Statewide Pharmacy Protocols Work Group

August 8, 2022

9:00 a.m.

Conference Room 2

Perimeter Center
9960 Mayland Drive, Suite 201
Richmond, VA 23233-1463

PERIMETER CENTER CONFERENCE CENTER
EMERGENCY EVACUATION OF BOARD AND TRAINING ROOMS
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Board Room 2

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Statewide Pharmacy Protocols
Work Group
Monday, August 8, 2022 @ 9:00 a.m.
Perimeter Center
9960 Mayland Drive, Suite 201, Board Room 2
Henrico, VA 23233

Call to Order and Roll Call

Emergency Egress Procedures ..... **i**

Introduction of Work Group Members

Adoption of Agenda

Public Comment on Agenda Items

New Business

1. Charge of the Work Group – William Harp, MD 1

2. Vaccines 10

3. Nicotine Replacement and other Tobacco Cessation Therapies 33

4. COVID-19 Testing 68

5. Announcements/Reminders 83

6. Adjourn

====No motion needed to adjourn if all business has been conducted====

AGENDA ITEM: Charge of the Work Group

STAFF NOTE: In the next few pages, you will find HB1323 from the 2022 Session of the General Assembly. Beginning on page 6 of the bill are the issues to be addressed in new and/or revised protocols.

ACTION: For information only.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

[H 1323]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and Human Services pursuant to federal law; administration of plan; contracts with health care providers.

A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance services pursuant to Title XIX of the United States Social Security Act and any amendments thereto. The Board shall include in such plan:

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the Department of Social Services or placed through state and local subsidized adoptions to the extent permitted under federal statute;

2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of $3,500 for the individual and an amount not in excess of $3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;

3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed $5,000. In any case in which the definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;

4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per admission;

5. A provision for deducting from an institutionalized recipient's income an amount for the maintenance of the individual's spouse at home;

6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

7. A provision for the payment for family planning services on behalf of women who were Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such family planning services shall begin with delivery and continue for a period of 24 months, if the woman continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the

purposes of this section, family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage or make direct referrals for abortions;

8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

9. A provision identifying entities approved by the Board to receive applications and to determine eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate contact information, including the best available address and telephone number, from each applicant for medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant for medical assistance with information about advance directives pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance directives and how the applicant may make an advance directive;

10. A provision for breast reconstructive surgery following the medically necessary removal of a breast for any medical reason. Breast reductions shall be covered, if prior authorization has been obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic;

11. A provision for payment of medical assistance for annual pap smears;

12. A provision for payment of medical assistance services for prostheses following the medically necessary complete or partial removal of a breast for any medical reason;

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate;

14. A requirement that certificates of medical necessity for durable medical equipment and any supporting verifiable documentation shall be signed, dated, and returned by the physician, physician assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60 days from the time the ordered durable medical equipment and supplies are first furnished by the durable medical equipment provider;

15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons age 40 and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen;

16. A provision for payment of medical assistance for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast;

17. A provision, when in compliance with federal law and regulation and approved by the Centers for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program and may be provided by school divisions, regardless of whether the student receiving care has an individualized education program or whether the health care service is included in a student's individualized education program. Such services shall include those covered under the state plan for medical assistance services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in § 1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for health care services provided through telemedicine services, as defined in § 38.2-3418.16. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services;

18. A provision for payment of medical assistance services for liver, heart and lung transplantation procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and application of the procedure in treatment of the specific condition have been clearly demonstrated to be medically effective and not experimental or investigational; (iii) prior authorization by the Department of

Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant center where the surgery is proposed to be performed have been used by the transplant team or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and restore a range of physical and social functioning in the activities of daily living;

19. A provision for payment of medical assistance for colorectal cancer screening, specifically screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in appropriate circumstances radiologic imaging, in accordance with the most recently published recommendations established by the American College of Gastroenterology, in consultation with the American Cancer Society, for the ages, family histories, and frequencies referenced in such recommendations;

20. A provision for payment of medical assistance for custom ocular prostheses;

21. A provision for payment for medical assistance for infant hearing screenings and all necessary audiological examinations provided pursuant to § 32.1-64.1 using any technology approved by the United States Food and Drug Administration, and as recommended by the national Joint Committee on Infant Hearing in its most current position statement addressing early hearing detection and intervention programs. Such provision shall include payment for medical assistance for follow-up audiological examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and performed by a licensed audiologist to confirm the existence or absence of hearing loss;

22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. 106-354), for certain women with breast or cervical cancer when such women (i) have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise eligible for medical assistance services under any mandatory categorically needy eligibility group; and (v) have not attained age 65. This provision shall include an expedited eligibility determination for such women;

23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and services delivery, of medical assistance services provided to medically indigent children pursuant to this chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the FAMIS Plan program in § 32.1-351. A single application form shall be used to determine eligibility for both programs;

24. A provision, when authorized by and in compliance with federal law, to establish a public-private long-term care partnership program between the Commonwealth of Virginia and private insurance companies that shall be established through the filing of an amendment to the state plan for medical assistance services by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for such services through encouraging the purchase of private long-term care insurance policies that have been designated as qualified state long-term care insurance partnerships and may be used as the first source of benefits for the participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

25. A provision for the payment of medical assistance for otherwise eligible pregnant women during the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health Insurance Program Reauthorization Act of 2009 (P.L. 111-3);

26. A provision for the payment of medical assistance for medically necessary health care services provided through telemedicine services, as defined in § 38.2-3418.16, regardless of the originating site or whether the patient is accompanied by a health care provider at the time such services are provided. No health care provider who provides health care services through telemedicine services shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services.

For the purposes of this subdivision, "originating site" means any location where the patient is located, including any medical care facility or office of a health care provider, the home of the patient, the patient's place of employment, or any public or private primary or secondary school or postsecondary institution of higher education at which the person to whom telemedicine services are provided is located;

27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a 12-month supply of hormonal contraceptives at one time. Absent clinical contraindications, the Department shall not impose any utilization controls or other forms of medical management limiting the

supply of hormonal contraceptives that may be dispensed or furnished to an amount less than a 12-month supply. Nothing in this subdivision shall be construed to (i) require a provider to prescribe, dispense, or furnish a 12-month supply of self-administered hormonal contraceptives at one time or (ii) exclude coverage for hormonal contraceptives as prescribed by a prescriber, acting within his scope of practice, for reasons other than contraceptive purposes. As used in this subdivision, "hormonal contraceptive" means a medication taken to prevent pregnancy by means of ingestion of hormones, including medications containing estrogen or progesterone, that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration for such purpose; and

28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months following the date of such surgery; and (v) patients with a chronic health condition who have had two or more hospitalizations or emergency department visits related to such chronic health condition in the previous 12 months. For the purposes of this subdivision, "remote patient monitoring services" means the use of digital technologies to collect medical and other forms of health data from patients in one location and electronically transmit that information securely to health care providers in a different location for analysis, interpretation, and recommendations, and management of the patient. "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence monitoring, and interactive videoconferencing with or without digital image upload.

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.

4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical assistance services as may be necessary to conform such plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

In the event conforming amendments to the state plan for medical assistance services are adopted, the Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular session of the General Assembly unless enacted into law.

D. The Director of Medical Assistance Services is authorized to:

1. Administer such state plan and receive and expend federal funds therefor in accordance with applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to the performance of the Department's duties and the execution of its powers as provided by law.

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other

health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when such corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316, or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of § 32.1-162.13.

For the purposes of this subsection, "provider" may refer to an individual or an entity.

E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

The Director may consider aggravating and mitigating factors including the nature and extent of any adverse impact the agreement or contract denial or termination may have on the medical care provided to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

F. When the services provided for by such plan are services which a marriage and family therapist, clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for covered services as provided in the state plan. The Board shall promulgate regulations which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers, licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria, including the professional credentials required for licensure.

G. The Board shall prepare and submit to the Secretary of the United States Department of Health and Human Services such amendments to the state plan for medical assistance services as may be permitted by federal law to establish a program of family assistance whereby children over the age of 18 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical assistance under the plan to their parents.

H. The Department of Medical Assistance Services shall:

1. Include in its provider networks and all of its health maintenance organization contracts a provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for medically necessary assessment and treatment services, when such services are delivered by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable expertise, as determined by the Director.

2. Amend the Medallion II waiver and its implementing regulations to develop and implement an exception, with procedural requirements, to mandatory enrollment for certain children between birth and age three certified by the Department of Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors and enrolled providers for the provision of health care services under Medicaid and the Family Access to Medical Insurance Security Plan established under § 32.1-351.

4. Require any managed care organization with which the Department enters into an agreement for the provision of medical assistance services to include in any contract between the managed care organization and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of the pharmacy benefits manager from conducting spread pricing with regards to the managed care organization's managed care plans. For the purposes of this subdivision:

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a managed care organization for the benefit of covered individuals.

"Pharmacy benefits manager" means a person that performs pharmacy benefits management.

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a managed care plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible recipients with special needs. The Board shall promulgate regulations regarding these special needs patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as defined by the Board.

J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law and regulation.

K. When the services provided for by such plan are services related to initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § 54.1-3303.1, the Department shall provide reimbursement for such service.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older *with whom the pharmacist has a bona fide pharmacist-patient relationship and* in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ *and vaccines for COVID-19*;

8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention*;*

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling; and

11. Tests for COVID-19 and other coronaviruses.

B. *Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:*

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. *No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that*

is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.). If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

~~C.~~ *D.* A pharmacist who administers a vaccination pursuant to ~~subdivision~~ *subdivisions* A 7 *and B 1* shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.

G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; ~~and~~

8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and*

9. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit:

1. An application and fee specified in regulations of the Board;

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

2. That the Board of Medicine, in collaboration with the Board of Pharmacy and the Department of Health, shall establish a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2022, and the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq., as amended.

3. That the provisions of subdivisions B 1 and 2 of § 54.1-3303.1 of the Code of Virginia, as amended by this act, shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

AGENDA ITEM: Vaccines

STAFF NOTE: This item is responsive to 2 sections of HB1323, specifically 54.1-3301(A)(7) and (B)(1). The first adds COVID-19 vaccines to the Immunization Schedule of the CDC. The second is similar but does not become effective until the federally declared emergency is over. In the following pages, you will find the current Pharmacist Vaccine State Protocol which became effective 12/22/2021, the CDC Recommended Child and Adolescent Immunization Schedule, CDC information on COVID-19 vaccines, the HHS renewal of the public health emergency on 7/15/2022, and a draft protocol for the Work Group's consideration.

ACTION: Discuss and determine that the draft "Vaccine Statewide Protocol" is comprehensive or if edits or additions are required. The Work Group should approve the document by a vote.

Adopted: 9/24/2021
Effective: 12/22/2021

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) or current emergency use authorization from the U.S. Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the vaccines to persons 18 years of age or older.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use or instructions indicated in the emergency use authorization, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions.

PATIENT INCLUSION CRITERIA

Pharmacist shall review applicable medical history prior to administering vaccine to ensure vaccine administration is appropriate for patient's medical condition(s), e.g., pregnancy, immunocompromised state. Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC;
- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC such as based on the patient's medical condition(s); or
- An individual who is fully vaccinated.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING

Adopted: 9/24/2021
Effective: 12/22/2021

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Recommended Child and Adolescent Immunization Schedule
for ages 18 years or younger

UNITED STATES
2022

Vaccines in the Child and Adolescent Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
Dengue vaccine	**DEN4CYD**	Dengvaxia®
Diphtheria, tetanus, and acellular pertussis vaccine	**DTaP**	Daptacel® Infanrix®
Diphtheria, tetanus vaccine	**DT**	No trade name
Haemophilus influenzae type b vaccine	**Hib (PRP-T)** **Hib (PRP-OMP)**	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	**HepA**	Havrix® Vaqta®
Hepatitis B vaccine	**HepB**	Engerix-B® Recombivax HB®
Human papillomavirus vaccine	**HPV**	Gardasil 9®
Influenza vaccine (inactivated)	**IIV4**	Multiple
Influenza vaccine (live, attenuated)	**LAIV4**	FluMist® Quadrivalent
Measles, mumps, and rubella vaccine	**MMR**	M-M-R II®
Meningococcal serogroups A, C, W, Y vaccine	**MenACWY-D** **MenACWY-CRM** **MenACWY-TT**	Menactra® Menveo® MenQuadfi®
Meningococcal serogroup B vaccine	**MenB-4C** **MenB-FHbp**	Bexsero® Trumenba®
Pneumococcal 13-valent conjugate vaccine	**PCV13**	Prevnar 13®
Pneumococcal 23-valent polysaccharide vaccine	**PPSV23**	Pneumovax 23®
Poliovirus vaccine (inactivated)	**IPV**	IPOL®
Rotavirus vaccine	**RV1** **RV5**	Rotarix® RotaTeq®
Tetanus, diphtheria, and acellular pertussis vaccine	**Tdap**	Adacel® Boostrix®
Tetanus and diphtheria vaccine	**Td**	Tenivac® Tdvax™
Varicella vaccine	**VAR**	Varivax®
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	**DTaP-HepB-IPV**	Pediarix®
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	**DTaP-IPV/Hib**	Pentacel®
DTaP and inactivated poliovirus vaccine	**DTaP-IPV**	Kinrix® Quadracel®
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	**DTaP-IPV-Hib-HepB**	Vaxelis®
Measles, mumps, rubella, and varicella vaccine	**MMRV**	ProQuad®

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

How to use the child and adolescent immunization schedule

1 Determine recommended vaccine by age **(Table 1)**

2 Determine recommended interval for catch-up vaccination **(Table 2)**

3 Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**

4 Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**

5 Review contraindications and precautions for vaccine types **(Appendix)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- ACIP Shared Clinical Decision-Making Recommendations www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Scan QR code for access to online schedule

