AMENDED
September 17, 2024

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1013(5)
Transmittal Sheet
August 12, 2020

PREVENTION AND CONTROL OF SEASONAL INFLUENZA WITH VACCINES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides policy for the prevention and control of seasonal influenza through the use of influenza vaccines.

2. SUMMARY OF MAJOR CHANGES:

a. **Amendment, dated September 17, 2024:** updates Appendix A: Guidance regarding Influenza Vaccine and Antiviral Medications with Activity Against Seasonal Influenza Viruses, based on the Centers for Disease Control and Prevention's (CDC's) most current recommendations, published July 22, 2024, by the CDC Advisory Committee on Immunization Practices (ACIP) for the 2024-25 influenza season. Consistent with the CDC recommendations for the 2024-25 influenza season, the composition of the 2024-25 vaccines has been updated and updated recommendations regarding influenza vaccines and influenza vaccination recommendations for solid organ transplant recipients have been included.

b. **Amendment, dated September 6, 2023,** updates:

(1) Paragraph 8: References.

(2) Appendix A: Guidance regarding Influenza Vaccine and Antiviral Medications with Activity Against Seasonal Influenza Viruses, based on the CDC's most recent recommendations for the 2023-24 influenza season. Consistent with CDC recommendations for the 2023-24 influenza season, the composition of the 2023-24 vaccines has been updated and recommendations regarding influenza vaccination of persons with egg allergy have been updated.

c. **Amendment, dated September 19, 2022,** updates:

(1) Paragraph 8: References.

(2) Paragraph 5.e.(6): Clarifies Employee Occupational Health reporting for the VA Adverse Drug Event Reporting System (VA ADERS).

(3) Appendix A: Guidance regarding Influenza Vaccine and Antiviral Medications with Activity Against Seasonal Influenza Viruses based on CDC's most recent recommendations for the 2022-23 influenza season. Consistent with CDC recommendations for the 2022-2023 seasonal influenza season, a preferential recommendation for use of high-dose or adjuvanted vaccine is made for persons 65 years of age or older.

(4) Appendix B: Delay or Shortage of Seasonal Influenza Vaccine based on CDC's most recent recommendations for the 2022-23 influenza season.

d. **Amendment, dated September 21, 2021,** updates:

(1) Paragraph 8: References.

(2) Appendix A: Guidance regarding Influenza Vaccine and Antiviral Medications with Activity Against Seasonal Influenza Viruses based on CDC's most recent recommendations for the 2021-22 influenza season.

e. Amendment, dated October 2, 2020, updated the following information:

(1) Link to the Vaccine Information System from the CDC website.

(2) Paragraph 3: Definition of a Health Care Personnel.

(3) Paragraph 5: Guidance for recording the administration of influenza vaccines, documentation requirements for the administration of the influenza vaccine to HCP, and management adverse event in an employee annual influenza vaccination program.

(4) Paragraph 8: References.

(5) Appendix A: Guidance regarding Influenza Vaccine and Antiviral Medications with Activity Against Seasonal Influenza Viruses.

(6) Appendix B: Guidance regarding Delay or Shortage of Seasonal Influenza Vaccine.

f. **As published on August 12, 2020,** this VHA directive provided updated and detailed requirements for the prevention and control of seasonal influenza with vaccines. Major changes from the 2015 policy, included updated responsibilities in paragraph 5 and updated reference listing in paragraph 8.

3. RELATED ISSUES: VHA Directive 1192.01, Seasonal Influenza Prevention Program for VHA Health Care Personnel, August 10, 2020.

4. RESPONSIBLE OFFICE: The Assistant Under Secretary for Health for Clinical Services (11), is responsible for the contents of this directive. Questions relating to this directive may be referred to the National Infectious Diseases Service at 513-246-0270.

5. RESCISSIONS: VHA Directive1013(3), Prevention and Control of Seasonal Influenza with Vaccines, dated February 5, 2015, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of August 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Lucille B. Beck, PhD.
Senior Advisor to the Under Secretary for Health

NOTE: *All references herein to Department of Veterans Affairs (VA) and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publication Distribution List August 14, 2020.

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PREVENTION AND CONTROL OF SEASONAL INFLUENZA WITH VACCINES

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy for the prevention and control of seasonal influenza through the use of influenza vaccines. **AUTHORITY:** Title 38 United States Code (U.S.C.) §§ 1701(6)(D), (9)(G), and (10), 1704, and 1712(e). ***NOTE:*** *Refer to VHA Directive 1192.01, Seasonal Influenza Prevention Program for VHA Health Care Personnel, August 10, 2020, for detailed information regarding policy for influenza vaccination of health care personnel (HCP).*

2. BACKGROUND

a. The influenza vaccination program is an essential component of the Department of Veterans Affairs (VA) health promotion and disease prevention programs. Influenza is a cause of substantial morbidity and mortality in the United States (U.S.). While the COVID-19 pandemic has demonstrated the effectiveness of stringent non-pharmaceutical interventions, such as masking and physical distancing, in influenza prevention, influenza vaccination is the most effective way to primarily protect against the disease and resultant complications. Vaccination also reduces the risk of transmitting influenza to family members, visitors, other patients, coworkers and health care personnel. VHA has made influenza vaccination a priority. The influenza vaccine for seasonal influenza is a safe and cost-effective means for preventing and controlling influenza.

