COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Statewide Protocol Workgroup Meeting

September 21, 2020 Virtual Meeting

9AM - 3PM

*******Refer to the Second Page of Agenda for Meeting Access Information*******

TOPIC	PAGES
Call to Order: Ryan Logan, Chairman	
• Welcome & Introductions	**1**
• Approval of Agenda	
Call for Public Comment: The Board will receive public comment at this time from those persons who submitted an email to kiara.christian@dhp.virginia.gov **no later than 4pm on September 18, 2020** indicating that they wish to offer comment. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
Agenda Items	
• Review charge of workgroup as described in the 3rd enactment clause of HB 1506	**2-4**
• Review request from Joint Commission on Health Care, dated 2/10/2020	**5**
• Overview of pharmacist educational/training standards, *VCU School of Pharmacy*	**6-11**
• Review workforce statistics of pharmacists	**12-17**
• Copies of recently adopted Virginia protocols	**18-36**
• Provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices, including	
o vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention;	**37-66**
o drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy;	**67-85**
o tuberculin purified protein derivative for tuberculosis testing;	**86-110**
o controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria;	**111-131**
o 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;	**132-149**
o drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription	**150**
Adjourn	

****The Board will have a working lunch at approximately 12pm.****

Virginia Board of Pharmacy

Instructions for Accessing September 21, 2020 Virtual Statewide Protocol Workgroup Meeting and Providing Public Comment

- **Access:** Perimeter Center building access is restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Disregard any reference to the Board of Dentistry as a shared subscription to WebEx is being utilized. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the public hearings and during the full board meeting from those persons who have submitted an email to Kiara.christian@dhp.virginia.gov **no later than 8am on September 21, 2020** indicating that they wish to offer comment. Verbal comment may be offered by these individuals when their names are announced by the chairman. Comments must be restricted to 3-5 minutes each.
- Public participation connections will be muted following the public comment periods.
- Please call from a location without background noise.
- Dial (804) 367-4578 to report an interruption during the broadcast.
- FOIA Council *Electronic Meetings Public Comment* form for submitting feedback on this electronic meeting may be accessed at http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm

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1-408-418-9388 United States Toll

Meeting number (access code): 132 940 9714

Meeting password: 4215060

JOIN THE INTERACTIVE MEETING
https://virginia-dhp.my.webex.com/virginia-dhp.my/j.php?MTID=mbb13d5587210253cd6284bf1cb81e946
Meeting Number: 132 940 9714
Meeting Password: HB1506!

Workgroup Members:

1. Ryan Logan, RPh, Workgroup Chairman, Board of Pharmacy Member
2. Sarah Melton, PharmD, Board of Pharmacy Member
3. Kris Ratliff, DPh, Board of Pharmacy Chairman, Non-Voting Workgroup Member
4. Jake Miller, DO, Board of Medicine Member
5. Brenda Stokes, MD, Board of Medicine Member
6. Will Hockaday, Tobacco Control Program/Outreach Coordinator, VDH
7. Kristin Collins, MPH, Policy Analyst, Office of Epidemiology, VDH
8. Diana Jordan, Director, Division of Disease Prevention, VDH
9. Stephanie Wheawill, PharmD, Division of Pharmacy Services Director, VDH
10. Joe DiPiro, PharmD, Dean, VCU School of Pharmacy
11. Michael Justice, PharmD, Assistant Professor, Appalachian College of Pharmacy
12. Al Arias, M.D, VCU, School of Medicine
13. John R. Lucas, DO, Edward Via College of Osteopathic Medicine
14. Donna Francioni-Proffitt, RPh, Pharmacy Program Manager, DMAS
15. Doug Gray, Executive Director, Virginia Association of Health Plans
16. Kelly Goode, PharmD, Virginia Pharmacists Association
17. Terri Babineau, MD, Medical Society of Virginia
18. Kerri Musselman, PharmD, BCACP, Virginia Society of Health-System Pharmacists
19. Summer Williams Kerley, PharmD,RPh Va. Association of Chain Drug Stores/National Association of Chain Drug Stores
20. Lincy Abraham, PharmD, National Association of Chain Drug Stores

Staff:

- Caroline Juran, RPh, Executive Director, Board of Pharmacy
- William Harp, MD, Executive Director Board of Medicine
- Elaine Yeatts, DHP, Senior Policy Analyst
- Jim Rutkowski, Assistant Attorney General
- Sammy Johnson, Pharmacist, Deputy Executive Director, Board of Pharmacy
- Beth O'Halloran, RPh, Deputy Executive Director, Board of Pharmacy
- Ellen Shinaberry, PharmD, Deputy Executive Director, Board of Pharmacy
- Kiara Christian, Executive Assistant, Board of Pharmacy

1st virtual meeting: 9/21 - 9am-3pm

2nd virtual meeting: 10/2 - 9am-3pm

CHAPTER 731

An Act to amend and reenact §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3303.1, relating to pharmacists; initiating treatment with and dispensing and administering of controlled substances.