CS310020-A

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2022

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

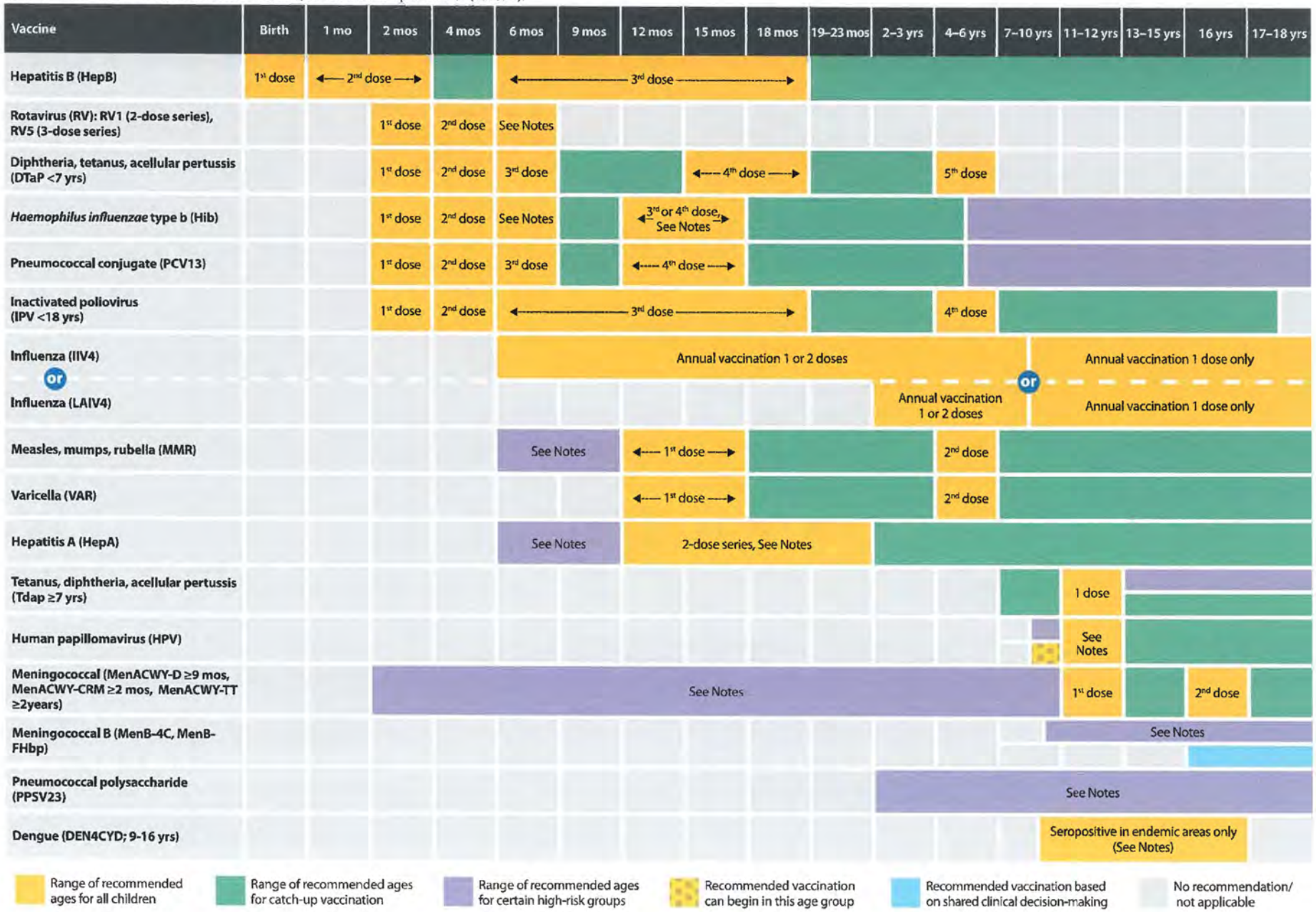

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2022

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Children age 4 months through 6 years

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months**
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib®, Pentacel®, Hiberix®), Vaxelis® or unknown **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; OR if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; OR if both doses were PedvaxHIB® and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months and previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); OR If current age is 12 months or older and at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 9 months MenACWY-D 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	

Children and adolescents age 7 through 18 years

Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2022

Always use this table in conjunction with Table 1 and the Notes that follow.

VACCINE	INDICATION										
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count[1]: <15% or total CD4 cell count of <200/mm³	HIV infection CD4+ count[1]: ≥15% and total CD4 cell count of ≥200/mm³	Kidney failure, end-stage renal disease, or on hemodialysis	Heart disease or chronic lung disease	CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Chronic liver disease	Diabetes
Hepatitis B										
Rotavirus		SCID[2]								
Diphtheria, tetanus, and acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
Influenza (IIV4)										
or										
Influenza (LAIV4)						Asthma, wheezing: 2–4yrs[3]				
Measles, mumps, rubella	*									
Varicella	*									
Hepatitis A										
Tetanus, diphtheria, and acellular pertussis (Tdap)										
Human papillomavirus	*									
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Dengue										

Vaccination according to the routine schedule recommended

Recommended for persons with an additional risk factor for which the vaccine would be indicated

Vaccination is recommended, and additional doses may be necessary based on medical condition or vaccine. See Notes.

Precaution—vaccine might be indicated if benefit of protection outweighs risk of adverse reaction

Contraindicated or not recommended—vaccine should not be administered

*Vaccinate after pregnancy

No recommendation/not applicable

1 For additional information regarding HIV laboratory parameters and use of live vaccines, see the *General Best Practice Guidelines for Immunization*, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2 Severe Combined Immunodeficiency
3 LAIV4 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

Notes

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2022

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2022.

Additional information

COVID-19 Vaccination

COVID-19 vaccines are recommended for use within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. ACIP recommendations for the use of COVID-19 vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.

CDC's interim clinical considerations for use of COVID-19 vaccines can be found at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

- Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:67–111).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All routine child and adolescent vaccines are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information, see www.hrsa.gov/vaccinecompensation/index.html.

Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in dengue endemic areas **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/vaccine/hcp/index.html

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix® or Quadracel®])

Routine vaccination

- 5-dose series at age 2, 4, 6, 15–18 months, 4–6 years
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- Wound management in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Haemophilus influenzae type b vaccination (minimum age: 6 weeks)

Routine vaccination

- **ActHIB®, Hiberix®, Pentacel®, or Vaxelis®:** 4-dose series (3 dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis® is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB®:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age 12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB® before age 12 months:** Administer dose 3 (final dose) at 12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Do not require catch-up vaccination

For other catch-up guidance, see Table 2. Vaxelis® can be used for catch-up vaccination in children less than age 5 years. Follow the catch-up schedule even if Vaxelis® is used for one or more doses. For detailed information on use of Vaxelis® see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm.

Special situations

- **Chemotherapy or radiation treatment:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated persons age 5 years or older*
  - 1 dose
- **Elective splenectomy:**
  Unvaccinated persons age 15 months or older*
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated persons age 5–18 years*
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

**Unvaccinated* = Less than routine series (through age 14 months) OR no doses (age 15 months or older)*

Notes

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2022

Hepatitis A vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination
- 2-dose series (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination
- Unvaccinated persons through age 18 years should complete a 2-dose series (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix®**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel
- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses, separated by at least 6 months, between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

Hepatitis B vaccination
(minimum age: birth)

Birth dose (monovalent HepB vaccine only)
- **Mother is HBsAg-negative:**
  - **All** medically stable infants ≥2,000 grams: 1 dose within 24 hours of birth
  - Infants <2,000 grams: Administer 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams).
- **Mother is HBsAg-positive:**
  - Administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** (in separate limbs) within 12 hours of birth, regardless of birth weight. For infants <2,000 grams, administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose.
- **Mother's HBsAg status is unknown:**
  - Administer **HepB vaccine** within 12 hours of birth, regardless of birth weight.
  - For infants <2,000 grams, administer **HBIG** in addition to HepB vaccine (in separate limbs) within 12 hours of birth. Administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
  - Determine mother's HBsAg status as soon as possible. If mother is HBsAg-positive, administer **HBIG** to infants ≥2,000 grams as soon as possible, but no later than 7 days of age.

Routine series
- 3-dose series at age 0, 1–2, 6–18 months (use monovalent HepB vaccine for doses administered before age 6 weeks)
- Infants who did not receive a birth dose should begin the series as soon as feasible (see Table 2).
- Administration of **4 doses** is permitted when a combination vaccine containing HepB is used after the birth dose.
- **Minimum age** for the final (3rd or 4th) dose: 24 weeks
- **Minimum intervals:** dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks (when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations)

Catch-up vaccination
- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB®** only).
- Adolescents age 18 years or older may receive a 2-dose series of HepB **(Heplisav-B®)** at least 4 weeks apart.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix®**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).
- For other catch-up guidance, see Table 2.

Special situations
- Revaccination is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination** (if anti-HBs < 10mIU/mL) is recommended for certain populations, including:
  - **Infants born to HBsAg-positive mothers**
  - **Hemodialysis patients**
  - **Other immunocompromised persons**

For detailed revaccination recommendations, see www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html.

Human papillomavirus vaccination
(minimum age: 9 years)

Routine and catch-up vaccination
- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- **Interrupted schedules:** If vaccination schedule is interrupted, the series does not need to be restarted.
- No additional dose recommended when any HPV vaccine series has been completed using the recommended dosing intervals.

Special situations
- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
- **History of sexual abuse or assault:** Start at age 9 years.
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant

Influenza vaccination
(minimum age: 6 months [IIV], 2 years [LAIV4], 18 years [recombinant influenza vaccine, RIV4])

Routine vaccination
- Use any influenza vaccine appropriate for age and health status annually:
  - 2 doses, separated by at least 4 weeks, for **children age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2021, or whose influenza vaccination history is unknown (administer dose 2 even if the child turns 9 between receipt of dose 1 and dose 2)
  - 1 dose for **children age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2021
  - 1 dose for **all persons age 9 years or older**
- For the 2021-2022 season, see www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm.
- For the 2022–23 season, see the 2022–23 ACIP influenza vaccine recommendations.

Special situations
- **Egg allergy, hives only**: Any influenza vaccine appropriate for age and health status annually
- **Egg allergy with symptoms other than hives** (e.g., angioedema, respiratory distress) or required epinephrine or another emergency medical intervention: see Appendix listing contraindications and precautions
- **Severe allergic reaction (e.g., anaphylaxis) to a vaccine component or a previous dose of any influenza vaccine:** see Appendix listing contraindications and precautions

Measles, mumps, and rubella vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination
- 2-dose series at age 12–15 months, age 4–6 years
- MMR or MMRV may be administered

Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination
- Unvaccinated children and adolescents: 2-dose series at least 4 weeks apart
- The maximum age for use of MMRV is 12 years.
- Minimum interval between MMRV doses: 3 months

Special situations
International travel
- **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.
- **Unvaccinated children age 12 months or older:** 2-dose series at least 4 weeks apart before departure

Meningococcal serogroup A,C,W,Y vaccination (minimum age: 2 months [MenACWY-CRM, Menveo], 9 months [MenACWY-D, Menactra], 2 years [MenACWY-TT, MenQuadfi])

Routine vaccination
- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination
- Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- Age 16–18 years: 1 dose

Special situations
Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:
- **Menveo**
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6 and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **Menactra**
  - **Persistent complement component deficiency or complement inhibitor use:**
    - Age 9–23 months: 2-dose series at least 12 weeks apart
    - Age 24 months or older: 2-dose series at least 8 weeks apart
  - **Anatomic or functional asplenia, sickle cell disease, or HIV infection:**
    - Age 9–23 months: Not recommended
    - Age 24 months or older: 2-dose series at least 8 weeks apart
    - **Menactra®** must be administered at least 4 weeks after completion of PCV13 series.
- **MenQuadfi®**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel in countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/)**:**
- Children less than age 24 months:
  - **Menveo® (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6 and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - **Menactra® (age 9–23 months)**
    - 2-dose series (dose 2 at least 12 weeks after dose 1; dose 2 may be administered as early as 8 weeks after dose 1 in travelers)
- Children age 2 years or older: 1 dose Menveo®, Menactra®, or MenQuadfi®

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:
- 1 dose **Menveo®, Menactra®,** or **MenQuadfi®**

Adolescent vaccination of children who received MenACWY prior to age 10 years:
- **Children for whom boosters are recommended** because of an ongoing increased risk of meningococcal disease (e.g., those with complement deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

Note: Menactra® should be administered either before or at the same time as DTaP. MenACWY vaccines may be administered simultaneously with MenB vaccines if indicated, but at a different anatomic site, if feasible.

For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Meningococcal serogroup B vaccination (minimum age: 10 years [MenB-4C, Bexsero®; MenB-FHbp, Trumenba®])

Shared clinical decision-making
- **Adolescents not at increased risk** age 16–23 years (preferred age 16–18 years) based on shared clinical decision-making:
  - **Bexsero®:** 2-dose series at least 1 month apart
  - **Trumenba®:** 2-dose series at least 6 months apart; if dose 2 is administered earlier than 6 months, administer a 3rd dose at least 4 months after dose 2.

Special situations
Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:
- **Bexsero®:** 2-dose series at least 1 month apart
- **Trumenba®:** 3-dose series at 0, 1–2, 6 months

Note: Bexsero® and **Trumenba®** are not interchangeable; the same product should be used for all doses in a series.

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Pneumococcal vaccination (minimum age: 6 weeks [PCV13], 2 years [PPSV23])

Routine vaccination with PCV13
- 4-dose series at age 2, 4, 6, 12–15 months

Catch-up vaccination with PCV13
- 1 dose for healthy children age 24–59 months with any incomplete* PCV13 series
- For other catch-up guidance, see Table 2.

Special situations
Underlying conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PCV13 and PPSV23 should not be administered during same visit.

Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

Age 6–18 years
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

Cerebrospinal fluid leak, cochlear implant:

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Age 6–18 years
- No history of either PCV13 or PPSV23: 1 dose PCV13, 1 dose PPSV23 at least 8 weeks later
- Any PCV13 but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV13
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent dose of PPSV23

Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose) and a dose 2 of PPSV23 5 years later

Age 6–18 years
- No history of either PCV13 or PPSV23: 1 dose PCV13, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a dose 2 of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13

Chronic liver disease, alcoholism:
Age 6–18 years
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series
See Tables 8, 9, and 11 in the ACIP pneumococcal vaccine recommendations (www.cdc.gov/mmwr/pdf/rr/rr5911.pdf) for complete schedule details.

Poliovirus vaccination (minimum age: 6 weeks)

Routine vaccination
- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination
- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- IPV is not routinely recommended for U.S. residents age 18 years or older.

Series containing oral polio vaccine (OPV), either mixed OPV-IPV or OPV-only series:
- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

Rotavirus vaccination (minimum age: 6 weeks)

Routine vaccination
- **Rotarix®:** 2-dose series at age 2 and 4 months
- **RotaTeq®:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq®** or unknown, default to 3-dose series.

Catch-up vaccination
- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

Tetanus, diphtheria, and pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination
- **Adolescents age 11–12 years:** 1 dose Tdap
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36.
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination
- **Adolescents age 13–18 years who have not received Tdap:** 1 dose Tdap, then Td or Tdap booster every 10 years
- **Persons age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Children age 7–9 years** who receive Tdap should receive the routine Tdap dose at age 11–12 years.
  - **Children age 10 years** who receive Tdap do not need the routine Tdap dose at age 11–12 years.
- **DTaP inadvertently administered on or after age 7 years:**
  - **Children age 7–9 years**: DTaP may count as part of catch-up series. Administer routine Tdap dose at age 11–12 years.
  - **Children age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.

Special situations
- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP OR 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

Varicella vaccination (minimum age: 12 months)

Routine vaccination
- 2-dose series at age 12–15 months, 4–6 years
- VAR or MMRV may be administered*
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4weeks may be counted as valid)

***Note:** For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination
- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid)
  - **Age 13 years and older**: routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of MMRV is 12 years.