b. The influenza vaccination program is based on annual recommendations of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), as published in the Morbidity and Mortality Weekly Report (MMWR). The program is consistent with The Joint Commission accreditation standards and VHA National Center for Health Promotion and Disease Prevention Guidance Statements on Clinical Preventive Services-Immunizations.

c. Because influenza viruses are always changing, each year's influenza vaccine is formulated to protect from the influenza viruses most likely to cause disease that year. Influenza A and B are the two types of influenza viruses that cause seasonal influenza, typically during the fall and winter months. The trivalent influenza vaccine formulations contain two influenza A virus strains and one influenza B virus strain, while quadrivalent influenza vaccine formulations contain the same strains as trivalent vaccines, also contain a second B virus strain.

d. Each year the National Center for Health Promotion and Disease Prevention (12NCHP), VHA Office of Patient Care Services collaborates with appropriate offices and programs within VA Central Office as described in VHA Directive 1120.05, The National Center for Health Promotion and Disease Prevention and the Coordination and Development of Clinical Preventive Services Guidance, dated August 29, 2024, to produce and post a VHA Clinical Preventive Services Guidance Statement on Seasonal Influenza Immunization. This Guidance Statement is a clinical resource to VHA staff for

the care of adult Veteran patients. It is available from the Guidance Statement home page at http://vaww.prevention.va.gov/Guidance_on_Clinical_Preventive_Services.asp (navigate to current year's Influenza Immunization Guidance Statement from this page). ***NOTE:*** *This is an internal VA website that is not available to the public.*

e. Abbreviations and naming conventions for influenza vaccines from the Advisory Committee on Immunization Practices (ACIP) are defined as follows:

(1) Primary influenza vaccine types include: IIV=inactivated influenza vaccine, RIV=recombinant influenza vaccine, and LAIV=live attenuated influenza vaccine.

(2) Numerals following letter abbreviations indicate the number of influenza virus hemagglutinin antigens represented in the vaccine: "3" for trivalent vaccines which include two influenza A strains and one influenza B strain; "4" for quadrivalent vaccines which include two influenza A strains and two influenza B strains.

(3) Prefixes are used when necessary to refer to some specific vaccine types: "a" for adjuvanted vaccine (e.g., aIIV3); "cc" for cell culture-based vaccine (e.g., ccIIV4); "HD" for high-dose vaccine (e.g., HD-IIV3); and "SD" for standard-dose vaccine (e.g., SD-IIV4).

f. All vaccines against seasonal influenza are covered under the National Vaccine Injury Compensation Program (VICP) and have been added to the Vaccine Injury Table that lists the vaccines covered under VICP. As required by Federal law under the National Childhood Vaccine Injury Act (codified at 42 U.S.C. §§ 300aa-1 to 300aa-34), all health care providers who administer any vaccine covered by the VICP must provide a copy of the relevant current edition of vaccine information materials, specifically Vaccine Information Statements (VIS) prior to administration of each dose of the vaccine. ***NOTE:*** *For VHA policy for VIS, see paragraph 5.e.(5)(a) and (b).*

(1) Vaccine Information Statements (VISs) are developed by the CDC. The VIS for IIV, which covers influenza vaccines given by injection with a needle, and the VIS for LAIV are available in several languages. The VISs, in English, for influenza vaccines are available from the CDC website at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

(2) The appropriate VIS must be provided to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and to any adult or legal representative of any adult to whom the provider intends to administer such vaccine.

(3) The materials must be supplemented with visual presentations or oral explanations, as appropriate. ***NOTE:*** *If the Food and Drug Administration (FDA) approves any updated licensing for any of the influenza vaccine products, any new or interim VIS need to be used as soon as available from the CDC.*

g. The immunization standard for long-term care facilities from the Department of Health and Human Services, Centers for Medicare and Medicaid Services became effective October 7, 2005. Participating Medicare and Medicaid long-term care facilities

are required to offer each resident immunization against influenza annually, as well as lifetime immunization against pneumococcal disease.

(1) For the influenza vaccine, the standard requires: education for the resident or legal representative regarding benefits and potential side effects prior to the annual offering of the vaccine; the right of the resident or legal guardian to refuse vaccination; and the pertinent documentation in the electronic health record (EHR). If further clarification is needed regarding informed consent for clinical treatments and procedures, see VHA Directive 1004.01(3), Informed Consent for Clinical Treatments and Procedures, dated December 12, 2023).