[H 1506]

Approved April 6, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3303.1 as follows:

§ 38.2-3408. Policy providing for reimbursement for services that may be performed by certain practitioners other than physicians.

A. If an accident and sickness insurance policy provides reimbursement for any service that may be legally performed by a person licensed in this Commonwealth as a chiropractor, optometrist, optician, professional counselor, psychologist, clinical social worker, podiatrist, physical therapist, chiropodist, clinical nurse specialist who renders mental health services, audiologist, speech pathologist, certified nurse midwife or other nurse practitioner, marriage and family therapist, or licensed acupuncturist, reimbursement under the policy shall not be denied because the service is rendered by the licensed practitioner.

B. If an accident and sickness insurance policy provides reimbursement for a service that may be legally performed by a licensed pharmacist, reimbursement under the policy shall not be denied because the service is rendered by the licensed pharmacist, provided that (i) the service is performed for an insured for a condition under the terms of a collaborative agreement, as defined in § 54.1-3300, ~~between a pharmacist and the physician with whom the insured is undergoing a course of treatment or~~ (ii) the service is for the administration of vaccines for immunization~~. Notwithstanding the provisions of § 38.2-3407, the insurer may require the pharmacist, any pharmacy or provider that may employ such pharmacist, or the collaborating physician to enter into a written agreement with the insurer as a condition for reimbursement for such services. In addition, reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of § 38.2-3407.7~~*, or (iii) the service is provided in accordance with § 54.1-3303.1*.

C. This section shall not apply to Medicaid, or any state fund.

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of

pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include *(i)* the proper and safe storage and distribution of drugs; *(ii)* the maintenance of proper records; *(iii)* the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; ~~and~~ *(iv)* the management of patient care under the terms of a collaborative agreement as defined in this section*; and (v) the initiating of treatment with or dispensing or administering of certain drugs in accordance with the provisions of § 54.1-3303.1*.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who meet the criteria set forth in the collaborative agreement*. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

~~No patient shall be required to participate in a collaborative procedure without such patient's consent.~~

B. A patient who *meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who* chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

C. Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

D. Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

E. Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

§ 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 and devices to persons 18 years of age or older 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; and

6. Medications 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.

B. 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. 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.

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating 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 created by this act, by November 1, 2020, and 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 Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board may deem appropriate to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices, including (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria; (v) 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; and (vi) drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

Joint Commission on Health Care

Senator George L. Barker, Interim Chair

February 10, 2020

David E. Brown, D.C., Director
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Dear Director Brown:

On behalf of the Joint Commission on Health Care, I respectfully request that the Board of Pharmacy and the Board of Medicine convene a work group of expert stakeholders to develop recommendations regarding the expansion of statewide standing orders to include additional conditions for which CLIA Waiver tests exist and drugs, (e.g., antiviral drugs, hormonal birth control and smoking cessation drugs) that may be dispensed by a licensed pharmacist without a practitioner prescription. Recommendations should include whether, and if so what, additional training is required in order for a licensed pharmacist to dispense any new drug added to a statewide standing order and whether, and if so what, other requirements may be needed to ensure that new dispensing authorities will pose no risk to individual or public health.

The work group should include members from the Virginia Boards of Pharmacy and Medicine and may include other expert stakeholders, such as representatives from the Virginia Department of Health, the Virginia Department of Medical Assistance Services and the Office of the Secretary of Health and Human Resources. The work group shall provide recommendations to the Joint Commission on Health Care by October 1, 2020 and may reconvene periodically thereafter to address any additions and/or changes to statewide standing orders. Recommendations from additional meetings shall be provided to the Commission as they are determined.

Thank you for your consideration of this request. Michele Chesser and Paula Margolis are happy to discuss any questions or concerns you or your staff may have. They may be reached at mchesser@jchc.virginia.gov, pmargolis@jchc.virginia.gov, and 804-786-5445.

Sincerely,

George L. Barker

Michele L. Chesser, Ph.D., Executive Director
Joint Commission on Health Care
P.O. Box 1322 / Richmond, Virginia 23218 / 804-786-5445

Overview of Pharm.D. Education and Training for HB1506

Dave L. Dixon, Pharm.D.
Associate Professor & Vice-Chair of Clinical Services
Director, Center for Pharmacy Practice Innovation
Email: dldixon@vcu.edu Phone: (804) 628-3784

VCU School of Pharmacy

Doctor of Pharmacy (Pharm.D.) Programs

- Since 1999, the Pharm.D. has been the first professional degree for pharmacists.
- 144 U.S.-based schools and colleges of pharmacy offer a Pharm.D. program
  - 75 at private institutions
  - 69 at publicly supported institutions

VCU School of Pharmacy

Source: American Association of Colleges of Pharmacy

General Prerequisites for Pharm.D. Programs

2 to 4 years of undergraduate courses

- Human anatomy/physiology
- Biological sciences
- Microbiology
- Chemistry
- Biochemistry
- Physics
- Math/Statistics
- Economics
- English/Communication
- Social/Behavioral sciences
- Psychology
- Electives