Appendix Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2022

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions available at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html *and ACIP's Recommendations for the Prevention and Control of 2021-22 seasonal influenza with Vaccines available at* www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm.

Interim clinical considerations for use of COVID-19 vaccines including contraindications and precautions can be found at
www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Vaccine	Contraindications[1]	Precautions[2]
Influenza, egg-based, inactivated injectable (IIV4)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with egg allergy with symptoms other than hives (e.g., angioedema, respiratory distress) or required epinephrine or another emergency medical intervention: Any influenza vaccine appropriate for age and health status may be administered. If using egg-based IIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable [(ccIIV4), Flucelvax® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable [(RIV4), Flublok® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg- based IIV, ccIIV, or LAIV of any valency. If using RIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated [LAIV4, Flumist® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Children age 2 – 4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years old or older • Persons with egg allergy with symptoms other than hives (e.g., angioedema, respiratory distress) or required epinephrine or another emergency medical intervention: Any influenza vaccine appropriate for age and health status may be administered. If using LAIV4 (which is egg based), administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states

Appendix

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2022

Vaccine	Contraindications[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised)	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria (DT)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For DTaP only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome (GBS) within 6 weeks after previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid— containing or tetanus-toxoid– containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid- containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Hiberix, ActHib, and PedvaxHIB only: History of severe allergic reaction to dry natural latex • Less than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • For Heplisav-B only: Pregnancy	• Moderate or severe acute illness with or without fever
Hepatitis A- Hepatitis B vaccine [HepA-HepB, (Twinrix®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY) [MenACWY-CRM (Menveo®); MenACWY-D (Menactra®); MenACWY-TT (MenQuadfi®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY-D and Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if less than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) [MenB-4C (Bexsero®); MenB-FHbp (Trumenba®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Pneumococcal conjugate (PCV13)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid– containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
Rotavirus (RV) [RV1 (Rotarix®), RV5 (RotaTeq®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid— containing or tetanus-toxoid– containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid– containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long- term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.

CDC Centers for Disease Control and Prevention

Stay Up to Date with Your COVID-19 Vaccines

Updated July 19, 2022

What You Need to Know

- CDC recommends COVID-19 primary series vaccines for everyone ages 6 months and older, and COVID-19 boosters for everyone ages 5 years and older, if eligible.
- People who are moderately or severely immunocompromised have specific recommendations for COVID-19 vaccines, including boosters. Learn more about COVID-19 vaccine recommendations for people who are moderately or severely immunocompromised.
- Use CDC's COVID-19 booster tool to learn if and when you can get boosters to stay up to date with your COVID-19 vaccines.
- The following COVID-19 vaccine and booster recommendations may be updated as CDC continues to use the latest data related to safety and how well vaccines work, including over time and against new variants.

About COVID-19 Vaccines

COVID-19 vaccines available in the United States are effective at protecting people—especially those who are boosted— from getting seriously ill, being hospitalized, and even dying. As with other diseases, you are protected best from COVID-19 when you stay up to date with the recommended vaccines.

Approved or Authorized Vaccines

Pfizer-BioNTech | Moderna | Novavax | Johnson & Johnson's Janssen

When Are You Up to Date?

You are **up to date** with your COVID-19 vaccines when you have received all doses in the primary series and all boosters recommended for you, when eligible.

- Vaccine recommendations are different depending on your age, the vaccine you first received, and time since last dose, as shown below.
- Learn more about COVID-19 vaccine recommendations specifically for people who are moderately or severely immunocompromised.

Adults ages 18 years and older

Pfizer-BioNTech

Primary Series:
2 doses of Pfizer-BioNTech given 3–8 weeks apart[1][2]

Fully Vaccinated: 2 weeks after final dose in primary series

Boosters:

1 booster, preferably of either Pfizer-BioNTech or Moderna COVID-19 vaccine

- For most people at least 5 months after the final dose in the primary series

2nd booster of either Pfizer-BioNTech or Moderna COVID-19 vaccine

- For adults ages 50 years and older at least 4 months after the 1st booster

Up to Date: Immediately after getting all boosters recommended for you[1][2]

Moderna

Primary Series:
2 doses of Moderna given 4–8 weeks apart[1][2]

Fully Vaccinated: 2 weeks after final dose in primary series

Boosters:

1 booster, preferably of either Pfizer-BioNTech or Moderna COVID-19 vaccine

- For most people at least 5 months after the final dose in the primary series

2nd booster of either Pfizer-BioNTech or Moderna COVID-19 vaccine

- For adults ages 50 years and older at least 4 months after the 1st booster

Up to Date: Immediately after getting all boosters recommended for you[1][2]

Johnson & Johnson's Janssen

Primary Series:
1 dose of Johnson & Johnson's Janssen

Fully Vaccinated: 2 weeks after vaccination

Boosters:

1 booster, preferably of either Pfizer-BioNTech or Moderna COVID-19 vaccine

- For most people at least 2 months after a J&J/Janssen COVID-19 vaccine

2nd booster of either Pfizer-BioNTech or Moderna COVID-19 vaccine

- For adults ages 50 years and older at least 4 months after the 1st booster

Up to Date: Immediately after getting all boosters recommended for you [4]

People ages 18 through 49 years who received a J&J/Janssen COVID-19 vaccine for both their primary dose and booster can choose to get a 2nd booster of either Pfizer-BioNTech or Moderna COVID-19 vaccine at least 4 months after their 1st booster. The 2nd booster is not required to be considered up to date for people ages 18 through 49 years who got a J&J/Janssen COVID-19 vaccine for both their primary dose and 1st booster.

Novavax

Primary Series:
2 doses of Novavax [1]

Fully Vaccinated AND Up to Date: 2 weeks after final dose in primary series, since a booster is not recommended at this time for anyone who has completed the Novavax COVID-19 primary series [2]

Children and teens ages 12–17 years

Pfizer-BioNTech

Primary Series:
2 doses of Pfizer-BioNTech given 3–8 weeks apart [1]

Fully Vaccinated: 2 weeks after final dose in primary series

Boosters:
1 booster of Pfizer-BioNTech COVID-19 vaccine is recommended at least 5 months after the final dose in the primary series

Up to Date: Immediately after getting 1st booster [2]

Moderna

Primary Series:
2 doses of Moderna given 4-8 weeks apart [1]

Fully Vaccinated AND Up to Date: 2 weeks after final dose in primary series, since a booster is not recommended at this time for any children or teens who have completed the Moderna COVID-19 primary series [1]

Children ages 11 years and under

Pfizer-BioNTech

Note: Pfizer-BioNTech and Moderna COVID-19 vaccines use different age groups for their children's vaccines.

5–11 YEARS

Primary Series:
2 doses of Pfizer-BioNTech given 3-8 weeks apart [1]

Fully Vaccinated: 2 weeks after final dose in primary series

Boosters:
1 booster of Pfizer-BioNTech COVID-19 vaccine is recommended at least 5 months after the final dose in the primary series

Up to Date: Immediately after getting 1st booster [2]

6 MONTHS–4 YEARS

Primary Series:
3 doses of Pfizer-BioNTech

- 2nd dose is given 3-8 weeks after 1st dose
- 3rd dose is given at least 8 weeks after 2nd dose

Fully Vaccinated AND Up to Date: 2 weeks after final dose in primary series, since a booster is not recommended for this age group at this time [2]

Moderna

Note: Pfizer-BioNTech and Moderna COVID-19 vaccines use different age groups for their children's vaccines.

6–11 YEARS

Primary Series:
2 doses of Moderna given 4-8 weeks apart [1]

Fully Vaccinated AND Up to Date: 2 weeks after final dose in primary series, since a booster is not recommended at this time for any children who have completed the Moderna COVID-19 primary series [2]

6 MONTHS–5 YEARS

Primary Series:
2 doses of Moderna given 4-8 weeks apart [1]

Fully Vaccinated AND Up to Date: 2 weeks after final dose in primary series, since a booster is not currently recommended for children in this age group who have received the Moderna primary series [2]

[1] Talk to your healthcare or vaccine provider about the timing for the 2nd dose in your primary series.

- **People ages 6 months through 64 years, and especially males ages 12 through 39 years**, may consider getting the 2nd primary dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) 8 weeks after the 1st dose. A longer time between the 1st and 2nd primary doses may increase how much protection the vaccines offer, and further minimize the rare risk of heart problems, including myocarditis and pericarditis.
- **People ages 65 years and older, people more likely to get very sick from COVID-19, or anyone wanting protection due to high levels of community transmission** should get:
  - the second dose of **Pfizer-BioNTech** COVID-19 vaccine **3 weeks (or 21 days)** after the first dose, or
  - the second dose of **Moderna** COVID-19 vaccine **4 weeks (or 28 days)** after the first dose.
  - **People ages 18 years and older** should get their second dose of Novavax **3-8 weeks after the first dose.**
  - **People ages 18 years and older** who are moderately or severely immunocompromised should get the second dose of Novavax 3 **weeks after the first dose.**

[2] If you have completed your primary series—but are not yet eligible for a booster—you are also considered up to date.

Mixing COVID-19 Vaccine Products

Primary series

CDC does not recommend mixing products for your primary series doses. If you received Pfizer-BioNTech or Moderna COVID-19 for the first dose of your primary series, you should get the same product for all following primary series doses.

Boosters

People ages 18 years and older may get a different product for a booster than they got for their primary series. Children and teens ages 5 through 17 years who got a Pfizer-BioNTech primary series must get Pfizer-BioNTech for a booster.

Timing of COVID-19 Vaccination After Infection

People who have COVID-19 should wait to receive any vaccine, including a COVID-19 vaccine, until after they recover and complete their isolation period.

Additionally, people who recently had COVID-19 *may* consider delaying their next vaccine dose (primary dose or booster) by 3 months from when their symptoms started or, if they had no symptoms, when they first received a positive test. Reinfection is less likely in the weeks to months after infection. However, certain factors, such as personal risk of severe disease, local COVID-19 community level, and the most common COVID-19 variant currently causing illness, could be reasons to get a vaccine sooner rather than later.

Vaccination Outside the United States

If you received COVID-19 vaccines outside the United States, whether you are up to date depends on which COVID-19 vaccine (and how many doses) you received. Learn more about when people vaccinated outside the United States are considered fully vaccinated.

Allergic Reaction to a COVID-19 Vaccine Product

If you had a severe allergic reaction after a previous dose of a COVID-19 vaccine or if you have a known (diagnosed) allergy to a COVID-19 vaccine ingredient, you should not get that vaccine. If you have been instructed not to get one type of COVID-19 vaccine, you may still be able to get another type.

Scheduling Your COVID-19 Vaccines

> **To find COVID-19 vaccine locations near you:** Search vaccines.gov, text your ZIP code to 438829, or call 1-800-232-0233.

There are several ways you can find a vaccine provider. You can get your COVID-19 vaccines at the same location, or different locations.

- If you need help scheduling your 2nd primary dose or a booster, contact the location that set up your previous appointment. It is never too late to get the added protection offered by completing your primary series or getting a COVID-19 booster.
- Some community vaccination clinics have closed. You can get your 2nd primary dose or a booster at a different location.

Learn more about getting your COVID-19 vaccine.

For Healthcare and Public Health

COVID-19 Clinical and Professional Resources

Related Pages

- Getting a COVID-19 Vaccine
- How COVID-19 Vaccines Work
- Possibility of COVID-19 after Vaccination: Breakthrough Infections
- Meeting Materials for the Advisory Committee on Immunization Practices

Last Updated July 19, 2022

Renewal of Determination That A Public Health Emergency Exists

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective April 16, 2022, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021, July 19, 2021, October 15, 2021, and January 14, 2022, that a public health emergency exists and has existed since January 27, 2020, nationwide.

April 12, 2022 /s/

Date Xavier Becerra

Public Health Emergency Declaration

Declarations of a Public Health Emergency (https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx)

Public Health Emergency Determinations to Support an Emergency Use Authorization (https://www.phe.gov/emergency/news/healthactions/determination/Pages/default.aspx)

Section 1135 Waivers (https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx)

Emergency Use Authorizations (https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm)

Was this page helpful?

O Yes, this page was helpful

O Partially, this page was partially helpful

O No, this page was not helpful

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HHS, Administration for Strategic Preparedness and Response (ASPR)
200 Independence Ave. Washington, DC 20201

VIRGINIA BOARD OF PHARMACY

Vaccine Statewide Protocol

(Effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.)

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention ("CDC") or current emergency use authorization from the U.S. Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer vaccines to persons 3 years of age or older.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use or instructions indicated in the emergency use authorization, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine, a pharmacy technician or pharmacy intern shall have completed a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s) (e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual 3 years of age or older whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC;
- An individual 3 years of age or older whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual 3 years of age or older preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who is fully vaccinated.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. A pharmacist who administers a vaccination to a minor shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

AGENDA ITEM: Nicotine Replacement and other Tobacco Cessation Therapies

STAFF NOTE: HB1323 authorizes pharmacists to initiate treatment for tobacco cessation, including controlled substances. This item requires a new protocol. In the following pages, you will find 2 articles provided courtesy of the American Cancer Society on nicotine replacement and prescription medicines (controlled substances), examples of protocols from Oregon, North Carolina, Indiana, Utah, and a draft Pharmacist Statewide Protocol for Tobacco Cessation.

ACTION: Discuss and determine that the draft "Pharmacist Statewide Protocol for Tobacco Cessation" is comprehensive or if edits or additions are required. The Work Group should approve the document by a vote.

Nicotine Replacement Therapy to Help You Quit Tobacco

Nicotine is the main addictive substance in tobacco. When a person uses tobacco, many parts of the body get used to having nicotine in them. When a person quits tobacco, they also quit nicotine and will likely have withdrawal symptoms from it. This is because the body has to get used to not having nicotine.

The nicotine in tobacco leads to actual physical dependence. This can cause unpleasant withdrawal symptoms when a person tries to quit. Nicotine replacement therapy (NRT) gives you nicotine – in the form of gum, patches, sprays, inhalers, or lozenges – but not the other harmful chemicals in tobacco. NRT can help relieve some of the physical withdrawal symptoms so that you can focus on the psychological (emotional) aspects of quitting.

Many studies have shown using NRT can nearly double the chances of quitting smoking. It hasn't been studied as much for quitting smokeless tobacco, but the NRT lozenges may help.

People who smoke and are significantly dependent on nicotine should consider nicotine replacement or drug therapy to help them quit. Signs of severe nicotine dependence include:

- Smoking more than 1 pack a day
- Smoking within 5 minutes of waking up
- Smoking even while sick
- Waking up at night to smoke
- Smoking to ease symptoms of withdrawal

The more of these that apply, the more serious the nicotine dependence.

How does nicotine replacement therapy work?