(2) Documentation must show that specific education was provided, that the resident either received influenza vaccine or did not receive the vaccine, and if they did not receive the vaccine, the reason they did not receive it. ***NOTE:*** *See paragraph 5.e.(5)(a) 2.h. for VHA policy for long-term care residents.*

3. DEFINITION

Health Care Personnel. HCP are individuals who, during the influenza season, work in VHA locations or who come into contact with VA patients or other HCP as part of their duties. VHA locations include, but are not limited to, VA hospitals and associated clinics, community living centers (CLCs), community-based outpatient clinics (CBOCs), domiciliary units, Vet centers and VA-leased medical facilities. HCP include all VA licensed and unlicensed, clinical and administrative, remote and onsite, paid and without compensation, full- and part-time employees, intermittent employees, fee basis employees, VA contractors, researchers, volunteers and health professions trainees (HPTs) who are expected to perform any or all of their work at these facilities. HPTs may be paid or unpaid and include residents, interns, fellows and students. HCP also includes VHA personnel providing home-based care to Veterans and drivers and other personnel whose duties put them in contact with patients outside VA medical facilities.

NOTE: *This definition does not include visitors to the medical facility, including individuals who enter to conduct occasional or sporadic services, surveyors, inspectors, political representatives, or media personnel. Also excluded are non-VA personnel providing home services through contracts with VA and private facilities providing care under contract with VA. However, the exclusion of contracted non-VA personnel and facilities from this policy does not preclude VA from requiring influenza vaccination of these personnel in their respective contracts; in fact, this practice should be strongly supported and encouraged.*

4. POLICY

It is VHA policy to have an annual influenza vaccination program for the prevention and control of seasonal influenza. ***NOTE:*** *For information regarding policy for influenza vaccination of HCP, see VHA Directive 1192.01*.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Ensuring that each VISN Director has the sufficient resources to implement this directive in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards and applicable regulations.

c. **National Infectious Diseases Service, National Program Executive Director.** The National Infectious Diseases Service (NIDS), National Program Executive Director is responsible for updating the content of this directive on a periodic basis.

d. **Veterans Integrated Service Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and implement an Influenza Vaccination Program.

e. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring an influenza vaccination program is implemented in accordance with this directive, applicable updates from CDC and any Seasonal Influenza Vaccine Advisories from the Office of the Under Secretary for Health.

(2) Ensuring targeted populations are covered. The influenza vaccination program must cover all persons aged 6 months or greater in the patient population served by the VA medical facility and when appropriate in joint VA and DOD facilities with a sharing agreement.

(3) Ensuring appropriate influenza vaccines are used. Appropriate influenza vaccines and antiviral medications with activity against influenza viruses are to be used for those covered by the facility's influenza vaccination program (see Appendix A).

(4) Ensuring a Veteran is provided information concerning which community providers and/or pharmacies have contracts with VA to provide influenza vaccine to Veterans.

(5) Ensuring proper consent and documentation as follows.

(a) Patient/Resident Consent and Documentation.

1. All patients and residents receiving influenza vaccine from VA must receive information about the vaccine and be given a copy of the most current and appropriate

Vaccine Information Statements (VIS), either the VIS for Inactivated Influenza Vaccine (IIV) or the VIS for live-attenuated influenza vaccine (LAIV), prior to administration of the vaccine.

2. The practitioner who has primary responsibility for the patient and resident, or the person who will perform the vaccination, must communicate all of the following in a language that is understandable to the patient or personal representative:

a. The nature of the procedure.

b. Expected benefits of receiving the vaccine.

c. Reasonably foreseeable associated risks of receiving the vaccine.

d. Complications or side effects of the vaccine and vaccination.

e. Reasonable and available alternatives.

f. Potential risks to the patient if the vaccine is not given.

g. Ensure the patient has no allergies to the vaccine or components of the vaccine.

h. Documentation must include all of the following:

(1) Type of vaccine given (e.g., inactivated influenza vaccine-trivalent, inactivated influenza vaccine-quadrivalent, live attenuated influenza vaccine).

(2) Date of administration of the vaccine.

(3) Lot number and expiration date.

(4) Manufacturer.

(5) Vaccine dosage (volume and units); route and site of vaccine administration.

(6) Oral informed consent by the patient or resident to the vaccination.

(7) Name and title of the individual administering the vaccine.

(8) Specific CDC VIS provided, indicating the edition date of the material and the date the VIS was provided.

3. In order to obtain accurate data, it is critical that administration of influenza vaccine to patients be recorded correctly into the EHR. For recording the administration of influenza vaccine, use the CVX codes specified by the CDC located at https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt, and Current Procedural Terminology (CPT) codes that are specified by CDC in their code set tables located at http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt.

4. Consent for administration of seasonal influenza vaccine to Veteran patients is required. This consent can be oral; signature consent is not required.

(b) HCP Consent and Documentation.

1. All HCP receiving influenza vaccine from VA must receive information about the vaccine and be given a copy of the most current and appropriate Vaccine Information Statements (VIS) prior to administration of the vaccine. The information, explained in terms the HCP understands, must include:

a. The nature of the procedure.

b. Expected benefits of receiving the vaccine.

c. Reasonably foreseeable associated risks of receiving the vaccine.

d. Complications or side effects of the vaccine and vaccination.

e. Reasonable and available alternatives.

f. Potential risks to the HCP if the vaccine is not given.

g. Ensure the HCP has no allergies to the vaccine or components of the vaccine.