VCU School of Pharmacy

Source: American Association of Colleges of Pharmacy

VCU Pharm.D. Curriculum (P1 Year)

Fall Semester 2019 | Course | Credit Hours	
IPEC 501 Foundations of Interprofessional Practice	1.0
MEDC 527 Basic Pharmaceutical Principles for the Practicing Pharmacist	3.0
MEDC 533 Pharmacognosy	2.0
PCEU 501 Pharmaceutical Calculations	1.0
PCEU 507 Pharmaceutics and Biopharmaceutics I	3.0
PHAR 509 Evidence-based Pharmacy I: Introduction to Pharmacy Information Skills*	1.5
PHAR 523 Foundations I	1.5
PHAR 545 The U.S. Health Care System	2.0
PHAR 652 Health Promotion and Communication in Pharmacy Practice	2.5
PHAR 515 Continuous Professional Development I	continues
TOTAL CREDIT HOURS	17.5

Spring Semester 2020 | Course | Credit Hours	
MEDC 553 Clinical Therapeutics Module: Introduction to Medicinal Chemistry*	1.0
PHTX 606 Clinical Therapeutics Module: Introduction to Pharmacology (Pharmacy)*	1.0
PHAR 529 Clinical Therapeutics Module: Introduction to Special Populations*	2.0
PCEU 508 Pharmacokinetics	3.0
PCEU 509 Pharmaceutics and Biopharmaceutics II	3.0
PHAR 513 Contemporary Pharmacy Practice	2.0
PHAR 524 Foundations II	1.5
PHAR 526 Community Pharmacy Practice Management I	2.0
PHAR 530 Introductory Pharmacy Practice Experience: Community Practice	4.0
PHAR 515 Continuous Professional Development I	1.0
TOTAL CREDIT HOURS	20.5

VCU School of Pharmacy

https://pharmacy.vcu.edu/admissions/pharmd/current-students/calendar--curriculum-/

VCU Pharm.D. Curriculum (P2 Year)

Fall Semester 2020 | Course | Credit Hours	
MEDC 543 Clinical Chemistry for the Pharmacist	1.0
PHAR 534 Foundations III	1.5
PHAR 541 Patient Assessment Skills for Pharmacy Practice	2.0
PHAR 544 Clinical Therapeutics Module: Cardiovascular*	4.5
PHAR 555 Clinical Therapeutics Module: Endocrinology*	2.5
PHAR 603 Clinical Therapeutics Module: Respiratory/Immunology*	3.0
PHAR 565 Evidence-based Pharmacy II: Research Methods and Statistics*	2.5
PHAR 546 Pharmacy-based Immunization Delivery	1.5
PHAR 615 Continuous Professional Development II	continues
TOTAL CREDIT HOURS	18.5

Spring Semester 2021 | Course | Credit Hours	
IPEC 502: Interprofessional Quality Improvement and Patient Safety	1.0
MEDC 542 Biotechnology-Derived Therapeutic Agents*	1.0
PCEU 615 Applied Pharmacokinetics	2.5
PHAR 535 Foundations IV	1.5
PHAR 566 Evidence-based Pharmacy III: Drug Literature Evaluation	2.0
PHAR 604 Clinical Therapeutics Module: Infectious Diseases*	4.5
PHAR 606 Clinical Therapeutics Module: Nephrology/Urology*	2.0
PHAR 532 Introductory Pharmacy Practice Experience: Hospital Practice	3.0
PHAR 615 Continuous Professional Development II	1.0
TOTAL CREDIT HOURS	18.5

VCU School of Pharmacy

https://pharmacy.vcu.edu/admissions/pharmd/current-students/calendar--curriculum-/

Patient/Physical Assessment at VCU School of Pharmacy

- Since 2016
  - PHAR 541: Patient Assessment in Pharmacy Practice
- 2012-2015
  - Integrated into pharmacotherapy & foundations courses
- 1999-2011
  - PHAR 747: Physical Assessment

- 2-credit hour course
- 4 lab practicals
- Teaches comprehensive patient assessment, including:
  - Review of pathophysiology
  - Normal/abnormal physical and laboratory findings
  - Patient interviewing skills
  - Systematic approach to determining cause of symptoms
  - Appropriate triage to higher level of care, when necessary

VCU School of Pharmacy

VCU Pharm.D. Curriculum (P3 Year)

Fall Semester 2021 | Course | Credit Hours	
PHAR 540 Self-Care and Alternative and Complementary Treatments	2.5
PHAR 549 Pharmacogenetics and Pharmacogenomics	1.0
PHAR 556 Clinical Therapeutics Module: Neurology*	4.0
PHAR 602 Clinical Therapeutics Module: Psychiatry*	3.0
PHAR 605 Clinical Therapeutics Module: Hematology/Oncology*	2.5
PHAR 640 Foundations V	1.5
PHAR 660 Community Pharmacy Practice Management II	2.0
PHAR 715 Continuous Professional Development III	continues
Elective (Must have a minimum of 5 elective credits for entire P3 year)*	2.0 - 4.0
TOTAL CREDIT HOURS	18.5 - 20.5