Nicotine replacement therapy (NRT) can help with the difficult withdrawal symptoms and cravings that most people say is their only reason for not giving up tobacco. Using NRT reduces those symptoms.

Many people can quit tobacco without using NRT, but most of those who attempt quitting do not succeed on the first try. In fact, people trying to quit usually need many tries before they're able to quit for good. Most people who try to quit on their own go back to smoking within the first month of quitting – often because of the withdrawal symptoms. **But the good news is that many do succeed. In fact, there are now**

more people who formerly smoked than people who currently smoke!

Together with counseling or other support, NRT may help increase the number of smokeless tobacco users who quit, too.

You can start using nicotine replacement therapy (NRT) as soon as you throw away your tobacco. You don't need to wait a certain length of time to put on the patch or start using the gum, lozenge, nasal spray, or inhaler. Double-check this information with the instructions on your chosen method of nicotine replacement, but in general there's no need to wait to start using NRT.

Getting the most from nicotine replacement therapy

Nicotine replacement therapy (NRT) only deals with the physical dependence. It's not meant to be the only thing you use to help you quit smoking. You'll need other methods that help with the psychological (emotional and mental) part of tobacco, such as a quit program. Use these support systems during treatment with NRT and for at least a few months after you quit. Studies have shown that this approach – pairing NRT with a program that helps to change behavior – can improve your chances of quitting and staying quit compared to approaches that use only one method.

The best time to start NRT is when you first quit. Often people first try to quit tobacco on their own then decide to try NRT a day or more into quitting. This does not give you the greatest chance of success, but don't let this discourage you. There are many options for quitting and staying quit. Just remember that it often takes many tries.

The Food and Drug Administration (FDA) has approved the NRT products discussed here as effective aids for helping people quit smoking. None of these products has been FDA-approved specifically to help people quit smokeless tobacco. Still, studies are being done, and some have shown the lozenge form may help.

Who should not use nicotine replacement therapy?

The US Agency for Healthcare Research and Quality states that nicotine replacement therapy (NRT) is safe for all adults who want to quit smoking except pregnant women and teens. Still, it's best to discuss NRT use with your health care provider before starting it. You may have medical problems that should be considered. When deciding whether to use NRT, the benefits of quitting tobacco must outweigh the potential health risks of NRT for each person.

People who are still smoking or using any other form of tobacco should not use NRT. The companies that make NRT products warn that you should not use them if you're still using tobacco, and the FDA has not approved them to be used in this way. Get the advice of a health care provider if you want to use NRT while continuing to smoke or chew.

NRT has not yet been proven to help people who smoke fewer than 10 cigarettes a day. But many tobacco treatment centers do use NRT for people who are "light smokers." Talk with your health care provider about a lower dose of NRT if you smoke less than that but feel you need nicotine replacement.

Types of nicotine replacement therapy

The US Food and Drug Administration (FDA) has approved 5 forms of nicotine replacement therapy (NRT):

- Patch
- Gum
- Nasal spray
- Inhalers
- Lozenges

Note that the patch, gum, and lozenge can be purchased over the counter, while the nasal spray and inhaler require a prescription.

The most important thing to do with any form of NRT is read and follow the package instructions very carefully.

Nicotine patches (transdermal nicotine systems)

Patches can be bought with or without a prescription.

Patches give a measured dose of nicotine through the skin. You're weaned off nicotine by switching to lower-dose patches over a course of weeks.

Many different types and strengths of patches are available, including 16-hour and 24-hour patches. Which patch you should use depends on how many cigarettes you smoke each day. Package instructions tell you how to use them, and list special considerations and possible side effects.

How to use nicotine patches: Depending on body size and smoking habits, most people who smoke should start using a full-strength patch (15-22 mg of nicotine) daily for several weeks, and then use a weaker patch (5-14 mg of nicotine) for another several weeks. The patch is changed every day. It should be put on in the morning on a clean, dry area of the skin without much hair. It should be placed below the neck and above the waist – for instance, on the upper arm or chest. The FDA has approved using the patch for a total of 3 to 5 months, but using it longer is better than going back to

smoking.

Possible side effects of the nicotine patch include:

- Skin irritation (redness and itching)
- Dizziness
- Racing heartbeat
- Sleep problems or unusual dreams (more common with the 24-hour patch)
- Headache
- Nausea
- Muscle aches and stiffness

No one has all of the side effects, and some people have none. Some side effects, such as racing heart, may mean the dose of nicotine is too high for you. Stop using the patch and talk to your health care provider if this happens. You could also have nicotine withdrawal symptoms if your NRT dose is too low.

What to do about side effects

- Try a different brand of patch if your skin becomes irritated.
- Reduce the amount of nicotine by using a lower-dose patch.
- Sleep problems may go away in 3 or 4 days. If not, and you're using a 24-hour patch, try switching to a 16-hour patch.
- Stop using the patch and try a different form of NRT.

Nicotine gum (nicotine polacrilex)

Nicotine gum can be bought without a prescription.

Nicotine gum is a fast-acting form of replacement. Nicotine is taken in through the mucous membrane of the mouth. You can buy it over the counter (without a prescription). It comes in 2 mg and 4 mg strengths.

In choosing your dose, think about whether you

- Smoke 25 or more cigarettes per day
- Smoke within 30 minutes of waking up
- Have trouble not smoking in restricted areas

If any of these describe you, you may need to start with the higher 4mg gum dose.

How to use nicotine gum

For best results, follow the instructions in the package. Nicotine gum is not meant to be used like regular gum. Chew the gum slowly until you get a peppery taste or tingle. Then tuck it inside your cheek until the taste fades. Chew it to get the peppery taste back, and hold it again. Do this off and on for 20 to 30 minutes. Food and drink can affect how well the nicotine is absorbed, so don't eat or drink for at least 15 minutes before and during gum use. This is important because many people misuse the nicotine gum and chew it like regular gum instead of how it should be used.

An advantage of nicotine gum is that it allows you to control the amount of nicotine you get. The gum can be used as needed or on a fixed schedule during the day. The most recent research has shown that scheduled dosing works better. A schedule of 1 to 2 pieces per hour is common. On the other hand, with an as-needed schedule, you can use it when you need it most – when you have cravings.

Chew no more than 24 pieces of gum in one day. Nicotine gum is usually recommended for 6 to 12 weeks, with the maximum being 6 months. Tapering down the amount of gum you use as you approach 3 months may help you stop using it. But it is better to keep using the gum rather than starting to smoke again.

Possible side effects of nicotine gum include:

- Bad taste
- Throat irritation
- Mouth sores
- Hiccups
- Nausea
- Jaw discomfort
- Racing heartbeat

The gum can also stick to and damage dentures and dental work.

Stomach and jaw discomfort are usually caused by improper use of the gum, such as swallowing the nicotine or chewing too fast. No one has all of the side effects, and some people have none. If your heart is racing or beating irregularly, stop using the gum and talk to your health care provider. You could also have nicotine withdrawal symptoms if your NRT dose is too low.

Nicotine nasal spray

Nicotine nasal spray is only available by prescription.

The nasal spray delivers nicotine to the bloodstream rapidly because it's absorbed through the nose. It relieves withdrawal symptoms very quickly and lets you control your nicotine cravings.

How to use nicotine nasal spray

Most people are told to use 1 to 2 doses per hour. (1 dose = 2 sprays, 1 in each nostril.) At least 8 doses (16 sprays) each day may be needed when you first start, but use as directed by your health care provider. You should not use more than 40 doses (80 sprays) per day. Instructions can vary. Talk to your provider about the plan that's best for you.

The FDA recommends that the spray be prescribed for 3-month periods and that it not be used for longer than 6 months.

Possible side effects of nicotine spray

The most common side effects of the spray get better in about 1 to 2 weeks and can include:

- Nasal irritation
- Runny nose
- Watery eyes
- Sneezing
- Throat irritation
- Coughing

Other side effects are related to nicotine:

- Racing heart
- Nervousness
- Headache

No one has all of the side effects, and some people have none. Some side effects, such as racing heart, may occur because you've gotten too much nicotine. Stop using the spray to see if the feelings get better and talk to your health care provider if this happens. You may need to use it less often. You could also have nicotine withdrawal symptoms if your NRT dose is too low.

If you have asthma, allergies, nasal polyps, or sinus problems, your provider may suggest another form of NRT.

Special note: This form of NRT poses a more serious risk to small children and pets because the empty bottles of nasal spray contain enough nicotine to harm them. Do not get the liquid on your skin. If there's any skin contact, rinse thoroughly with plain water right away. If a bottle breaks or liquid leaks out, put on plastic or rubber gloves to clean it up. Call Poison Control and get emergency help if there's any question of overdose.

Nicotine inhalers

Inhalers are available only by prescription.

The nicotine inhaler is a thin plastic tube with a nicotine cartridge inside. Unlike other inhalers, which deliver most of the medicine to the lungs, the nicotine inhaler delivers most of the nicotine vapor to the mouth and throat where it's absorbed into the bloodstream.

Nicotine inhalers are the FDA-approved nicotine replacement method that's most like smoking a cigarette, which some people trying to quit find helpful. They are not the same as electronic cigarettes, which are not approved by the FDA to help people quit smoking. At this time, inhalers are the most expensive form of NRT available.

How to use the nicotine oral inhaler

You puff on the inhaler and the cartridge sends a pure nicotine vapor into your mouth. You may use up the cartridge all at once over about 20 minutes, or puff on it only a few minutes at a time. The recommended dose is between 4 and 20 cartridges a day, slowly tapering off over 6 months.

Possible side effects of the nicotine inhaler

The most common side effects, especially when first using the inhaler, include:

- Coughing
- Mouth and/or throat irritation
- Runny nose
- Upset stomach

Other side effects are related to nicotine:

- Racing heart
- Nervousness
- Headache

No one has all of the side effects, and some people have none. Some side effects, such as racing heart, may occur because you've gotten too much nicotine. Stop using the inhaler to see if the feelings get better and talk to your health care provider if this happens. You may need to use it less often. You could also have nicotine withdrawal symptoms if your NRT dose is too low.

Special note: This form of NRT poses an extra risk to small children and pets because the used cartridges still have enough nicotine in them to cause harm if it gets on skin or mucous membranes (for instance, if licked or touched to the eyes, mouth, or other mucous membrane). Be sure to store and dispose of the cartridges away from children and pets. Call Poison Control and get emergency help if there's any question of overdose.

Nicotine lozenges

Nicotine lozenges can be bought without a prescription.

The lozenge is available in 2 strengths: 2 mg and 4 mg. The needed dose should be based on how long after waking up a person normally has their first cigarette. So, if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine lozenges. If you smoke your first cigarette more than 30 minutes after waking up, use 2 mg-nicotine lozenges. Some people who are using NRT prefer the lozenge to the gum because its use is less conspicuous.

How to use nicotine lozenges

The recommended dose is 1 lozenge every 1 to 2 hours for 6 weeks, then 1 lozenge every 2 to 4 hours for weeks 7 to 9, and finally, 1 lozenge every 4 to 8 hours for weeks 10 to 12. The lozenge makers also recommend:

- Do not eat or drink for at least 15 minutes before using a lozenge or while using a lozenge. (Some drinks can reduce how well the lozenge works.)
- Do not use more than 1 lozenge at a time and do not use one right after another.
- Suck on the lozenge until it is fully dissolved, about 20 to 30 minutes. Move it from side to side in your mouth. Do not bite or chew it like a hard candy, and don't swallow it. The nicotine absorbs through the mucous membranes of the mouth.
- Do not use more than 5 lozenges in 6 hours, or more than 20 lozenges per day.

- Stop using the lozenge after 12 weeks. If you still feel you need to use the lozenge, talk to your doctor.

Possible side effects of the nicotine lozenge

- Nausea
- Hiccups
- Sore throat
- Coughing
- Heartburn
- Headache
- Gas
- Trouble sleeping
- Racing heart

Choosing and using the right nicotine replacement therapy for you

No one type of nicotine replacement therapy (NRT) - by itself or in combination - is necessarily any better than another. When choosing the type of NRT you will use, think about which method will best fit your lifestyle and pattern of smoking or using smokeless tobacco. For example, do you want/need something in your mouth or something to keep your hands busy? Are you looking for once-a-day convenience? How urgent are your cravings for nicotine?

Here are some important points to think about as you decide:

- Nicotine gums, lozenges, and inhalers are substitutes you can put into your mouth that let you control your dosage to help keep cravings under better control.
- Nicotine gums and lozenges are generally sugar-free, but if you are diabetic and have any doubts, check with the manufacturer.
- Nicotine nasal spray works very quickly when you need it.
- Nicotine inhalers allow you to mimic the use of cigarettes by puffing and holding the inhaler. It also works very quickly.
- Nicotine patches are convenient and only have to be put on once a day.
- Both inhalers and nasal sprays require a doctor's prescription.
- Some people may not be able to use patches, inhalers, or nasal sprays because of allergies or other conditions.
- Nicotine gum may stick to dentures or dental work making it hard to chew before "parking."

Whatever type you use, take your NRT at the recommended dose. NRT is not recommended for long-term use, but if it's needed to prevent relapse, continuing to use NRT is preferable than returning to smoking.

If you use a different dose or stop taking it too soon, NRT can't be expected to work like it should. If you smoke very heavily very lightly, or are a smokeless tobacco user, talk with your health care provider about how to get the NRT dose that best fits your needs.

What is light, average, and heavy smoking?

Most nicotine replacement therapy (NRT) products recommendations are based on how much you smoke. But there's no formal category in any textbook or group that defines how much smoking is considered light, average, or heavy smoking.

These are general guidelines:

- Light smoking: Fewer than 10 cigarettes per day
- Heavy smoking: A pack a day or more
- Average smoking falls in between.

How do I know what NRT dose to use based on my smokeless tobacco use?

NRT products are supposed to roughly match the amount of nicotine you typically took in through tobacco. It can be more of a challenge to get the dose right for smokeless tobacco users, since NRT products are labeled for people who smoke.

Certain types of NRT may help more than others. If you look at the way the tobacco is used, nicotine gum and lozenges are most like using smokeless tobacco. They also let you control your dose to help keep nicotine cravings down. To avoid withdrawal symptoms, you want to aim for a nicotine dose fairly close to what you got from snuff or tobacco use.

These are general guidelines:

- A heavy user is a person who uses more than 3 cans of snuff or 3 pouches of tobacco a week, and would typically use the higher doses of NRT (the dose for people who smoke heavily).
- Those who use 2 to 3 cans or pouches per week would usually try the moderate doses.
- Those who use less than 2 would start with the lowest doses of NRT.

If you've decided to try NRT, discuss your dose with a health care provider before you quit tobacco.

Combining the patch and other nicotine replacement products

Using the nicotine patch along with shorter-acting products, like the gum, lozenge, nasal spray, or inhaler, is another method of NRT. The idea is to get a steady dose of nicotine with the patch and then use one of the shorter-acting products when you have strong cravings. In general, people who have smoked heavily do better with this combination approach. If you're thinking about using more than one NRT product, be sure to talk to your health care provider first.