2. Occupational Health staff and other VHA staff administering the influenza vaccine on behalf of Occupational Health to HCP must document the vaccination administration per current CDC recommendations and this directive (See paragraph 5.e.(a) 2.h.). Maintenance of such documentation and HCP medical records concerning influenza vaccine must be in accordance with VA Handbook 5019, Employee Occupational Health Service, dated August 3, 2017.

3. Documentation (vaccination or exemption) requirements for VHA HCP related to VHA Seasonal Influenza Vaccination Program for VHA Health Care Personnel can be found in VHA Directive 1192.01, dated August 10, 2020.

4. Consent for administration of seasonal influenza vaccine to HCP is required. This consent can be oral; signature consent is not required.

(6) Ensuring adverse events are reported. Adverse events related to drug products and vaccines must be reported appropriately to the VA Adverse Drug Event Reporting System (VA ADERS) at https://vaww.cmop.med.va.gov/MedSafe_Portal. (select VA ADERS Launch). However, adverse events related to vaccine administration through Employee Occupational Health must be documented in OHRS 2.0, which interfaces directly with VA ADERS (see VA Handbook 5019, Part IV, Health Maintenance Programs, Examinations and Vaccinations, page IV-2). ***NOTE:*** *This is an internal VA website that is not available to the public. Procedures in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018 must be followed, as applicable*.

(a) All adverse events related to vaccines must be reported to the FDA and CDC Vaccine Adverse Event Reporting System (VAERS) program through VA ADERS. The Vaccine Adverse Event Report submitted in VA ADERS will then be submitted directly to the FDA/CDC from VA ADERS.

(b) An adverse event in an employee annual influenza vaccination program may or may not constitute a work-related Occupational Safety and Health Administration (OSHA) recordable event This does not preclude the employee from filing a claim for benefits with the Office of Workers' Compensation Programs for eligibility. Occupational Health reports adverse events in VA ADERS. Reporting adverse events to an influenza vaccination should be done for all employees, including Veteran patient and non-Veteran patient employees.

(7) Ensuring necessary procedures are in place if there is an influenza vaccine delay or shortage. If an influenza vaccine delay or a shortage occurs, prioritization plans for influenza vaccine must be developed at the local VA medical facility level. Vaccination efforts are to focus on targeted Veteran patient and employee groups as identified in Appendix B. If there is a continued national influenza vaccine delay or shortage, the prioritization plans developed at the local VA medical facility level may need to be altered to be in alignment with applicable CDC updates and VHA communications from the Under Secretary for Health, Deputy Under Secretary for Health or Assistant Under Secretary for Health for Operations through Influenza Vaccine Advisories.

6. TRAINING

All Veterans and HCP are provided with the current edition of vaccine information materials, specifically Vaccine Information Statements (VIS) prior to administration of each dose of the vaccine. Education is provided for all HCP about, at a minimum, the influenza vaccine, non-vaccine control and prevention measures and the diagnosis, transmission and impact of influenza.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

8. REFERENCES

a. 38 U.S.C. §§ 1701(6)(D), (9)(G), and (10).

b. 38 U.S.C. § 1704.

c. 38 U.S.C. § 1712(e).

d. 42 U.S.C., Chapter 6A, Subchapter XIX, Part I.

e. 42 U.S.C. §§ 300aa-1 to 300aa-34.

f. 29 C.F.R. § 1904.5.

g. 42 C.F.R. § 483.

h. VA Handbook 5019, Employee Occupational Health Service, dated August 3, 2017.

i. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

j. VHA Directive 1192.01, Seasonal Influenza Prevention Program for VHA Health Care Personnel, August 10, 2020.

k. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

l. VHA Directive 1004.01(3), Informed Consent for Clinical Treatments and Procedures, dated December 12, 2023.

m. VHA Directive 1120.05, The National Center for Health Promotion and Disease Prevention and The Coordination and Development of Clinical Preventive Services Guidance, dated August 29, 2024.

n. CDC. “Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years and Older — United States, 2022”, MMWR/February 18, 2022/71(7). https://www.cdc.gov/mmwr/volumes/71/wr/mm7107a1.htm.

o. CDC. Influenza Antiviral Medications for Clinicians at https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm.

p. CDC. “General Best Practice Guidelines for Immunization of the Advisory Committee on Immunization Practices (ACIP). Updated at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

q. CDC. “Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States,”. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

r. CDC. Vaccine Information Statement at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.html.

s. CDC. Influenza (Flu) at http://www.cdc.gov/flu/.

t. CDC. Live Intranasal Influenza Vaccine, Vaccine Information Statement at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flulive.html.

u. CDC. “Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)-United States, 2024-25 Influenza Season. https://www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm.

v. CDC. Contraindications and Precautions: General Best Practices for Immunization. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

w. CDC. Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Safety of Influenza Vaccines for Persons with Egg Allergy. https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy.html.

x. VA. Public Health Information from VA. Influenza (Flu) athttps://www.prevention.va.gov/flu/.