Spring Semester 2022 | Course | Credit Hours	
PHAR 621 Pharmacoeconomics	2.0
PHAR 607 Clinical Therapeutics Module: Dermatology, EENT, & Joint*	2.0
PHAR 618 Clinical Therapeutics Module: Gastrointestinal/Nutrition*	2.5
PHAR 619 Clinical Therapeutics Module: Women's Health & Bone*	2.0
PHAR 620 Clinical Therapeutics Module: Critical Care/Toxicology & Complex Patients*	2.5
PHAR 645 Foundations VI	1.5
PHAR 724 Pharmacy Law	2.5
PHAR 533 Introductory Pharmacy Practice Experience: Patient Care	0.5
PHAR 715 Continuous Professional Development III	1.0
Elective (Must have a minimum of 5 elective credits for entire P3 year)*	2.0 - 4.0
TOTAL CREDIT HOURS	18.5 - 20.5

VCU School of Pharmacy

https://pharmacy.vcu.edu/admissions/pharmd/current-students/calendar--curriculum-/

VCU Pharm.D. Curriculum (P4 Year)

P4 Year (Over 45 weeks)

2022 - 2023 | Course | Credit Hours	
PHAR 760 Acute Care Pharmacy Practice I	5.0
PHAR 761 Advanced Hospital Pharmacy Practice	5.0
PHAR 762 Geriatrics Pharmacy Practice	5.0
PHAR 763 Ambulatory Care Pharmacy Practice	5.0
PHAR 765 Elective I	5.0
PHAR 766 Elective II	5.0
PHAR 768 Advanced Community Pharmacy Practice	5.0
PHAR 730 Advanced Community Pharmacy Practice	0.5
PHAR 773 Acute Care Pharmacy Practice II	5.0
IPEC 561 Virtual Geriatric Case	2.0
TOTAL CREDIT HOURS	42.5

Total of 1600 hours

VCU School of Pharmacy

https://pharmacy.vcu.edu/admissions/pharmd/current-students/calendar--curriculum-/

VCU Pharm.D. Training on Specific Aspects of HB1506

- Students receive **2 to 4+ hours** of didactic and clinical laboratory skills training on each of the following topics:
  - Naloxone
  - Epinephrine
  - Prenatal vitamins
  - Hormonal contraception
  - Dietary fluoride supplements
  - Over-the-counter (OTC) medications

This does NOT include additional experience and training obtained during clinical rotations (P4 year)

VCU School of Pharmacy

General Guidance on the Protocol and Training

- Detailed dosing guidelines are likely unnecessary.
  - Dosing for epinephrine, naloxone, prenatal vitamins, fluoride, and OTC medications is standardized and does not change.
- Hormonal contraception dosing is based on symptoms and patient preference.
  - Additional guidance or training on assessing symptoms and patient preferences may be appropriate.
- Pharmacists regularly dispense and make dosing recommendations for the medications being discussed today.
  - Additional guidance or training is not needed.

VCU School of Pharmacy

THANK YOU!

VCU School of Pharmacy

Agenda Topic: Review workforce statistics of pharmacists

Included in Agenda Package:

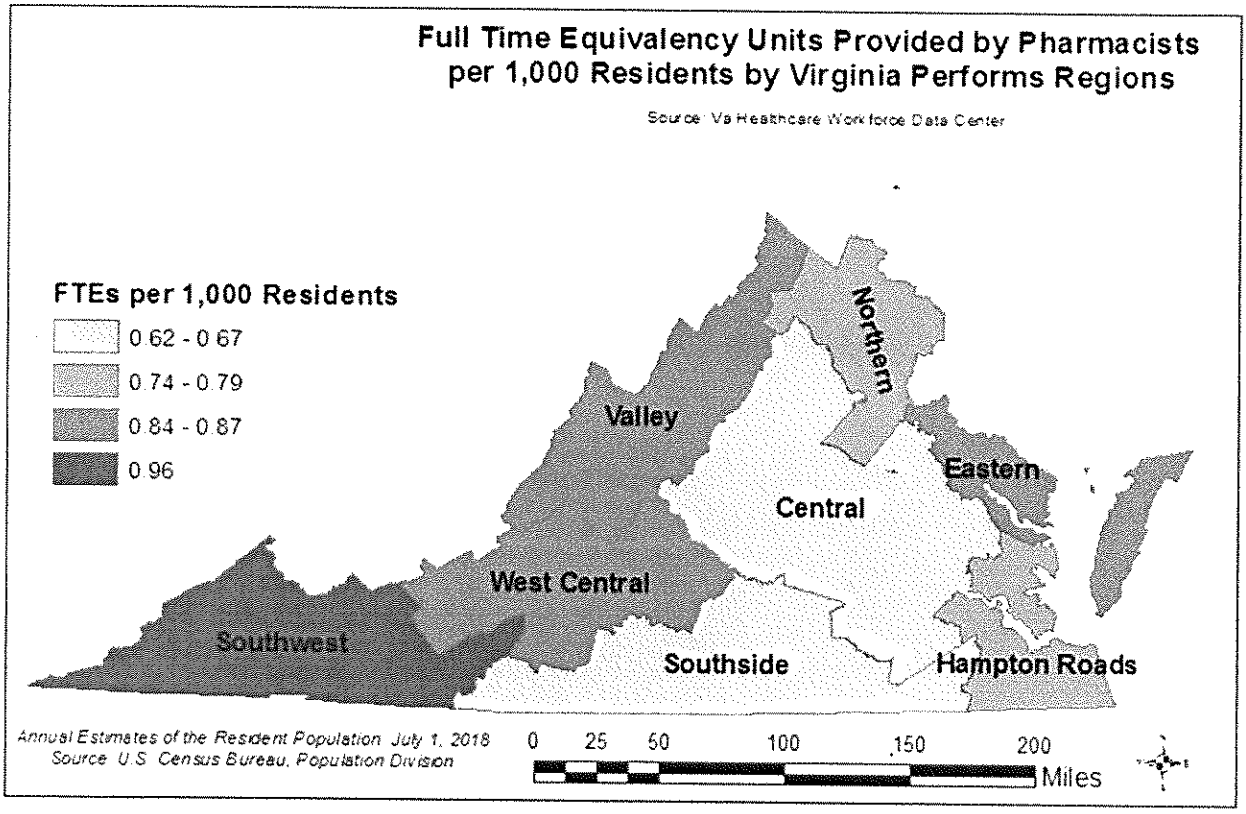
- **Excerpts from 2019 Virginia's Pharmacists Workforce Report**