High-dose nicotine replacement therapy for people who smoke heavily

For people who have been smoking heavily, Another option is to use NRT at a higher than usual dose based on the amount of nicotine that they've been getting from cigarettes. At this time, not much is known about this option. High-dose NRT should be considered only with a health care provider's guidance and close supervision.

Can you get too much nicotine from NRT?

Nicotine overdose is rare, but possible. Nicotine replacement therapy (NRT) products are labeled to match the amount of nicotine you get from NRT to the amount you got from tobacco. If used this way, you should get a nicotine dose fairly close to what you've been getting. You don't want to get more than that, because higher doses of nicotine can cause harm. To avoid this, follow dosing instructions carefully. Also, don't use heat (like a heating pad or heat lamp) on the skin near your nicotine patch – you could absorb more nicotine due to the increased blood supply.

Nicotine absorbs through the skin and mucous membranes, so you must store and dispose of your NRT safely. Nicotine overdose can be fatal, but this is rare and requires taking in very high doses of nicotine. Overdose is more of a problem in children and pets because of their smaller size. Keep NRT and used gum, patches, empty cartridges, bottles, etc., safely away from children and pets. Never drop them on the street or in open trash cans where kids and animals can reach them.

Symptoms of nicotine overdose

Here are some symptoms of too much nicotine:

- Headache
- Nausea and vomiting
- Belly pain
- Diarrhea
- Agitation, restlessness

- Fast or irregular heartbeat
- Cold sweat
- Pale skin and mouth
- Weakness
- Tremors (shaking)
- Confusion
- Disturbed vision and hearing
- Weakness
- High blood pressure, which then drops
- Dizziness or faintness due to low blood pressure
- Seizures
- Fast breathing in early poisoning, breathing may stop later

Call Poison Control and get emergency help if you suspect an overdose. If you're taking NRT as prescribed and are still having mild symptoms such as headache, vomiting, diarrhea, or sweating, lower your dose and talk to your health care provider.

Does nicotine cause cancer?

No, nicotine has not been found to cause cancer. While nicotine is the addictive substance in tobacco, it is other compounds in tobacco that can cause cancer. Using NRT to quit tobacco does not increase your risk of cancer – in fact, it can help lower your risk if it helps you stop using tobacco.

Stopping nicotine replacement therapy

Nicotine replacement therapy (NRT) is meant to be used for a limited period of time. Use should be tapered down before NRT is stopped. Studies to date have not shown that extending NRT use longer than the recommended time greatly impacts quit success. However, long-term NRT use is still preferable to smoking.

Research is still being done to refine the use of NRT. If you feel that you need NRT for a different length of time than is recommended, it's best to discuss this with your health care provider.

Long-term nicotine replacement therapy dependence

Nicotine replacement therapy (NRT) has the potential for long-term dependence. Nicotine is addictive, and people can transfer their dependence from tobacco to the NRT.

Use NRT only as long as you need it, as prescribed by your health care provider. Talk to your provider if you're having trouble stopping NRT.

Hyperlinks

1. smokingcessationleadership.ucsf.edu/

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Last Revised: August 2, 2021

Prescription Medicines to Help You Quit Tobacco

There are prescription drugs that have been shown to help people quit tobacco. Some can be used along with nicotine replacement therapy (NRT). You often need to start taking them in the weeks before your Quit Day (the day you plan to quit).

People who are significantly dependent on nicotine should consider nicotine replacement and/or drug therapy to help them quit. Signs of severe nicotine dependence in people who smoke include:

- Smoking more than 1 pack a day
- Smoking within 5 minutes of waking up
- Smoking even while sick
- Waking up at night to smoke
- Smoking to ease symptoms of withdrawal

The more of these that apply, the more serious the dependence.

Talk to your health care provider if you think you might want to use one of these drugs to help you quit tobacco. You'll need a prescription. It's also a good idea to talk to your health insurance about coverage for these medications.

If you plan to use a prescription drug to quit tobacco, talk with your health care provider about exactly when to start, and how to use the medicine. Also find out what side effects to watch for and report. Put a note on your calendar to remind you when to start taking it.

Varenicline (Chantix)

Varenicline (also called Chantix) is a prescription medicine developed to help people stop smoking. It works by interfering with nicotine receptors in the brain. This means it has 2 effects:

- It lessens the pleasure a person gets from smoking.
- It reduces the symptoms of nicotine withdrawal.

For people trying to quit smokeless tobacco, several studies have shown varenicline can increase their chance of quitting when compared to taking no medicines at all, at least in the short term. (Some studies have also found NRT lozenges can help.)

You typically start taking varenicline (a pill) about a month to a week before your Quit Day. Take it after meals, with a full glass of water. The daily dose increases over the

first 8 days you take it. If you have problems with the higher doses, a lower dose may be used while you try to quit.

Typically, varenicline is given for 12 weeks, but people who quit during that time may get another 12 weeks of treatment to boost their chances of staying off tobacco. It's important to keep up with other support systems during this time and for at least a few months after quitting.

Tell your provider about any medical conditions and allergies you have before you start varenicline, including if you might be pregnant.

Side effects of varenicline

Reported side effects have included:

- Nausea
- Vomiting
- Headache
- Trouble sleeping, unusual dreams, or sleepwalking
- Constipation
- Gas
- Changes in taste
- Skin rashes
- Seizures
- Heart or blood vessel problems (mostly in people who already have these problems)
- Mood or behavior changes, such as depression, hallucinations, delusions, aggression, hostility, agitation, anxiety, panic, or even suicidal thoughts

Talk to your health care team about what to expect while taking this drug, and what to do if you or others notice possible side effects. Be sure to let your provider know if you've ever had depression or other mental health problems, or if you start feeling depressed or have thoughts about suicide.

Using varenicline along with NRT or bupropion for quitting smoking

Research is being done to find out if varenicline can be used at the same time as nicotine replacement therapy (NRT). A few studies have suggested that using varenicline along with NRT is well-tolerated and safe, but others have found this has no long-term benefit in helping people quit. More research is needed.

Research on using both varenicline and bupropion at the same time is also being done. While there may be a benefit to combining the drugs vs. taking only varenicline, more research is needed to understand if this could cause more severe side effects.

Bupropion (Zyban)

Bupropion alsomay be called by the brand names Zyban, Wellbutrin, or Aplenzin. It's a prescription antidepressant in an extended-release form that helps reduce cravings and symptoms of nicotine withdrawal. It does not contain nicotine. This drug acts on chemicals in the brain that are related to nicotine craving. Bupropion works best if it's started 1 or 2 weeks before you quit smoking. The usual dosage is one or two 150 mg tablets per day.

If you're still not using tobacco after taking bupropion for 7 to 12 weeks, your provider may have you keep taking it for some time afterward to help stop you from going back to smoking. Keep up with your other support systems during this time and for at least a few months after you quit.

This drug **should not be taken** if you have or have ever had:

- Seizures (it can cause or worsen seizures)
- Heavy alcohol use
- Cirrhosis
- A serious head injury
- Bipolar (manic-depressive) illness
- Anorexia or bulimia (eating disorders)

You also shouldn't take it if you're taking sedatives or have recently taken a monoamine oxidase inhibitor (MAOI, an older type of antidepressant).

Tell your doctor about any medical conditions and allergies you have before you start bupropion, including if you might be pregnant.

Side effects of bupropion

Reported side effects of bupropion include:

- Dry mouth
- Stuffy nose
- Trouble sleeping and nightmares
- Tiredness
- Constipation
- Nausea
- Headaches
- High blood pressure
- Seizures

- Feeling depressed, anxious, agitated, hostile, aggressive, overly excited or hyperactive, or confused; or having suicidal thoughts

If you are using bupropion, call your health care provider if you feel depressed or start thinking of suicide. Also be sure to ask what to expect while taking this drug, and what to do if you or others notice possible side effects.

Bupropion can cause drug interactions and shouldn't be used with certain other drugs or supplements. Be sure your provider knows about everything you take, such as prescription drugs, vitamins, herbs, supplements, and any medicines you take on your own when you need them, like acetaminophen (Tylenol) or aspirin. Also be sure to tell every provider you see that you're taking bupropion.

Using bupropion along with NRT or varenicline for quitting smoking

There is some consensus that using bupropion along with NRT might increase the odds of quitting. Research on using both varenicline and bupropion at the same time is also being done.

Other prescription drugs used to help people quit tobacco

For those who can't use either of the US Food and Drug Administration (FDA)-approved drugs to help them quit, or for those who haven't been able to quit using them, other drugs have shown promise in studies. They're recommended by the Agency for Healthcare Research and Quality for this kind of use, but have not been approved by the FDA for this purpose and so are used "off-label." (See Off-label Drug Use[1] for more on this.) These drugs are only available with a prescription and are not recommended for pregnant women, teens, or people who smoke fewer than 10 cigarettes a day.

Nortriptyline

This is an older anti-depressant drug that helps reduce tobacco withdrawal symptoms. It has been found to increase chances of success in quitting smoking when compared to those taking no medicine. It's typically started 10 to 28 days before a person stops smoking to allow it to reach a stable level in the body.

Some people have side effects like a fast heart rate, blurred vision, trouble urinating, dry mouth, constipation, weight gain or loss, and low blood pressure when they stand up. The drug can affect a person's ability to drive or operate machinery, and certain drugs cannot be used along with it.

If you and your health care provider decide to use this drug, be sure your provider and pharmacist know exactly what other drugs you're taking before you start this medicine.

Also be sure you know how to take it and how to taper off it when you are ready to stop. The dose of nortriptyline must be slowly lowered, since the drug cannot be stopped suddenly without the risk of serious effects. People with heart disease should use this drug cautiously. Be sure to tell all your health care providers that you are taking this drug.

Clonidine

Clonidine is another older drug that has been shown to help people quit. It's FDA-approved to treat high blood pressure. When used to quit smoking, it can be taken as a pill twice a day or worn as a skin patch that's changed once a week.

If you're planning to use this drug, be sure your health care provider and pharmacist know exactly what else you're taking before you start taking it. The most common side effects of clonidine are constipation, dizziness, drowsiness, dry mouth, and unusual tiredness or weakness. There are rarely more severe side effects, such as allergic reactions, a slow heart rate, and very high or very low blood pressure. Your health provider might want to watch your blood pressure while you are on this drug. The drug can affect your ability to drive or operate machinery.

You can start taking clonidine up to 3 days before you quit smoking, but it can also be started the day you quit. It shouldn't be stopped suddenly. The dose must be lowered over a few days to prevent tremors, confusion, agitation, or a rapid increase in blood pressure.

Other drugs being studied to help people quit tobacco

A plant-based drug called **cytisine** has shown promise in other countries and is now being studied in the United States.

Naltrexone is a drug used to help those with alcohol and opioid abuse disorders. Studies are looking at ways to combine it with varenicline to help people quit smoking, especially people who smoke and are also heavy drinkers.

Also being tested are possible **anti-smoking vaccines** that are given as injections.

So far these new options seem to be safe, but their effect on smoking cessation has been disappointing.

Hyperlinks

1. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/off-label-drug-use.html
2. smokingcessationleadership.ucsf.edu/

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PREVENTIVE CARE

TOBACCO CESSATION – NRT (Nicotine Replacement Therapy) and Non-NRT

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe individual or multiple Nicotine Replacement Therapy (NRT) OTC and Rx for tobacco cessation.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe non-NRT medications for tobacco cessation.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Tobacco Cessation Patient Intake Form (pg. 2-3)
- Utilize the standardized Tobacco Cessation Assessment and Treatment Care Pathway (pg. 4-6)

PHARMACIST TRAINING/EDUCATION:

- Minimum 2 hours of documented ACPE CE related to pharmacist prescribing of tobacco cessation products

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date ____/____/_____ Date of Birth ____/____/_____ Age____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____
Any allergies to foods (ex. menthol/soy)? Yes / No If yes, please list _____
List of medicine(s) you take:_____

_____

_____

Do you have a preferred tobacco cessation product you would like to use?_____
Have you tried quitting smoking in the past? If so, please describe _____
What best describes how you have tried to stop smoking in the past?

- ☐ "Cold turkey"
- ☐ Tapering or slowly reducing the number of cigarettes you smoke a day
- ☐ Medicine
  - o Nicotine replacement (like patches, gum, inhalers, lozenges, etc.)
  - o Prescription medications (ex. bupropion [Zyban®, Wellbutrin®], varenicline [Chantix®])
- ☐ Other_____

Health and History Screen – Background Information:

1.	Are you under 18 years old?	□ Yes □ No
2.	Are you pregnant, nursing, or planning on getting pregnant or nursing in the next 6 months?	□ Yes □ No □ Not sure
3.	Are you currently using and trying to quit non-cigarette products (ex. Chewing tobacco, vaping, e-cigarettes, Juul)?	□ Yes □ No

Medical History:

4.	Have you ever had a heart attack, irregular heartbeat or angina, or chest pains in the past two weeks?	□ Yes □ No □ Not sure
5.	Do you have stomach ulcers?	□ Yes □ No □ Not sure
6.	Do you wear dentures or have TMJ (temporomandibular joint disease)?	□ Yes □ No □ Not sure
7.	Do you have a chronic nasal disorder (ex. nasal polyps, sinusitis, rhinitis)?	□ Yes □ No □ Not sure
8.	Do you have asthma or another chronic lung disorder (ex. COPD, emphysema, chronic bronchitis)?	□ Yes □ No □ Not sure

Tobacco History:

9.	Do you smoke fewer than 10 cigarettes a day?	□ Yes □ No

Blood Pressure Reading ____/____ mmHg (**Note: Must be taken by a pharmacist*)

Stop here if patient and pharmacist are considering nicotine replacement therapy or blood pressure is ≥ 160/100 mmHg.

If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) and blood pressure is < 160/100mmHg continue to answer the questions below.