y. VHA Clinical Preventive Services Guidance Statements available at http://vaww.prevention.va.gov/Guidance_on_Clinical_Preventive_Services.asp. (navigate to current year’s Influenza Immunization Guidance Statement from this page). ***NOTE****: This is an internal VA website that is not available to the public.*

z. VHA Seasonal Influenza Manual. https://dvagov.sharepoint.com/sites/vhaseasonal-influenza-flu/Flu%20Manual%20Toolkit/Forms/AllItems.aspx?RootFolder=%2Fsites%2Fvhaseasonal%2Dinfluenza%2Dflu%2FFlu%20Manual%20Toolkit%2FFlu%20Manual%20Toolkit&FolderCTID=0x012000304A38DD6CE2664ABC7E0EE10A8A94A7 ***NOTE:*** *This is an internal VA website that is not available to the public.*

INFLUENZA VACCINE AND ANTIVIRAL MEDICATIONS WITH ACTIVITY AGAINST SEASONAL INFLUENZA VIRUSES

1. ANNUAL INFLUENZA VACCINATION

a. Annual influenza vaccination is recommended for all persons aged6 months or older who do not have contraindications. For the 2024-25 season, only trivalent influenza vaccines are available including trivalent inactivated influenza vaccines (IIV3s), trivalent recombinant influenza vaccine (RIV3) and trivalent live attenuated influenza vaccine (LAIV3). LAIV3 may be used for healthy, non-pregnant persons 2 years through 49 years of age. These influenza vaccines are to be given in alignment with the package inserts provided by manufacturers, Center for Disease Control and Prevention (CDC) recommendations and any Veterans Health Administration (VHA) communications from the Under Secretary for Health pertinent to influenza vaccines for the current influenza season. ***NOTE:*** *Information pertinent to influenza vaccines can be found in the VHA Seasonal Influenza Manual at* https://dvagov.sharepoint.com/sites/vhaseasonal-influenza-flu/Flu%20Manual%20Toolkit/Forms/AllItems.aspx?RootFolder=%2Fsites%2Fvhaseasonal%2Dinfluenza%2Dflu%2FFlu%20Manual%20Toolkit%2FFlu%20Manual%20Toolkit&FolderCTID=0x012000304A38DD6CE2664ABC7E0EE10A8A94A7 *This is an internal VA website that is not available to the public.*

b. Recommendations for vaccination of adult solid organ transplant recipients have been updated to include high-dose inactivated influenza vaccine (HD-IIV3) or adjuvanted inactive influenza vaccine (aIIV3) as acceptable options for solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens (without a preference over other age-appropriate IIV3s or RIV3).

c. For the 2024-25 annual vaccination program, Advisory Committee on Immunization Practices (ACIP) recommends all persons receive an age-appropriate influenza vaccine (i.e., one approved for their age), Except for vaccination for adults aged ≥65 years, ACIP makes no preferential recommendation for a specific vaccine when more than one licensed and recommended vaccine is available.

d. ACIP recommends that adults 65 years and older preferentially receive any one of the following higher-dose or adjuvanted influenza vaccines: trivalent high-dose inactivated influenza vaccine (HD-IIV3: Fluzone®-HD), trivalent recombinant influenza vaccine (RIV3: Flublok®), or trivalent adjuvanted inactivated influenza vaccine (aIIV3: Fluad®). If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used. ***NOTE****: Each influenza season there are multiple manufacturers of influenza vaccine available in the U.S. The U.S. Food and Drug Administration (FDA) maintains a list of all currently FDA approved influenza vaccines (with brand name, type of vaccine, presentation, age indications and presence of latex or mercury (from thimerosal) at*

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/influenza-virus-vaccine-safety-availability

e. All influenza vaccines available in the United States for the 2024–25 season are trivalentt vaccines.

(1) For the 2024–25 season, U.S. egg-based influenza vaccines (i.e., vaccines other than ccIIV3 and RIV3) will contain hemagglutinin (HA) derived from:

(a) an influenza A/Victoria/4897/2022 (H1N1) pdm09-like virus;

(b) an influenza A/Thailand/8/2022 (H3N2)-like virus; and

(c) an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus.

(2) For the 2024–25 season, U.S. cell culture–based inactivated (ccIIV3) and recombinant (RIV3 influenza vaccines will contain HA derived from:

(a) an influenza A/Wisconsin/67/2022 (H1N1) pdm09-like virus;

(b) an influenza A/Massachusetts/18/2022 (H3N2)-like virus;

(c) an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus.

f. During the 2024-25 influenza season, it is expected that SARS-CoV-2 will continue to circulate in the United States, and COVID-19 vaccinations are expected to continue. Current guidance for the administration of COVID-19 vaccines (available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) indicates that these vaccines can be administered with other vaccines, including influenza vaccines. For most adults (particularly adults aged ≥65 years) and for pregnant persons in the first or second trimester, vaccination during July and August should be avoided unless there is concern that vaccination later in the season might not be possible.