No Action Necessary

The Pharmacist Workforce: At a Glance:

The Workforce		Background		Current Employment	
Licensees:	15,875	Rural Childhood:	33%	Employed in Prof.:	91%
Virginia's Workforce:	8,734	HS Degree in VA:	48%	Hold 1 Full-time Job:	71%
FTEs:	7,137	Prof. Degree in VA:	49%	Satisfied?:	84%
Survey Response Rate		**Education**		**Job Turnover**	
All Licensees:	91%	Baccalaureate:	34%	Switched Jobs in 2019:	5%
Renewing Practitioners:	97%	Pharm.D./Professional:	66%	Employed over 2 yrs:	62%
Demographics		**Finances**		**Primary Roles**	
Female:	66%	Median Inc.:	$120k-$130k	Patient Care:	75%
Diversity Index:	52%	Health Benefits:	70%	Administration:	7%
Median Age:	44	Under 40 w/ Ed debt:	74%	Education:	1%

Source: Va. Healthcare Workforce Data Center



Results in Brief

A total of 14,415 pharmacists voluntarily took part in the 2019 Pharmacist Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacists. These survey respondents represent 91% of the 15,875 pharmacists who are licensed in the state and 97% of renewing practitioners. The HWDC estimates that 8,734 pharmacists participated in Virginia's workforce during the survey period and they provided 7,137 full-time equivalency units (FTE).

The majority of Virginia's pharmacists are female, and the median age among those in the workforce is 44. About one-third of pharmacists grew up in a rural area, and nearly one-quarter of these professionals currently work in non-metro areas of the state. Overall, 11% of Virginia's pharmacists work in a non-metro area. Around 66% of Virginia's pharmacist workforce have earned a doctorate or other professional degree as their highest educational attainment. About 43% of pharmacists currently carry educational debt, including nearly three-quarters of those under the age of 40. The median debt for those pharmacists with educational debt is between $110,000 and $120,000.

Nine out of every ten pharmacists are currently employed in the profession, with 71% holding one full-time position. Over the past year, 3% of pharmacists were involuntarily unemployed, while another 3% were underemployed. The typical pharmacist earned between $120,000 and $130,000 in 2019. Around 84% of all pharmacists are satisfied with their current employment situation, including 44% who indicated that they are "very satisfied".

About 91% of all pharmacists work in the private sector, including 65% who work at a for-profit organization. Large community pharmacies (i.e. pharmacies with more than 10 locations) were the most common working establishment type for Virginia's pharmacist workforce, employing 27% of all professionals. Hospital systems and smaller pharmacies were also common employers. About 4 in 10 pharmacists expect to retire by the age of 65 and 7% of the current workforce expect to retire in the next two years. Half of the current workforce expect to retire by 2044.

Summary of Trends

The total number of licensed pharmacists has grown by 29% since 2013. Of these, the number working in the state workforce has also increased but the increase of 12% is more modest by comparison. However, the 1.2% increase in FTE provided by pharmacists in the same period is even a more modest increase.

The diversity index of Virginia's pharmacists increased from 47% in 2013 to 52% in 2019. The percentage of pharmacist who are female also continues to inch up by about one percent every year, from 62% in 2013 to 66% in the current report. Median age has been relatively stable between 44 to 45 years in the past seven surveys. Even the percent under age 40, which increased from 37% in 2013 to 40% in 2016, has stayed at 40% in the past three years.