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Medical History Continued:

10.	Have you ever had an eating disorder such as anorexia or bulimia?	□ Yes □ No □ Not sure
11.	Have you ever had a seizure, convulsion, significant head trauma, brain surgery, history of stroke, or a diagnosis of epilepsy?	□ Yes □ No □ Not sure
12.	Have you ever been diagnosed with chronic kidney disease?	□ Yes □ No □ Not sure
13.	Have you ever been diagnosed with liver disease?	□ Yes □ No □ Not sure
14.	Have you been diagnosed with or treated for a mental health illness in the past 2 years? (ex. depression, anxiety, bipolar disorder, schizophrenia)?	□ Yes □ No □ Not sure

Medication History:

15.	Do you take a monoamine oxidase inhibitor (MAOI) antidepressant? (ex. selegiline [Emsam®, Zelapar®], Phenelzine [Nardil®], Isocarboxazid [Marplan®], Tranylcypromine [Parnate®], Rasagiline [Azilect®])	□ Yes □ No □ Not sure
16.	Do you take linezolid?	□ Yes □ No □ Not sure
17.	Do you use alcohol or have you recently stopped taking sedatives? (ex. Benzodiazepines)	□ Yes □ No □ Not sure

The Patient Health Questionnaire 2 (PHQ 2):

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3

Suicide Screening:

Over the last 2 weeks, how often have you had thoughts that you would be better off dead, or have you hurt yourself or had thoughts of hurting yourself in some way?	0	1	2	3

Patient Signature_____Date_____

Tobacco Cessation Assessment & Treatment Care Pathway

STEP 1: Health and History Screen Part 1 Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	No = No Contraindicating Conditions. Continue to step 2	Yes/Not sure = Contraindicating Conditions. Refer	Refer to PCP and/or Oregon Quit Line 1-800-QUIT-NOW
STEP 2: Health and History Screen Part 2 Review Tobacco Cessation Patient Questionnaire (Question 3)	Smoking Cigarettes. Continue to step 3	Yes to question 3 Refer	Refer to Oregon Quit Line 1-800-QUIT-NOW to receive counseling and NRT
STEP 3: Blood Pressure Screen Take and document patient's current blood pressure. (Note: RPh may choose to take a second reading if initial is high)	BP < 160/100. Continue to step 4	BP ≥ 160/100 Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW
STEP 4: Medical History Nicotine Replacement Therapy Questions (Questions 4-5)	No, to question 4 and 5. Continue to step 5	Yes, to question 4 and/or 5 Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW

STEP 5: Medical History Nicotine Replacement Therapy Questions (Questions 6-8) Question 6 = if Yes, avoid using nicotine gum Question 7 = if Yes, avoid using nicotine nasal spray Question 8 = if Yes, avoid using nicotine inhaler	If patient wants NRT, prescribe NRT*	If patient wants bupropion or varenicline, continue to step 6.

Prescribing NRT*(pg.6): • Combination NRT is preferred (Nicotine patch + Acute NRT) • Acute NRT = Nicotine gum, Nicotine lozenge, Nicotine nasal spray, Nicotine inhaler	**Tobacco History (Question 9 on questionnaire)** If Yes to smoking </=10 cigs/day, start with nicotine patch 14mg/day If No to smoking > 10 cigs/day start with nicotine patch 21mg/day

STEP 6: Medical History Bupropion and varenicline screening Questions 10-14	Consider NRT* if yes to any question from 10-14		
	a) If yes to any question → avoid bupropion. If patient still wants bupropion, refer.	Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW; NRT* can be considered
	b) If yes to any questions from 12-14→ avoid varenicline. If patient still wants varenicline, refer.	Refer	
	If patient answered no to questions 10 – 14, continue to step 7. If patient answered no to questions 12-14, but yes to question 10 and/or 11, AND wants varenicline (but not bupropion), skip to step 8		

STEP 7: Medication History Questions 15-17 on questionnaire.	If patient answered no to questions 15-17, review depression screening step 8.	If patient answered yes to any question from 15-17 → Avoid bupropion. - Refer if patient still wants bupropion. - If patient wants varenicline, continue to depression screening step 8.	Refer	Refer to PCP if patient wants bupropion; NRT* can be considered

STEP 8: The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	Score < 3 on PHQ2. Review Suicide Screening in step 9.	Score ≥ 3 on PHQ. Avoid bupropion and varenicline, refer to PCP for treatment. NRT* can be offered.	Refer	Refer to PCP; NRT* can be considered

STEP 9: Suicide Screening	Score of 0 on suicide screening. May prescribe bupropion or varenicline.	Score ≥ 1 on suicide screening. **Immediate** referral to PCP.	Refer	Call PCP office to notify them of positive suicide screening and determine next steps. After hours, refer to suicide hotline 1-800-273-8255

Prescribing Bupropion:	**Prescribing Varenicline:**
150mg SR daily for 3 days then 150mg SR twice daily for 8 weeks or longer. Quit day after day 7. Consider combining with Nicotine patch or Nicotine lozenge or Nicotine gum for increased efficacy.* For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.	0.5mg daily for 3 days then 0.5mg twice daily for 4 days then 1mg twice daily for 12 to 24 weeks. Quit day after day 7 or alternatively quit date up to 35 days after initiation of varenicline. Generally not used in combination with other smoking cessation medications as first line therapy.

Tobacco Cessation Assessment & Treatment Care Pathway

*Nicotine Replacement Dosing:

	Dose
Long Acting NRT	
Nicotine Patches	• Patients smoking >10 cigarettes/day: begin with 21mg/day for 6 weeks, followed by 14mg/day for 2 weeks, finish with 7mg/day for 2 weeks • Patients smoking ≤ 10 cigarettes/day: begin with 14mg/day for 6 weeks, followed by 7mg/day for 2 weeks • **Note:** Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).
Acute NRT	
Nicotine Gum	• Chew 1 piece of gum when urge to smoke occurs. If strong or frequent cravings are present after 1 piece of gum, may use a second piece within the hour (do not continuously use one piece after the other). • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: Chew 1 piece of gum every 1 to 2 hours (maximum: 24 pieces/day); if using nicotine gum alone without nicotine patches, to increase chances of quitting, chew at least 9 pieces/day during the first 6 weeks o Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day) o Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day)
Nicotine Lozenges	• 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: 1 lozenge every 1 to 2 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day); if using nicotine lozenges alone without nicotine patches, to increase chances of quitting, use at least 9 lozenges/day during the first 6 weeks o Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) o Weeks 10 to 12: 1 lozenge every 4 to 8 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)
Nicotine Inhaler	• *Initial treatment*: 6 to 16 cartridges/day for up to 12 weeks; maximum: 16 cartridges/day • Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. • *Discontinuation of therapy:* After initial treatment, gradually reduce daily dose over 6 to 12 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.
Nicotine Nasal Spray	• Initial: 1 to 2 doses/hour (each dose [2 sprays, one in each nostril] contains 1 mg of nicotine) • Adjust dose as needed based on patient response; do not exceed more than 5 doses (10 sprays) per hour [maximum: 40 mg/day (80 sprays)] or 3 months of treatment • If using nicotine nasal spray alone without nicotine patches, for best results, use at least the recommended minimum of 8 doses per day (less is likely to be effective). • Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. • *Discontinuation of therapy:* Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.

Oregon licensed pharmacist must adhere to Prescribing Parameters, when issuing any prescription for tobacco cessation.

PRESCRIBING PARAMETERS:

- 1st prescription(s) up to 30 days
- Maximum duration = 12 weeks
- Maximum frequency = 2x in a rolling 12-month period

TREATMENT CARE PLAN:

- Documented follow-up: within 7-21 days, phone consultation permitted

Tobacco Cessation Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

- ☐ Verified DOB with valid photo ID
- ☐ Referred patient to Oregon Quit Line (1-800-QUIT-NOW or www.quitnow.net/oregon)
- ☐ BP Reading: ____/____ mmHg *must be taken by a RPh

Note: RPh must refer patient if blood pressure ≥ 160/100

Rx

Written Date: _____

Prescriber Name: _____ Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes: _____

_____

_____

_____

_____

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

North Carolina State Health Director's Standing Order for Nicotine Replacement Therapy
March 24, 2022

Pursuant to S.L. 2021-110, this standing order signed by the North Carolina State Health Director authorizes immunizing pharmacists practicing in the state of North Carolina and licensed by the North Carolina Board of Pharmacy to dispense, deliver, or administer the following nicotine replacement therapy products as directed below.
https://www.ahrq.gov/prevention/guidelines/tobacco/clinicians/index.html

Nicotine Replacement Therapy (NRT) Dispensing Protocol

Eligible Candidates	Any person currently using nicotine containing products, who indicate a readiness to quit. This standing order may be used for persons < 18 years of age with a parent or legal guardian consent.		
Initiate therapy based on maximum use of nicotine/ day at therapy initiation	High Nicotine Use*^ 11+ cigarettes per day OR ≥2 cans or pouches per week of snuff or chew OR 6-12+mg/mL e-liquid	Medium Nicotine Use*^ 5-10 cigarettes per day OR 1 to 2 cans or pouches per week of snuff or chew OR 3-6mg/mL e-liquid	Low Nicotine Use*^ 0-4 cigarettes per day OR less than 1 can or pouch per week of snuff or chew
*Combination Nicotine Replacement therapy is strongly recommended. Monotherapy may also be appropriate. *Therapy choice should be based on time to first use, quantity, patient preference and comorbidities, data from past attempts, and desired quit date. NRT use in women who are pregnant or breastfeeding: the patient should be educated on the risks of smoking or vaping versus the unknown risks of NRT. If the patient consents to NRT, then intermittent delivery formulations (gum, lozenge or inhaler) are believed to be safer than continuous delivery (avoid use of Transdermal Dermal patch). If the patient is pregnant, educate on importance of	Per Product Label: •Nicotine Patch 21mg/24hrs for 8 weeks. Then, •Nicotine Patch 14mg/24hrs for 2 weeks. Then, •Nicotine Patch 7mg/24hrs for 2 weeks. AND / OR any of the following as needed NRT products •Nicotine Gum 4mg every hour as needed for cravings. (Max 20pieces/day) x 12 weeks. OR •Nicotine lozenge 4mg every hour as needed for cravings. (Max 15/day) x 12 weeks. OR Nicotine Oral Inhaler Puff 6-16 cartridges per day as needed for cravings x12 weeks. OR Nicotine Nasal Inhaler 1-2 doses/hour; 8-40 doses per day as needed for cravings x 12 weeks.	Per Product Label: •Nicotine Patch 14mg/24hrs for 8 weeks. Then, •Nicotine Patch 7mg/24hrs for 4 weeks. AND / OR any of the following as needed NRT products •Nicotine Gum 2mg every hour as needed for cravings. (Max 20 pieces/day) x 12 weeks. OR •Nicotine lozenge 2mg every hour as needed for cravings. (Max 15/day) x 12 weeks. OR Nicotine Oral Inhaler Puff 6-16 cartridges per day as needed for cravings x12 weeks. OR Nicotine Nasal Inhaler 1-2 doses/hour; 8-40 doses per day as needed for cravings x 12 weeks.	Per Product Label: •Nicotine Gum 2mg every hour as needed for cravings. (Max 20pieces/day) x 12 weeks. OR •Nicotine lozenge 2mg every hour as needed for cravings. (Max 15/day) x 12 weeks. OR Nicotine Oral Inhaler Puff 6-8 cartridges per day as needed for cravings x 12 weeks. OR Nicotine Nasal Inhaler 1-2 doses/hour; 8-20 doses per day as needed for cravings x 12 weeks.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

PCP/ObGyn for further prenatal care.			
Patient Education & Behavioral Support	Every person dispensed NRT pursuant to this standing order shall receive education regarding appropriate use and potential adverse effects for the provided NRT product(s). Patients shall also be provided with behavioral support education or provided with referral information for support services. All North Carolinians can receive support for quitting through QuitlineNC by calling 1-800-QUITNOW (1-800-784-8669), texting READY at 200-400 or through the website www.QuitlineNC.com		
Refills	PRN		
Contraindications *If patient has any of the following, refer to medical provider for further care.	Per product labeling: Myocardial infarction or Stroke/TIA within the last 2 weeks. Diagnosed with worsening or serious angina within the last 6 months Diagnosed within last 6 months with very rapid or irregular heartbeat that required a change in activities or addition of medication. A history of known hypersensitivity or serious adverse reaction to NRT or any of its components. Contraindications for Nicotine Patch – Severe eczema or psoriasis		
Notification of primary care provider:	Pharmacists choosing to dispense NRT under the authority of this standing order shall notify the patient's primary care provider within 72 hours after administration. Notification should include the pharmacist's name and NPI #, and the pharmacy/practice name and phone number. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary care provider, and provide information regarding primary care providers, including private practices, federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.		

Approved by: CTilson

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

Date signed: 3-24-2022

(Legal Authority Session Law 2021-110 HouseBill 96 This order is effective immediately upon signing and may be revised or revoided by the State Health Director according to his/her discretion. This order shall remain in effect until the later of the development of the protocols described in Section 4(a) Session Law 2021-110 HouseBill 96 or January 1, 2023 .

INDIANA STATE DEPARTMENT OF HEALTH

Statewide Standing Order for Tobacco Cessation Products

Purpose: To broaden patient access to FDA-approved medications for smoking cessation through pharmacists who are trained to screen, prescribe, and dispense appropriate medication(s) for cessation, and provide evidence-based counseling interventions with referral, as appropriate. This standing order is to be used in conjunction with the Protocol for Dispensing Tobacco Cessation Products under Statewide Standing Order ("the Protocol").

Eligible Providers: Pharmacists properly licensed pursuant to Indiana Code ch. 25-26-13 may operate under this standing order.

Eligible Recipients: Any individual 18 years or older who is:

1. Ready to quit based on individual assessment; and
2. Not determined to be high-risk after a health screening conducted by the pharmacist.

Eligible Products: Eligible products are FDA approved tobacco cessation products which are allowed under the Protocol.

Procedure:

1. **Assessment:** The pharmacist shall assess a patient's readiness to quit and apply the 5 A's approach for quitting: Ask, Advise, Assess, Assist, and Arrange, as described in the Clinical Practice Guideline for Treating Tobacco Use and Dependence, or a similar strategy based on current evidence.
2. **Health Screening:** The pharmacist shall perform and document a health screening on the patient based on clinical guidelines as outlined in the protocol to identify appropriate candidates for treatment by the pharmacist. The health screenings should be reviewed and revised as necessary to reflect current practice.
3. **Referral of High-Risk Patients:** If a patient is determined to be high-risk based on the health screening, the pharmacist shall refer the patient to a primary care provider or to another provider as appropriate.
4. **Dispensing Eligible Products.** The pharmacists, in consultation with the patient, may select and dispense any eligible products. Combination therapy (e.g. the nicotine patch plus the nicotine gum, lozenge, inhaler, or nasal spray; or bupropion SR plus the nicotine patch) may be used, per the current clinical guideline recommendations, and is appropriate based on patient needs and preferences.
5. **Counseling:**
   a. The pharmacist shall provide necessary information about the product pursuant to 856 IAC 1-33-2 regarding counseling when dispensing a tobacco cessation product under the standing order.
   b. The pharmacist shall provide counseling to the patient on the administration, possible side effects, contraindications, and warnings associated with the therapy. The pharmacist shall provide educational material on any therapies dispensed and encourage patients to ask questions.
   c. The pharmacist shall provide appropriate behavioral counseling and/or refer the patient to other resources for assistance, such as (but not limited to) the Indiana Tobacco Quitline 1-800-QUITNOW.
6. **Follow-up:** Pharmacists are encouraged to follow-up with patients as outlined in the protocol.
7. **Notification:**
   a. The pharmacist shall inform the patient that the patient must have a follow-up consultation with the patient's licensed prescriber or consult a licensed prescriber of the patient's choice.
   b. If the patient has a primary care provider, the pharmacist must notify the primary care provider of the prescription record and follow-up care plan within three business days.
   c. The pharmacist must provide the patient with a record of the drug(s) or device(s).
8. **Documentation:** The pharmacist or pharmacy shall maintain documentation of patient's health screening and the prescription record for all drugs and devices in the pharmacy records for seven years in accordance with Indiana Code 16-39-7-1. A copy shall be made available to the patient and/or patient's provider upon request.