2. INACTIVATED INFLUENZA VACCINE

a. Inactivated influenza vaccines (IIVs) as a class include trivalent inactivated influenza vaccines and quadrivalent inactivated influenza vaccine. Trivalent influenza vaccine formulations contain two influenza A virus strains and one influenza B virus strain. Quadrivalent influenza vaccine formulations contain the same strains as trivalent vaccines, but also contain a second B virus strain. Each annual seasonal influenza vaccine is formulated to protect against influenza viruses most likely to cause disease during the season. IIVs encompass a variety of strengths and formulations, including standard dose IIVs, adjuvanted influenza vaccine (aIIVs), cell culture-based influenza vaccines (ccIIVs), and higher-dose vaccines (IIV-HD). ccIIV (Flucelvax) is cell-culture based and manufactured without the use of eggs. Refer to CDC Flu Vaccine and People with Egg Allergies: https://www.cdc.gov/flu/prevent/egg-allergies.htm.

b. IIV is administered annually.

c. IIV has vaccine virus strains updated annually.

d. IIV contains noninfectious virus (i.e., inactivated, killed).

e. IIV is given by injection with a needle. ***NOTE:*** *Adults and older children need to be vaccinated in the deltoid muscle. Consideration needs to be given to using a needle length of at least one inch because shorter needles may not penetrate muscle tissue in certain adults and older children. Infants and young children less than 12 months should be vaccinated in the anterolateral aspect of the thigh using a needle length of 7/8 – 1 inch.*

f. IIV cannot cause influenza.

g. IIV can be co-administered with influenza antivirals.

h. IIV can be administered in the presence of minor illnesses with or without fever. ***NOTE:*** *Influenza vaccine can be administered in this situation. This is and has been so stated in CDC recommendations for administration of influenza vaccine. See https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.*

i. IIV usage for those who have experienced Guillain-Barré Syndrome (GBS) as an issue.

(1) Whether influenza vaccination specifically might increase the risk for recurrence of GBS is unknown. However, as a precaution, persons who are not at high risk for severe influenza complications and who are known to have experienced GBS within 6 weeks of receipt of an influenza vaccine generally should not be vaccinated. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons.

(2) Although data are limited, the established benefits of influenza vaccination might outweigh the risks for many persons who have a history of GBS and who are also at high risk for severe complications from influenza.

j. CDC recommendations indicate that IIVs and RIV may be administered simultaneously or sequentially with other inactivated vaccines or live vaccines. Injectable vaccines that are given concomitantly should be administered at separate anatomic sites. LAIVcan be administered simultaneously with other live or inactivated vaccines. However, if two live vaccines are not given simultaneously, at least 4 weeks should pass after administration of one live vaccine (such as LAIV) before another live vaccine is administered.

k. Moderate or severe acute illness with or without fever is a precaution for IIV. This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of superimposing adverse effects of the vaccine on the underlying illness. ***NOTE:*** *If there is more than minor illness, then usually*

people are not vaccinated until their symptoms abate. However, individuals experiencing moderate or severe illness, need to be clinically evaluated to consider what effect the potential harms of not being vaccinated and potentially becoming ill with influenza would have on the individual. Concerns that the vaccine may not be effective in the presence of moderate or severe illness depends also on what the illness is and must be evaluated in light of any potential harms of not vaccinating. Therefore, it makes administration of influenza vaccine a precaution in these individuals calling for a clinical evaluation and decision making. This is and has been so stated in CDC recommendations. See https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

l. While IIV can be used for any person aged 6 months or older, including those who are healthy and those with chronic medical conditions, live attenuated influenza vaccine (LAIV) currently is recommended only for healthy, non-pregnant persons aged 2 years through 49 years of age. This would be appropriate for those facilities that are in a joint VA/DoD facility with a sharing agreement to provide services to the pediatric population, Because of this difference, persons who should be vaccinated with IIV include:

(1) Persons aged 50 years and older. For the subset of persons 65 years of age or older, ACIP recommends they preferentially receive higher-dose or adjuvanted influenza vaccines. The FDA has approved the following three higher-dose or adjuvanted influenza vaccines: high-dose inactivated influenza vaccine (HD-IIV, recombinant influenza vaccine (RIV), or adjuvanted inactivated influenza vaccine (aIIV). If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.

(2) Children and adolescents (aged 6 months to 18 years) who are receiving long-term aspirin therapy and who, therefore, might be at risk for experiencing Reye's syndrome after influenza virus infection. ***NOTE:*** *The goal is to keep children and adolescents who are on long-term aspirin therapy from getting influenza because if they do get influenza, they run the risk of developing Reye's Syndrome. This is and has been so stated in CDC recommendations for administration of influenza vaccine.*

(3) Women who are pregnant during the influenza season. Vaccination soon after vaccine becomes available may also be considered for pregnant women during the third trimester because vaccination of pregnant women reduces risk for influenza illness in their infants during the first months of life (a period during which they are too young to receive influenza vaccine).

(4) Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological or neuromuscular conditions, hematological or metabolic disorders (including diabetes mellitus).

(5) Adults and children who are immunosuppressed, including immunosuppression caused by medications or by human immunodeficiency virus.