Educational attainment continues to increase among the pharmacist workforce. In 2013, only 51% had a pharmacy doctorate compared to 66% in 2019. Not surprisingly, the percent reporting educational debt has also increased annually from 35% in 2013 to 43% in 2019. Meanwhile, the median educational debt, which increased from $90K-$100K in 2013 to $110K-$120K in 2018, stayed the same in 2019.

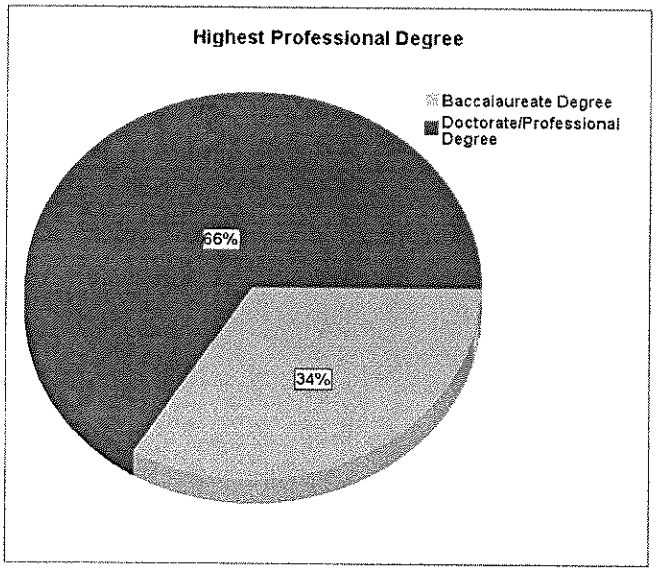
The labor market was a bit slack for pharmacists in the past year; 3% reported being involuntarily unemployed compared to the 1% involuntary employment rate in nearly all pre-2017 surveys. However, around 91% still reported being employed in the profession and the current involuntary unemployment rate in December 2019, when the survey took place, was 2%. Median income has been stable at $120K to $130K between 2016 and 2019 after increasing from $110K-$120K in 2013. However, the percent earning above $140,000 increased from 17% in 2016 to 22% in 2019; only 12% earned in that income range in 2013. Job satisfaction dropped precipitously in the past year, from 87% in 2018 to 84% in 2019; pharmacists who reported being very satisfied with their job also declined from 47% to 44% in the period.

Pharmacists intending to retire in the next decade increased from 22% in the pre-2017 surveys to 23% in 2017; it has stayed at 23% since then. The percent planning to retire in the next two years increased from 6% in 2013 to 7% in recent years. Regarding future plans, only 10% intended to pursue additional education in 2019 compared to 13% in 2013.

A Closer Look:

Highest Professional Degree		
Degree	#	%
B.S. Pharmacy	2,322	34%
Pharm.D.	4,581	66%
Total	6,903	100%

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

At a Glance:

Education

B.S. Pharmacy: 34%
Pharm.D.: 66%

Educational Debt

Carry debt: 43%
Under age 40 w/ debt: 74%
Median debt: $110k-$120k

Source: Va. Healthcare Workforce Data Center

66% of pharmacists hold a Doctorate in Pharmacy as their highest professional degree, while all remaining professionals have earned a Bachelor's degree in Pharmacy.

43% of pharmacists currently have educational debt, including 74% of those under the age of 40. For those with educational debt, the median debt is between $110,000 and $120,000. Among those under the age of 40 with debt, median is $150,000 to $160,000.

Educational Debt				
Amount Carried	All Pharmacists		Pharmacists Under 40	
	#	%	#	%
None	3,373	57%	613	26%
$20,000 or less	195	3%	77	3%
$20,001-$40,000	190	3%	83	4%
$40,001-$60,000	211	4%	103	4%
$60,001-$80,000	228	4%	112	5%
$80,001-100,000	225	4%	146	6%
$100,001-$120,000	211	4%	145	6%
$120,001-$140,000	155	3%	116	5%
$140,001-$160,000	164	3%	135	6%
$160,001-$180,000	156	3%	133	6%
$180,001-$200,000	144	2%	119	5%
Over $200,000	621	11%	537	23%
Total	5,873	100%	2,319	100%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

At a Glance:

Top Specialties

Immunization:	16%
Community Pharmacy:	8%
Ambulatory Care:	4%

Top Board Certifications

BPS - Pharmacotherapy:	6%
BPS - Ambulatory Care:	1%
BCGP - Geriatrics:	1%

Top Residencies (PGY1)

Pharmacy Practice (Post 1993):	10%
Community Pharmacy:	5%
Pharmacy Practice (Pre 1993):	4%

Source: Va. Healthcare Workforce Data Center

Board Certifications		
Certification	#	%
BPS-Pharmacotherapy	485	6%
BPS-Ambulatory Care	93	1%
BCGP-Geriatrics	85	1%
BPS-Oncology	30	<1%
BPS- Psychiatric	22	<1%
BPS- Nutrition	12	<1%
BPS-Nuclear Pharmacy	12	<1%
ABAT-Applied Toxicology	1	0%
Other Board Certification	211	2%
At Least One Certification	**857**	**10%**