Geographic Region: This standing order is applicable statewide.

Standing Orders Authorization: This standing order is issued pursuant to Indiana Code § 16-19-4-11, which allows the State Health Commissioner to issue a standing order that allows pharmacists to administer or dispense a tobacco cessation product. This standing order is effective August 1, 2019 through December 31, 2020.

Kristina Box, MD, FACOG
Physician License No. 01033558A

Utah Guidance for Tobacco Cessation Products

Approved xx, yy, 2021

This guidance is for Utah-licensed pharmacists ("Pharmacists") to prescribe and dispense safe and effective tobacco cessation products according to and in compliance with all applicable state and federal laws and rules. The pharmacists will perform an assessment and may then determine the need for and dispense a tobacco cessation product pursuant to the terms of the attached guidance. Pharmacists must have a valid Utah pharmacist license and have completed an Accreditation Council for Pharmacy Education (ACPE) accredited program in tobacco cessation.

PHARMACISTS GENERAL REQUIREMENTS:

a. All pharmacists participating in this protocol for tobacco cessation drug therapy will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update (or subsequent updates as they become available). Additionally, all product information (PI) and dosing from any products dispensed;

b. Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco; and

c. Pharmacists services will include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by the Utah Quit Line program.

SCREENING AND HISTORY

a. Under this protocol, pharmacists should offer assistance to tobacco users motivated and ready to quit. Medications should be offered as appropriate.

b. A standardized screening tool will be used to assess the following for each patient intending to use medications:

1. Medical and social history including current medications;
2. Previous medication attempts, failures, intolerances;
3. Allergies and hypersensitivities;
4. Potential drug interactions with potential medication treatments (per Guidelines/Dispensing Information);
5. Precautions/contraindications of potential medication treatments (per Guidelines/Dispensing Information); and
6. Patient preferences with regards to treatment options

c. A standardized screening tool will be used to identify patients who do **NOT** qualify for specified medication therapies under this protocol and will be referred to a primary care provider for further assessment:

1. Age under 18 years (any/all medications);
2. Pregnancy or plan to become pregnant (any/all medications);
3. History of seizure disorder (bupropion);
4. History of eating disorder (bupropion)

5. Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs (bupropion);
6. Hypersensitivity to any previous use of nicotine, bupropion or varenicline;
7. Use of a monoamine oxidase inhibitor (MAOI) within 14 days (bupropion);
8. Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina (nicotine replacement);
9. Known moderate/severe hepatic or renal impairment (any/all medications); and
10. Smokeless tobacco use (any/all medications).

DISPENSING

a. FDA First-Line Approved Medications which may be prescribed (dosing per Clinical Practice Guidelines/Package Inserts). This information should be updated no less frequently than every 2 years.

1. Nicotine Replacement Therapies

Patch

• Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods. Patches of different doses sometimes are available as well as different recommended dosing regimens. Clinicians should consider individualizing treatment based on specific patient characteristics, such as previous experience with the patch, amount smoked, degree of dependence, etc.

• Step-down Dosage

4 weeks	21 mg/24 hours
then 2 weeks	14 mg/24 hours
then 2 weeks	7 mg/24 hours

Gum

• Nicotine gum is available in 2-mg and 4-mg (per piece) doses. The 2-mg gum is recommended for patients smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.

Lozenge

• Nicotine lozenges are available in 2-mg and 4-mg (per piece) doses. The 2-mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, and the 4-mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least nine lozenges per day in the first 6 weeks; the lozenge should be used for up to 12 weeks, with no more than 20 lozenges to be used per day.

Nasal Spray

• A dose of nicotine nasal spray consists of one 0.5-mg dose delivered to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.

Inhaler

• A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Patient should taper dosage during the final 3 months of treatment.

2. Bupropion

• Begin bupropion SR treatment 1–2 weeks before they quit smoking. Patients should begin with a dose of 150 mg every morning for 3 days, then increase to 150 mg twice daily. Dosage should not exceed 300 mg per day. Dosing at 150 mg twice daily should continue for 7–12 weeks. For long-term therapy, consider use of bupropion SR 150 mg for up to 6 months post-quit.

3. Varenicline

• Start varenicline 1 week before the quit date at 0.5 mg once daily, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months.

Note: Patient should be instructed to quit smoking on day 8 when dosage is increased to 1 mg twice daily.

4. Evidence-Based Combination Therapies

• Bupropion + Nicotine patch (standard dosing as detailed above). If this combination is used, patient shall be monitored for treatment emergent hypertension and include a follow up blood pressure within 1-2 weeks.

• Long term nicotine patch (>14 weeks) + other nicotine replacement products (gum and spray) – doses as detailed above.

• Nicotine patch + Nicotine inhaler (doses as detailed above)

b. Duration of the above therapies, if not specifically detailed above, shall not exceed 6 months.

c. Dosing, Precautions, Contraindications and Monitoring considerations shall follow Clinical Practice Guidelines and manufacturer prescribing information.

d. Patients will be supplied with written educational information on any therapies prescribed.

e. Pharmacists will implement an appropriate monitoring and follow up plan with each patient.

f. Pharmacists may continue to provide over-the-counter smoking cessation products to tobacco users without the use of this guidance.

RECORDS

a. Pursuant to Utah Admin Code R156-17b-627 (2)(e), the pharmacist may communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

b. Pharmacists shall comply with Utah Admin Code R156-17b-627(3) with respect to the maintenance of proper records.

Smoking Cessation Information to be posted on DOPL's Website

1. This protocol
2. Utah Tobacco Prevention and Control Program https://tobaccofreeutah.org/
3. AHRQ Treating Tobacco Use and Dependence:2008 Update-Clinical Practice Guideline https://www.ahrq.gov/prevention/guidelines/tobacco/index.html
4. CDC Smoking and Tobacco Use Resources https://www.cdc.gov/tobacco/
5. UCSF RX for Change: Clinician-Assisted Tobacco Cessation https://rxforchange.ucsf.edu/
6. JCCP Pharmacist Patient Care Process https://jcpp.net/patient-care-process/
7. National Cancer Institute https://smokefree.gov/
8. Utah Quite Line 1-800-Quit Now available 24/7 https://waytoquit.org/get-help-quitting/

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol for Tobacco Cessation

Consistent with Virginia Code § 54.1-3303.1, a pharmacist may initiate treatment nicotine replacement with Nicotine Replacement Therapy ("NRT") and other tobacco cessation therapies ("Non-NRT"), including controlled substances as defined in the Drug Control Act (Va. Code § 54.1-3400 *et seq.*), together with providing appropriate patient counseling.

PHARMACIST INITIATION OF TREATMENT
A licensed pharmacist may prescribe an individual 18 years of age or older NRT and Non-NRT for tobacco cessation.

PHARMACIST EDUCATION AND TRAINING
Pharmacists initiating treatment for tobacco cessation shall receive appropriate training to conduct the activity in a safe and effective manner. This includes a minimum of two hours of documented continuing education provided by the Accreditation Council for Pharmacy Education ("ACPE") related to pharmacists prescribing tobacco cessation products.

OBTAINING HISTORY
The pharmacist shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of tobacco cessation therapy.

RECORDKEEPING
The pharmacist shall maintain records in accordance with 18VAC110-21-46.

AGENDA ITEM: COVID-19 Testing

STAFF NOTE: This item is responsive to the requirement in HB1323 under 54.1-3301(B)(2). As with (B)(1), this section does not become effective until the federal emergency ends. In the following pages, you will find CDC information on COVID-19 testing, FDA test basics, Virginia Department of Health reporting of COVID-19 test results, and a draft Pharmacist Statewide Protocol for Coronavirus Testing.

ACTION: Discuss and determine that the draft "Pharmacist Statewide Protocol for Coronavirus Testing" is comprehensive or if edits or additions are required. The Work Group should approve the document by a vote.

CDC Centers for Disease Control and Prevention

COVID-19 Testing: What You Need to Know

Updated May 3, 2022

Free At-Home COVID-19 Tests: Order 8 free tests now so you have them when you need them.

Types of COVID-19 Tests

COVID-19 tests can detect either **SARS-CoV-2** or **biomarkers** of SARS-CoV-2, the virus that causes COVID-19, or **antibodies** that your body makes after getting COVID-19 or after getting vaccinated.

Tests for SARS-CoV-2 tell you if you have an infection at the time of the test. This type of test is called a "viral" test because it looks for viral infection. Antigen tests, Nucleic Acid Amplification Tests (NAATs) and other tests are viral tests.

Tests for antibodies may tell you if you have had a past infection with the virus that causes COVID-19. Your body creates antibodies after getting infected with SARS-CoV-2 or after getting vaccinated against COVID-19. These tests are called "antibody" or "serology" tests.

Testing is very important to help reduce the spread of COVID-19. You should always discuss your test results with your healthcare provider.

Viral Tests

A viral test tells you if you are infected with SARS-CoV-2, the virus that causes COVID-19, using samples that come from your nose or mouth. There are two types of viral tests: rapid tests and laboratory tests. COVID-19 testing is one of many risk-reduction measures, along with vaccination, masking, and physical distancing, that protect you and others by reducing the chances of spreading COVID-19.

- **Rapid Point-of-Care tests,** test performed or interpreted by someone other than the individual being tested, can be performed in minutes and can include antigen tests, some NAATs, and other tests.
  - Self-tests are rapid tests that can be taken at home or anywhere, are easy to use, and produce rapid results.
- **Laboratory tests** can take days to complete and include RT-PCR and other types of NAATs.

Watch Video: Viral Test for COVID-19 [00:01:08]

Antibody Tests

An antibody test (also known as a serology test) can detect antibodies to SARS-CoV-2 in your blood. **Antibodies** are proteins that your immune system makes to help fight infection and protect you from getting sick in the future.

Antibody tests should not be used to diagnose a current infection, but they may indicate if you had a past infection. Antibody tests help learn about how human immune systems defend against the virus, as well as learn about population-level protection. If you get an antibody test after receiving a vaccine, you might test positive by some (but not all) antibody tests.

This depends on which type of antibody the specific test detects.

Antibody testing is not currently recommended to determine:

- If you have a current infection.
- If you have immunity to SARS-CoV-2 following COVID-19 vaccination.
- Whether you need to get a booster following COVID-19 vaccination.
- Whether you need to quarantine after a known or suspected exposure to COVID-19.

Watch Video: Antibody Test for COVID-19 [00:01:06]

Need a COVID-19 Test?

Reasons to Get Tested

- If you have COVID-19 symptoms
- At least 5 days after known or suspected close contact to COVID-19
- For screening (schools, workplaces, congregate settings, etc.)
- Before and after travel
- When asked by a healthcare professional or public health official

Types of Viral Tests

Laboratory Test

- Sample can either be a nasal swab or saliva
- Results usually in 1-3 days
- Results are reliable for people with and without symptoms
- No follow-up test required
- Common example: PCR test

Rapid Test

- Sample is usually a nasal swab
- Results usually in 15-30 minutes
- Results may be less reliable for people without symptoms
- Follow-up test may be required
- Common example: Antigen test

Actions After Result

If Positive Result

- Isolate for at least 5 days. Learn more about isolation timelines and precautions
- Seek a confirmatory, follow-up laboratory test if recommended by healthcare professional
- Monitor your symptoms

If Negative Result

- If up to date on vaccines: return to normal activities. Wear a mask indoors in areas where the COVID-19 Community Level is high.
- If not up to date on vaccines and have symptoms or exposure: quarantine for at least 5 days.
- If not up to date on vaccines and have no symptoms or exposure: return to normal activities. Take steps to get up to date on vaccines to protect yourself and others.

Download Graphic: Need a COVID-19 Test? [1 Page, 341 KB]

Testing Tools

These chatbots ask a series of questions, and provide recommended actions and resources based on your responses.

Coronavirus Self-Checker

A tool to help you make decisions on when to seek testing and medical care.

Get Started About the Tool

Need additional help? CDC's Viral Testing Tool is an online, mobile-friendly tool that asks a series of questions, and provides recommended actions and resources based on a user's responses.

Print Resources

Do Your Part: Get Tested

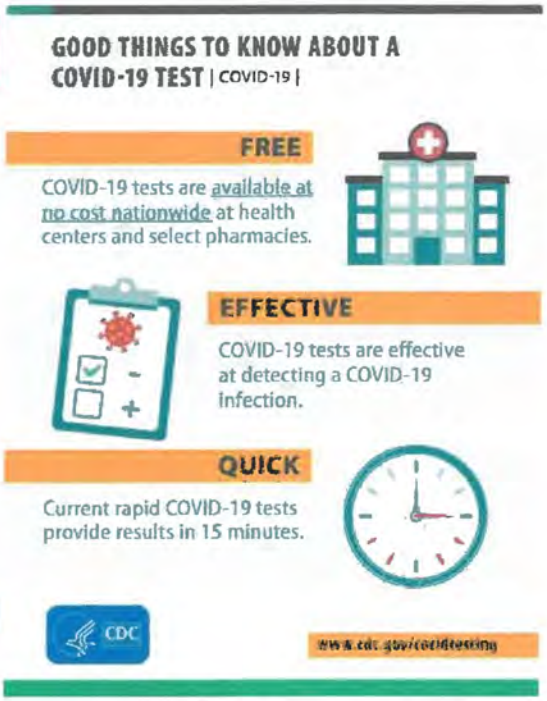
[PDF - 426 KB, 1 Page]

COVID-19 Testing If You Are Vaccinated

[PDF - 1 page, 129 KB]

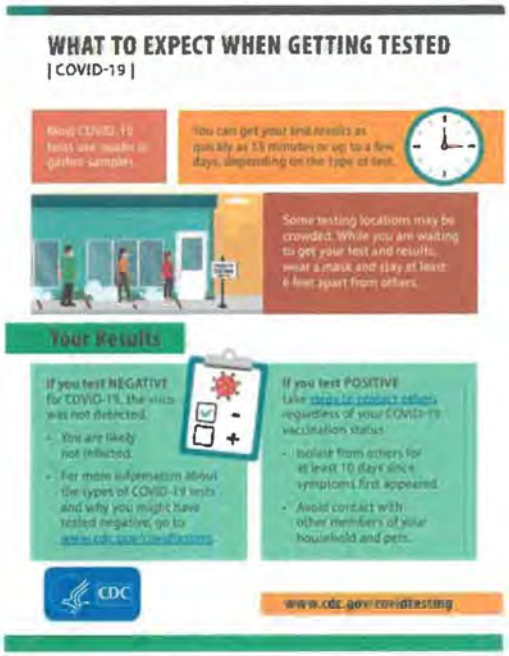
What Your Test Results Mean

[PDF - 216 KB, 1 page]