(6) Residents of Community Living Centers, nursing homes and other long-term care facilities.

(7) Family members, health care personnel and others who have close contact with immunosuppressed persons requiring a protected environment (e.g., hematopoietic stem cell transplant recipients).

m. Persons who should not be vaccinated with IIV include those with a previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction. According to the 2024-25 ACIP recommendations, all persons aged 6 months or older with egg allergy should receive influenza vaccine.

(1) Any influenza vaccine (egg-based or nonegg-based) that is otherwise appropriate for the recipient's age and health status can be used. See https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy.html.

(2) It is no longer recommended that persons who have had an allergic reaction to egg involving symptoms other than a severe allergic reaction (e.g., urticaria or anaphylaxis) should be vaccinated in an inpatient or outpatient medical setting supervised by a health care provider who is able to recognize and manage severe allergic reactions if an egg-based vaccine is used. Egg allergy does not indicate additional safety measures for flu vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. Administer all vaccines in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

NOTE: *Although egg allergy is neither a contraindication nor precaution to the use of any influenza vaccine, there are contraindications and precautions related to allergies to vaccine components other than egg and to previous allergic reactions to influenza vaccines. See Persons with Previous Allergic Reactions to Influenza Vaccines and Dosage, Administration, Contraindications, and Precautions at: https://www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm#:~:text=complications%20from%20influenza.-,Persons%20with%20a%20History%20of%20Egg%20Allergy,-ACIP%20recommends%20that.*

3. LIVE, ATTENUATED INFLUENZA VACCINE

a. Live, attenuated influenza vaccine (LAIV) may be used for healthy non-pregnant persons 2 years through 49 years of age. ***NOTE:*** *Since safety or effectiveness has not been established in persons with underlying medical conditions that confer a higher risk of influenza complications, it is generally stated for use in healthy, non-pregnant persons aged 2 years to 49 years of age (use of the term healthy in this recommendation refers to persons who do not have any of the underlying medical conditions that confer high risk for severe complications).* For the 2024-2025 influenza season, there is only one LAIV available in the U.S.: LAIV, FluMist ® [AstraZeneca].

b. LAIV is administered annually.

c. LAIV is updated annually with vaccine virus strains.

d. LAIV is administered intranasally by sprayer.

e. LAIV contains live attenuated influenza viruses that have the potential to cause mild signs or symptoms related to mild virus infection from the attenuated virus (e.g., rhinorrhea, nasal congestion, fever or sore throat).

f. LAIV can be administered to appropriate persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration needs to be considered until resolution of the illness or other age-appropriate seasonal influenza vaccine formulations should be administered instead.

g. If the LAIV recipient sneezes after administration, the dose should not be repeated.

h. CDC recommendations indicate that LAIV can be simultaneously administered (on the same day) with other vaccines; however, co-administration has been evaluated systematically only among children aged 12 months to 15 months of age who received measles, mumps and rubella or varicella vaccine. CDC further suggests that it may be prudent to space non-simultaneous vaccinations of LAIV and other live vaccines at least 4 weeks apart.

i. As a precautionary measure, health care personnel who receive LAIV need to avoid providing care to severely immunosuppressed patients requiring a protective environment (e.g., hematopoietic stem cell transplant recipients) for 7 days after vaccination.

j. Hospital visitors who received LAIV need to avoid contact with severely immunosuppressed persons requiring a protective environment (e.g., hematopoietic stem cell transplant recipients) for 7 days after vaccination.

k. Medical personnel at higher risk for influenza complications (including persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma and persons aged 50 years or older) can administer LAIV.

l. LAIV should not be administered by severely immunosuppressed persons.

m. LAIV is an option for vaccination of healthy, non-pregnant persons aged 2 years through 49 years, including health care personnel and other close contacts of high-risk persons.

n. A moderate or severe illness with or without fever is a precaution for use of LAIV.

o. Development of GBS within 6 weeks following a previous dose of influenza vaccine is considered to be a precaution for the use of influenza vaccines.

p. Asthma in persons aged 5 years or older is a precaution for use of LAIV.

q. Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]) are precautions for the use of LAIV.

r. Persons who should not be vaccinated with LAIV include:

(1) Children less than 2 years of age.

(2) Persons aged 50 years or older.

(3) Persons with a previous severe allergic reaction to the vaccine or to a previous dose of any influenza vaccine.

(4) Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months.

(5) Adults and children who have immunosuppression due to any cause (including immunosuppression caused by medications, congenital or acquired immunodeficiency states, human immunodeficiency virus (HIV) infection, anatomic asplenia, or functional asplenia (e.g., sickle-cell anemia).

(6) Children or adolescents aged 6 months to 18 years receiving aspirin or other salicylates (because of the association of Reye’s syndrome with wild-type influenza virus infection).

(7) Pregnant women.

(8) Close contacts and caregivers of severely immunosuppressed persons who require a protected environment.

(9) Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak

(10) Persons with cochlear implants

(11) Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir.