Source: Va. Healthcare Workforce Data Center

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	916	10%
Community Pharmacy	415	5%
Pharmacy Practice (Pre 1993)	317	4%
Managed Care Pharmacy	40	<1%
Other	0	0%
Total	**1,688**	**19%**
PGY2		
Ambulatory Care	105	1%
Critical Care	64	1%
Internal Medicine/Cardiology	44	1%
Drug Information	39	<1%
Infectious Disease	32	<1%
Pediatrics	28	<1%
Oncology	27	<1%
Health-system Pharmacy Administration	25	<1%
Geriatrics	23	<1%
Psychiatry	22	<1%
Managed Care Pharmacy Systems	16	<1%
Pharmacotherapy	15	<1%
Informatics	15	<1%
Other	167	2%
At Least One	**622**	**7%**

Source: Va. Healthcare Workforce Data Center

10% of pharmacists hold a board certification, including 6% who hold a certification in Pharmacotherapy. 33% also have a self-designated specialty area, including 16% who have a specialization in immunization.

At a Glance:

Top Services

Immunization: 32%
Medication Management: 29%
Compounding: 25%

Disease Management

Anticoagulation: 15%
Diabetes: 3%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Services Provided	Primary		Secondary	
Services	#	%	#	%
Primary Service, Immunization	2,800	32%	2,800	32%
Primary Service, Medication Therapy Management	2,539	29%	274	3%
Primary Service, Compounding	2,225	25%	227	3%
Primary Service, Central Filling	1,188	14%	155	2%
Primary Service, Remote Order Processing	937	11%	84	1%
Primary Service, Collaborative Practice Agreement	580	7%	74	1%
At Least One	**4,679**	**54%**	**3,044**	**35%**

Source: Va. Healthcare Workforce Data Center

Disease Management in Collaborative Practice	#	%
Anticoagulation	79	15%
Diabetes	16	3%
Hypertension, Hypercholesterolemia, Anticoagulation, Diabetes	15	3%
Anticoagulation, Diabetes	14	3%
Hypertension, Hypercholesterolemia, Asthma, Anticoagulation, Diabetes	13	2%
Hypertension, Diabetes	11	2%
Hypertension, Hypercholesterolemia, Asthma, Diabetes	13	2%
Hypertension, Anticoagulation	4	1%
Hypertension, Asthma, Anticoagulation , Diabetes	4	1%
Hypertension	3	1%
Hypertension, Hypercholesterolemia, Asthma	3	1%
Hypertension, Hypercholesterolemia	2	0%
Asthma, Diabetes	1	0%
Asthma, Tobacco cessation	1	0%
Hypercholesterolemia	1	0%
Hypercholesterolemia, Asthma	1	0%
Hypertension , Asthma, Tobacco cessation, Diabetes	1	0%
Hypertension , Asthma, Tobacco cessation, Travel medications	1	0%
Hypertension , Asthma, Travel medications , Diabetes	1	0%
Hypertension, Hypercholesterolemia, Anticoagulation	1	0%
Other	343	66%
Total	**528**	**100%**

Source: Va. Healthcare Workforce Data Center

Agenda Topic: Update on recently adopted Virginia protocols

Included in Agenda Package:

- Copies of statewide protocols developed in collaboration with Board of Medicine and Department of Health, and adopted by Virginia Board of Pharmacy on 9/9/2020

No Action Necessary

VIRGINIA BOARD OF PHARMACY

Pharmacist Naloxone Statewide Protocol

Consistent with the naloxone manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- intranasal naloxone (nasal spray formulation or for administration by mucosal atomization device);
- intramuscular naloxone, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone;
- naloxone auto-injector; or,
- any other opioid antagonist formulation approved by the FDA for overdose reversal, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

PATIENT INCLUSION CRITERIA

Patients eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose, e.g., patient has a history of prior overdose, substance misuse, a morphine milligram equivalency of 120MME/day, or is currently prescribed an opioid with a concomitant benzodiazepine present;
- A family member, friend, or other person, 18 years of age or older, in a position to assist an individual who is experiencing or at risk of experiencing an opioid-related overdose.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual less than 18 years of age;
- An individual receiving treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, (iv) a patient in palliative care, (v) a patient enrolled in a clinical trial as authorized by state or federal law. Refer patient to primary care provider to determine if naloxone appropriate.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and ~~he or she shall~~ counsel the patient or the patient's agent on how

to properly identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

RECORDKEEPING

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

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.

VIRGINIA BOARD OF PHARMACY

Pharmacist Epinephrine Statewide Protocol

Consistent with the epinephrine manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Epinephrine auto-injector; or,
- Injectable epinephrine, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering epinephrine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognition and management of anaphylaxis.

PATIENT INCLUSION CRITERIA

Patients eligible for epinephrine under this protocol:

- Any person, 18 years of age or older, demonstrating signs and symptoms of anaphylaxis or at risk for experiencing anaphylaxis, e.g., patients reporting having previously been prescribed epinephrine for treatment of possible anaphylaxis or reporting a diagnosis of allergies that may result in anaphylaxis.