Good Things to Know About A COVID-19 Test

[PDF - 55KB, 1 Page]



What to Expect When Getting Tested

[PDF - 183 KB, 1 page]

Resources

COVID-19 Testing Resources

Science at CDC

Scientific evidence and studies behind specific COVID-19 guidance and recommendations

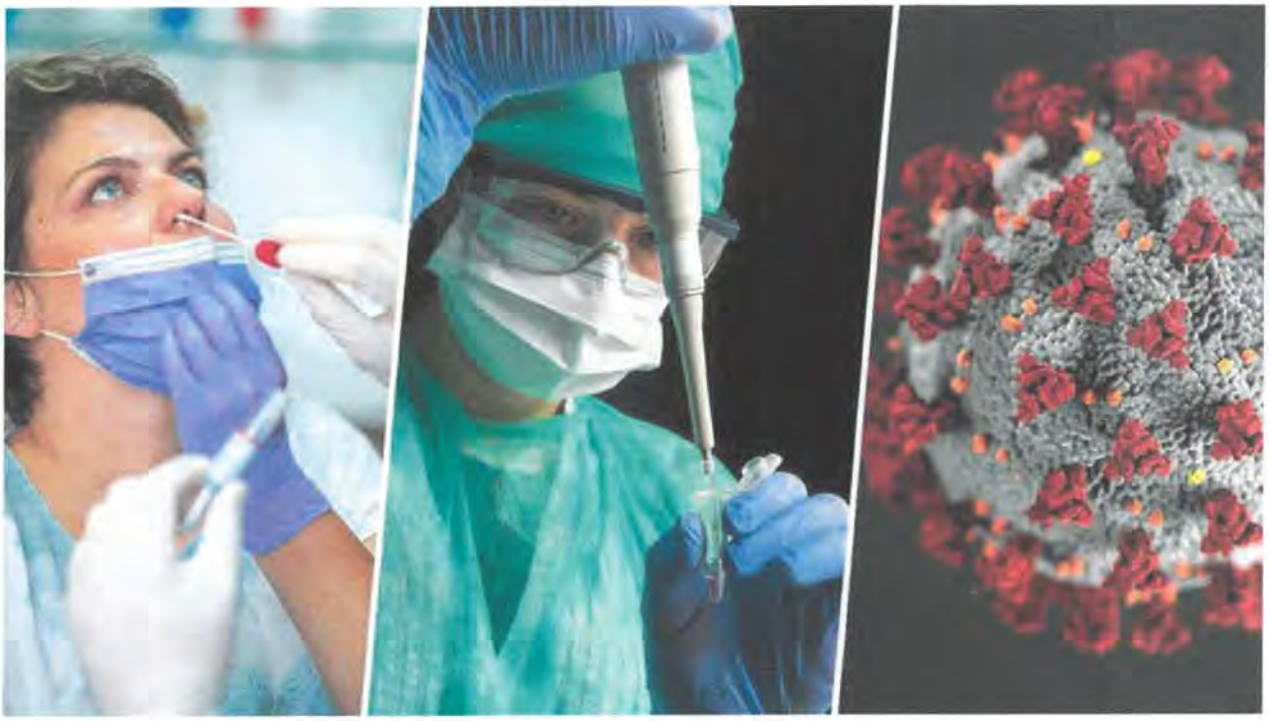
Science Briefs | *MMWR* COVID-19 Reports

Related Pages

- Test for Current Infection
- Test for Past Infection

Last Updated May 3, 2022

COVID-19 Test Basics



Español (/consumers/articulos-en-espanol/conceptos-basicos-de-las-pruebas-para-el-covid-19)

简体中文 (/consumers/consumer-updates/2019xinguanfeiyanceshijichuzhishi)

한국어 (/consumers/consumer-updates/kobideu-19-covid-19-geomsa-gibon-sahang)

Tagalog (/consumers/consumer-updates/mga-panguhaning-pagsusuri-ng-covid-19)

Việt (/consumers/consumer-updates/co-ban-ve-kiem-tra-covid-19)

COVID-19 testing plays a critical role in the fight against the virus. Understanding COVID-19 tests, including the different types of tests and their uses, and the types of samples the tests use, is key to making an informed decision that meets your needs.

Types of Tests

There are different types of COVID-19 tests – **diagnostic tests** and **antibody tests**.

Diagnostic tests can show if you currently are infected with SARS-CoV-2, the virus that causes COVID-19. There are two types of COVID-19 diagnostic tests:

- Molecular tests, such as polymerase chain reaction (https://medlineplus.gov/lab-tests/pcr-tests/) (PCR) tests

- Antigen tests, often referred to as rapid tests

Samples for COVID-19 diagnostic tests are typically collected using an anterior nares (nasal) swab sample. Some diagnostic tests use mid-turbinate, nasopharyngeal, oropharyngeal, or saliva samples. COVID-19 diagnostic tests can be performed at a laboratory, a standalone testing site, a doctor's office or health clinic, or at home. For some COVID-19 diagnostic tests, you go to a testing site to have your sample collected and for others you can collect your own sample at home using a home collection kit and mail it to a laboratory for testing. Other tests can be performed completely at home, giving you results within minutes, without needing to send your sample to a laboratory.

If you think you need a COVID-19 diagnostic test, you can find a community testing site (https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html) in your state. You can also use an FDA-authorized at-home COVID-19 diagnostic test (/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests) which gives you the option of self-testing (https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html) where it is convenient for you. Be aware that COVID-19 diagnostic tests are authorized (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic) for specific uses. For example, some tests can be used by people with and without symptoms (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html) and other tests are only for people with symptoms. Also, laboratory-based tests, such as PCR tests, are generally more accurate than at-home tests.

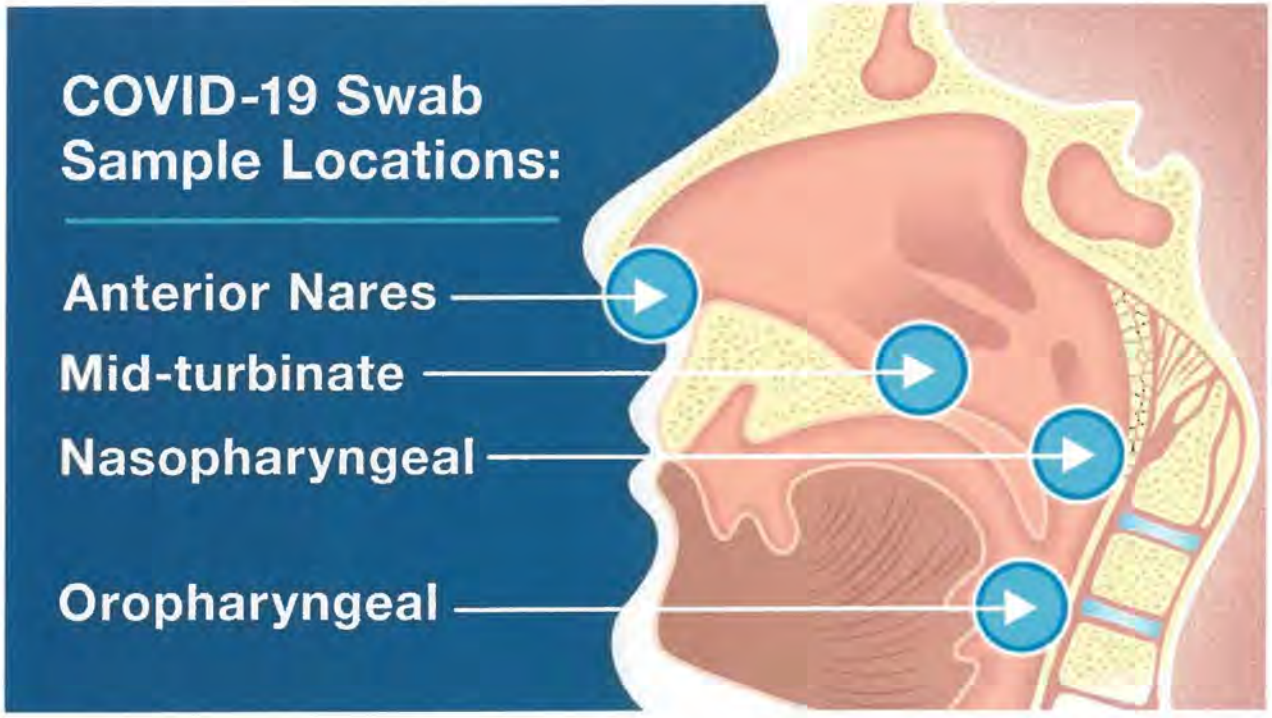
For details about each authorized COVID-19 diagnostic test, see the lists of authorized Molecular Diagnostic Tests (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2) and Antigen Diagnostic Tests (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2), as well as the At-Home COVID-19 Diagnostic Tests (/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests) webpage. Using the search box in the EUA tables, you can use keywords to search and filter the type of test or collection kit you are looking for. As new tests are authorized for use, they are added to these tables so that anyone can access up-to-date information on all authorized tests and collection kits.

Antibody (or serology) tests look for antibodies in your blood that your immune system produced in response to SARS-CoV-2, the virus that causes COVID-19. **Antibody tests should not be used to diagnose a current SARS-CoV-2 infection or COVID-19** and, at this time, should also not be used to check for immunity. More research is needed to determine what, if anything, antibody tests can tell us about a person's immunity.

Samples for antibody tests are typically collected by a doctor or other medical professional by taking blood from a finger stick or your vein. For more information about antibody testing, visit Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers (/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers).

Types of Samples

Different tests are authorized to be used with different types of samples. The most common sample types are:



Swab samples use a swab (similar to a long Q-Tip) to collect a sample from the nose or throat. The types of samples include:

- Anterior Nares (Nasal) – takes a sample from just inside the nostrils
- Mid-turbinate – takes a sample from further up inside the nose
- Nasopharyngeal – takes a sample from deep inside the nose, reaching the back of the throat, and should only be collected by a trained health care provider
- Oropharyngeal – takes a sample from the middle part of the throat (pharynx) just beyond the mouth, and should only be collected by a trained health care provider

Saliva samples are collected by spitting into a tube rather than using a nose or throat swab.

Blood samples are only used to test for antibodies and not to diagnose COVID-19. Venous blood samples are typically collected at a doctor's office or clinic. Some antibody tests use blood samples from a finger stick.

Report Adverse Events

The FDA encourages health care professionals and patients to report adverse events or side effects as well as performance issues related to the use of COVID-19 tests or other medical products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) through the FDA's MedWatch website.
- Download the form (https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1-800-332-1088 to request a form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178.

WELCOME!

Virginia Department of Health COVID-19 Point of Care (POC) Test Reporting Guidance

The Virginia Department of Health COVID-19 POC portal allows health care professionals, who are unable to report electronically via HL7 or flat file, the ability to submit rapid COVID-19 test results through this portal to meet the COVID-19 reporting requirements.

What is Point of Care testing?

Point of Care testing is medical diagnostic testing conducted outside of a traditional laboratory setting that occurs at the time and place of patient care (i.e., physician's office, pharmacy, nursing home, etc.).

When should reporting occur?

Facilities/Providers should report POC test results through the online portal within 24 hours of receiving a COVID-19 result. You should only report via this portal if you are unable to report it electronically via HL7 or flat file to VDH.

Testing sites that perform COVID-19 surveillance testing on de-identified samples, regardless of their CLIA status, should not report the results of their surveillance testing to local, state, territorial, or tribal health departments. If at any time a facility intends to report a patient-specific test result, it must first obtain a CLIA certificate and meet all requirements to perform testing.

How to report? And next steps...

Facilities/Providers utilizing POC testing, who are unable to report via HL7 or flat file to VDH, are requested to report individual results using the VDH

New User? Enroll Here

CLICK BELOW FOR REGISTRATION GUIDE

COVID 19 POC PORTAL REGISTRATION GUIDE

For more information on CLIAs, click here.

For the current list of tests available in the portal, click here.

Click here for the COVID-19 variance letter.

COVID-19 POC reporting portal. To ensure proper access and reporting via this portal...

- A single, main point of contact for each facility/provider should create a user account.
- This user will register your POC facility for online reporting via the Facility/Practice Registration page. Each facility needs to be registered once. **One point of contact per facility please.**
- After successfully registering your facility, you will receive a registration confirmation.
- VDH team will review your request for access to the COVID-19 POC portal for test result submission. You will receive an email notification that access has been granted to the online portal. **Access to the online portal may take 2-3 days.**
- **Once access has been granted, the main point of contact will be able to add additional facilities and contacts that will assist in data entry of POC results.**
- **The Bulk upload and multi facility registration functionalities are now available through the portal. For POC users to have access to more than one facility and/or the bulk upload feature, the main point of contact must email POCReporting@vdh.virginia.gov with their request. Please note that each user's current role will apply to all facilities to which they have access.**

For questions or problems please contact

Virginia Department of Health
Phone: (804) 864-8141
Email: POCReporting@vdh.virginia.gov

Last Updated: 06/24/2022 Version: 1.8.7

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol for Coronavirus Testing

Consistent with Virginia Code § 54.1-3303.1 and CLIA requirements administered by the U.S. Food and Drug Administration, a pharmacist may initiate treatment with, dispense, or administer tests for COVID-19 and other coronaviruses to persons 18 years of age or older.

PHARMACIST EDUCATION AND TRAINING

Pharmacists collecting specimen samples and performing tests for COVID-19 or other coronaviruses shall receive appropriate training to conduct the activity in a safe and effective manner. This includes adherence to the testing device manufacturer's instructions. Completion of training must be documented. For additional information, refer to the "General Guidelines" section on CDC's website and information from the Virginia Department of Health COVID-19 Viral Testing Information for Pharmacists.

PATIENT INCLUSION CRITERIA

Any patient 18 years or older may receive or be administered a test for COVID-19 or other coronaviruses.

OBTAINING HISTORY

The pharmacist shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of the test.

RECORDKEEPING

The pharmacist shall maintain records in accordance with 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

EFFECTIVENESS OF PROTOCOL

This protocol authorizes a pharmacist to initiate treatment with, dispense, or administer tests for COVID-19 and other coronaviruses to persons 3 years of age or older upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

EXCLUSIONS

Nothing shall preclude a pharmacist, pharmacy technician, or pharmacy intern under the supervision of a pharmacist from performing CLIA-waived tests in accordance with the Food and Drug Administration's CLIA requirements.

Travel Reminder

Non-state employees are eligible for a $50.00 per diem and mileage reimbursement.

The travel regulations require that "travelers must submit the Travel Expense Reimbursement Voucher with 30 days after completion of their trip". (CAPP Topic 20335, State Travel Regulations, p.7)

In order for the agency to be in compliance with the state travel regulations, please submit your request for today's meeting no later than

September 8, 2022