4. RECOMBINANT INFLUENZA VACCINE

a. As of the 2021-22 and the current influenza season, FluBlok® (RIV) is the only recombinant influenza vaccine (RIV) available for use in the U.S. RIV is manufactured without the use of eggs. Refer to CDC Flu Vaccine and People with Egg Allergies at https://www.cdc.gov/flu/prevent/egg-allergies.htm and https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy.html.

b. RIV can be administered to persons with egg allergy of any severity who are aged 18 years and older and do not have other contraindications.

c. RIV is administered by intramuscular injection.

d. Moderate or severe acute illness with or without fever is a general precaution for vaccination.

e. GBS within 6 weeks following a previous dose of influenza vaccine is considered a precaution for use of influenza vaccines.

f. RIV is currently not licensed for use in anyone younger than 18 years of age.

5. ANTIVIRAL MEDICATIONS WITH ACTIVITY AGAINST INFLUENZA VIRUSES

a. Antiviral medications with activity against influenza viruses are useful adjuncts in the prevention of influenza and effective when used early in the course of illness for treatment and for chemoprophylaxis after an exposure to the influenza virus. These agents are not a substitute for vaccination, although they are critical adjuncts in preventing and controlling influenza. Currently, recommended antiviral medications include oral oseltamivir, inhaled zanamivir, on the basis of the most recent data indicating that greater than 99% of currently circulating influenza virus strains are sensitive to these medications. Additionally, intravenous peramivir and oral baloxavir are recommended as treatment for influenza in specific situations. Amantadine and rimantadine should not be used because of the high levels of resistance to these drugs among circulating influenza A viruses. Because antiviral resistance patterns can change over time, clinicians should monitor local antiviral resistance surveillance data.

b. CDC publishes and regularly updates Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza recommendations of the Advisory Committee on Immunization Practices (ACIP), available at http://www.cdc.gov/flu/professionals/antivirals/index.htm that includes the following recommendations for use of antivirals for the prevention and control of influenza:

(1) Antiviral treatment with oral oseltamivir is recommended as soon as possible for patients with confirmed or suspected influenza who have severe, complicated or progressive illness or who require hospitalization. The dose and duration of oseltamivir in hospitalized patients with severe illness may need to be modified. Inhaled zanamivir and oral baloxavir are not recommended in hospitalized patients because of a lack of data showing clinical benefit. There are also insufficient data for treatment of hospitalized patients with intravenous peramivir.

(2) Antiviral treatment with oral oseltamivir is recommended as soon as possible for outpatients with confirmed or suspected influenza who are at higher risk for influenza complications on the basis of their age or underlying medical conditions; clinical judgment should be an important component of outpatient treatment decisions. Antiviral treatment is recommended as early as possible for pregnant women or women who are up to 2 weeks postpartum (including following pregnancy loss) with suspected or confirmed influenza.

(3) For outpatients with severe or confirmed uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir or oral baloxavir may be used for treatment, depending on approved age and contraindications.

(4) Antiviral treatment may be considered on the basis of clinical judgment for any outpatient with confirmed or suspected influenza who does not have known risk factors for severe illness if treatment can be initiated within 48 hours of illness onset.

(5) CDC does not recommend widespread or routine use of antiviral medications for chemoprophylaxis except as one of multiple interventions to control institutional influenza outbreaks (e.g., long-term care). An emphasis on close monitoring and early initiation of antiviral treatment is an alternative to chemoprophylaxis.

(6) Antiviral medications can be considered as chemoprophylaxis in patients at high risk of complications during the first 2 weeks following vaccination after exposure to a person with influenza, patients at high risk for influenza complications who cannot receive flu vaccine due to a contraindication, prevention for patients with severe immune deficiencies who may not respond to influenza vaccination.

DELAY OR SHORTAGE OF SEASONAL INFLUENZA VACCINE

When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to the following individuals (no hierarchy is implied by order of listing).
NOTE: *See this CDC link for the source for this listing*
https://www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm.

1. Persons aged 50 years and older.

2. Children aged 6 through 59 months.

3. Persons who have chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic hematologic, neurologic, or metabolic disorders (including diabetes mellitus).

4. Persons who are immunocompromised due to any cause, including (but not limited to) medications or by human immunodeficiency virus (HIV) infection.

5. Women who are or will be pregnant during the influenza season.

6. Children and adolescents (aged 6 months – 18 years of age) who are receiving aspirin- or salicylate-containing medications who might be at risk for Reye syndrome associated with influenza.

7. Residents of nursing homes and long-term care facilities.

8. American Indians/ Alaska Natives.

9. Persons who are extremely obese (body-mass index of 40 or greater for adults).

10. Caregivers and contacts of those at risk:

a. Health care personnel, including all paid and unpaid persons working in health-care settings who have potential for exposure to patients and/or to infectious materials, whether or not directly involved in patient care;

b. Household contacts (including children aged 6 months or greater) and caregivers of children aged ≤59 months (i.e., <5 years), particularly contacts of children aged <6 months, and adults aged ≥50 years;

c. Household contacts (including children aged 6 months or greater) and caregivers of persons with medical conditions associated with increased risk of severe complications from influenza.