphenhydramine orally, standard dose of 1–2 mg/kg every 4–6 hours. Maximum single dose is 40 mg for children age <12 years; for children age ≥12 years, 100 mg.
- 3. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure (BP) is adequate to prevent loss of consciousness. If BP is low, elevate legs. Monitor BP and pulse every 5 minutes.
- 4. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minute for up to 3 doses, depending on patient's response or as directed by emergency medical system personnel.
- 5. Record the adverse event to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, route, response, and the name of the medical personnel who administered the medication, and other relevant clinical information. (See Appendix 2 for the Emergency Treatment Log).
- 6. Provide vital signs and administered medications to EMS provider and notify the patient's PCP.
- 7. Notify your Regional Manager and report to VAERS.

For convenience, approximate dosages based on weight and age are provided in the following charts. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine		Epinephrine Dose		
Recommended dose is 0.01 mg/ kg body weight up to 0.5 mg. May	Age Group	Range of Weight (lb)	1 mg/ml injectable (1:1000 dilution); intramuscular Minimum dose: 0.05ml	Epinephrine auto-injector, 0.15mg or 0.3mg
be repeated every 5-15 mins for a	24-36 mos	20-32 lbs	0.1 ml (or mg)	Off label
total of 3 doses.	37-59 mos	33-39 lbs	0.15 ml (or mg)	0.15 mg/dose
	5-7 yrs	40-56 lbs	0.2-0.25 ml (or mg)	0.15 mg/dose
	8-10 yrs	57-76 lbs	0.25-0.3 ml (or mg)	0.15 or 0.3 mg/dose
	11-12 yrs	77-99 lbs	0.35-0.4 ml (or mg)	0.3 mg/dose
	13 yrs & up	100+ lbs	0.5 ml (or mg)- max dose	0.3 mg/dose

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or is not readily available, dosing by age is appropriate.



Section VI: Non-Patient Specific Order for the Management of Vaccine Reactions

Optional Treatment: Diphenhydramine			Diphenhydramine Dose
Recommended dose is 1-2 mg/kg body weight every	Age Group	Range of Weight (lb)	Liquid: 12.5 mg/5 ml Tablets: 25mg or 50 mg
body weight every 4-6 hrs.	24-36 mos	20-32 lbs	10-15 mg/dose
4 0 11131	37-59 mos	33-39 lbs	15-20 mg/dose
	5-7 yrs	40-56 lbs	20-25 mg/dose
	8-12 yrs	57-99 lbs	25-50 mg/dose
	13 yrs & up	100+ lbs	50 mg/dose (up to 100mg single dose)

This order shall remain in effect for all patients of	for the period of 2 years.
Authorizing Providers Signature:	Date:
Authorizing Providers Signature:	Date:

Reviewed 7/23. Adapted from "Medical Management of Vaccine Reactions in Children and Adult Patients" from Immunization Action Coalition, Updated 4/2023. Available at: http://www.immunize.org/catg.d/p3082.pdf and http://www.immunize.org/catg.d/p3082a.pdf

⁻Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.

⁻Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. Allergy Clin Immunol 2010; 126(6):S1–S57.



Section VII: Preparing & Scheduling Vaccination Clinic

Establish the purpose and goal(s) of your clinic, including target population, whether it is open to the public or only for specific groups, numbers to be served, and vaccine(s) to be offered.

Once the purpose and intent for the vaccine clinic is established, HealthDirect Pharmacy can supply you with vaccine, necessary paperwork associated with vaccine delivery and reporting, or help deliver vaccinations on-site, and will partner with you every step of the way to coordinate vaccine administration at your community.

To ensure accurate and timely vaccine administration on clinic day, we recommend the following communication procedures with the Pharmacy:

- 1. Identify Vaccine Clinic Personnel Leader and who will be assisting from site
- 2. Engage Pharmacy Leadership to fully understand vaccine clinic needs
- 3. Pharmacy Leadership will require the following information:
 - a. Vaccine type being offered, anticipated number of recipients
 - b. Proposed clinic date(s) and time(s), finalized date will be provided based on clinic needs, staffing availability and scheduling requests
 - c. Facility personnel on-site who will be coordinating clinic and assisting vaccinators
 - i. This person should indicate patient flow of clinic to pharmacy upon scheduling (ie: central location or room to room)
 - ii. For room-to-room administration, each vaccinating team will need a representative from the community to identify vaccine recipients and assist vaccinators
- 4. Recipients Eligibility Screening and Consent Forms need to be filled out and provided to Pharmacy 10 days prior to scheduled clinic date:
 - a. Can be delivered directly to pharmacy leadership via email or returned to pharmacy via client services or pharmacy carrier personnel
 - b. Eligibility Screening questionnaire mostly contains pertinent medical history, recipient well-being will be assessed day of administration
 - c. Payor information for non-residents or new admits required with their Eligibility Screening & Consent form document submission
- 5. An up-to-date recipient roster day of clinic to reference on location
- 6. After the vaccine clinic is completed; HealthDirect will provide copies of administration records to added to the patient's medical records and vaccination history records.
 - a. Administration record copies can be provided on site before HD staff departs
- 7. Vaccine recipients should be acutely monitored post vaccine delivery for 15 minutes, Systemic and Allergy type reactions should be reported to the HHS Vaccine Adverse Event Reporting System, VAERS, in addition to being documented in the recipient's medical record.



Section VIII: HealthDirect Seasonal Vaccine Order Request Form

The order request form below is intended to be utilized for bulk vaccine purchasing through HealthDirect Pharmacy. Contact your local HealthDirect Pharmacy partner for current vaccine pricing. Patient labeled vaccines can be dispensed pursuant to a valid prescription order.

Vaccine Name	Quantity (Doses) Requested	Delivery Date
Flu Vaccine		
Fluzone High-Dose PFS (65+)		
Fluzone PFS		
Flucelvax PFS (egg-free)		
Afluria MDV (5 mL)		
COVID-19 Vaccine		
Moderna SpikeVax (12+)		
2024-2025 Moderna COVID-19 Vaccine (6 mo- 11 years)		
Pfizer-BioNTech Comirnaty (12+)		
2024-2025 Pfizer-BioNTech COVID-19 Vaccine (6 mo – 11 years)		
2024-2025 Novavax COVID-19 Vaccine, adjuvanted (12+)		
Pneumococcal (PNA) Vaccine		
PCV15 Vaxneuvance		
PCV20 Prevnar-20		
PCV21 Capvaxive		
PPSV23 Pneumovax		

For on-site vaccine storage and handling, we recommend following the CDC Vaccine Storage and Handling Toolkit available at- https://www.cdc.gov/vaccines/hcp/storage-handling/.

While RSV vaccines are available to our customers, they should be ordered resident specific via valid prescription, <u>NOT</u> in bulk, for billing purposes. **RSV** and **Herpes Zoster (Shingrix)** vaccines for billing / payor reasons should be dispensed and processed by the Pharmacy, pursuant to a valid patient prescription or administered under a vaccine standing order protocol.



Appendicies: CDC Vaccine Information Sheets

Document	QR Code
COVID-19 Vaccine (2 pages)	
Influenza Vaccine (2 pages)	
Pneumococcal Conjugate Vaccine (2 pages)	
Pneumococcal Polysaccharide Vaccine (2 pages)	
RSV (Respiratory Syncytial Virus) Vaccine (2 pages)	
Shingles (Recombinant Zoster) Vaccine (2 pages)	





Appendicies: Promotional/Marketing Materials

Document	QR Code
Facility Clinic Event Flyer (1 page)	
Vaccination Products & Programs (1 page)	