COUNSELING

The pharmacist shall counsel the patient or the patient's agent on how to properly recognize and mangage anaphylaxis, including proper administration of the epinephrine.

RECORDKEEPING

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

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.

VIRGINIA BOARD OF PHARMACY

Pharmacist Hormonal Contraceptive Statewide Protocol
(Excluding Emergency Contraception)

Consistent with the hormonal contraceptive manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

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

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering injectable or self-administered hormonal contraceptive under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited educational training program related to the prescribing of contraceptives by a pharmacist.

PATIENT INCLUSION CRITERIA

Patients eligible for injectable or self-administered hormonal contraceptives approved by the FDA under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire** and who the pharmacist has determined is eligible for a hormonal contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use*, i.e., the prescribed drug is assessed at a "1" or "2" for all conditions applicable to the patient.

*Note: A pharmacy may create and use an electronic routine hormonal contraceptive self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

To determine patient eligibility, the pharmacist shall:

1. Obtain from each new patient and, at a minimum of every twelve months for each returning patient, a completed *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire**; and,
2. Utilize and follow the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives* or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate* to perform the patient assessment.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for a hormonal contraceptive as indicated

by the *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use* and the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives* or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate*, as applicable, shall be referred to a healthcare practitioner and may not receive a hormonal contraceptive under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall 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.

FURTHER CONDITIONS

1. For each new patient requesting a contraceptive service a participating pharmacist must provide the patient with a visit summary.
2. A pharmacist shall not:
   a. Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit. Such evidence may be obtained by the response on the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire* regarding the date of the patient's last women's health clinical visit.
   b. Prescribe in instances that the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives* or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate*, as applicable, requires referral to a provider.

DRUG INCLUSION CRITERIA

The following drug formulations approved by the FDA to prevent pregnancy are included in this statewide protocol:

- injectable depot medroxyprogesterone acetate;
- transdermal patches;
- vaginal rings; and,
- contraceptives intended to be taken orally.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER; COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a hormonal contraceptive, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider and obstetrician/gynecologist (OB/GYN), 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; and,
2. Additionally, 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.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <20 yrs:**2**		Menarche to <20 yrs:**2**		Menarche to <18 yrs:**1**		Menarche to <18 yrs:**2**		Menarche to <18 yrs:**1**		Menarche to <40 yrs:**1**	
		≥20 yrs:**1**		≥20 yrs:**1**		18-45 yrs:**1**		18-45 yrs:**1**		18-45 yrs:**1**		≥40 yrs:**2**	
						>45 yrs:**1**		>45 yrs:**2**		>45 yrs:**1**			
Anatomical abnormalities	a) Distorted uterine cavity	**4**		**4**									
	b) Other abnormalities	**2**		**2**									
Anemias	a) Thalassemia	**2**		**1**		**1**		**1**		**1**		**1**	
	b) Sickle cell disease‡	**2**		**1**		**1**		**1**		**1**		**2**	
	c) Iron-deficiency anemia	**2**		**1**		**1**		**1**		**1**		**1**	
Benign ovarian tumors	(*including cysts*)	**1**		**1**		**1**		**1**		**1**		**1**	
Breast disease	a) Undiagnosed mass	**1**		**2**		**2***		**2***		**2***		**2***	
	b) Benign breast disease	**1**		**1**		**1**		**1**		**1**		**1**	
	c) Family history of cancer	**1**		**1**		**1**		**1**		**1**		**1**	
	d) Breast cancer‡												
	i) Current	**1**		**4**		**4**		**4**		**4**		**4**	
	ii) Past and no evidence of current disease for 5 years	**1**		**3**		**3**		**3**		**3**		**3**	
Breastfeeding	a) <21 days postpartum					**2***		**2***		**2***		**4***	
	b) 21 to <30 days postpartum												
	i) With other risk factors for VTE					**2***		**2***		**2***		**3***	
	ii) Without other risk factors for VTE					**2***		**2***		**2***		**3***	
	c) 30-42 days postpartum												
	i) With other risk factors for VTE					**1***		**1***		**1***		**3***	
	ii) Without other risk factors for VTE					**1***		**1***		**1***		**2***	
	d) >42 days postpartum					**1***		**1***		**1***		**2***	
Cervical cancer	Awaiting treatment	**4**	**2**	**4**	**2**	**2**		**2**		**1**		**2**	
Cervical ectropion		**1**		**1**		**1**		**1**		**1**		**1**	
Cervical intraepithelial neoplasia		**1**		**2**		**2**		**2**		**1**		**2**	
Cirrhosis	a) Mild (*compensated*)	**1**		**1**		**1**		**1**		**1**		**1**	
	b) Severe‡ (*decompensated*)	**1**		**3**		**3**		**3**		**3**		**4**	
Cystic fibrosis‡		**1***		**1***		**1***		**2***		**1***		**1***	
Deep venous thrombosis (DVT)/Pulmonary embolism (PE)	a) History of DVT/PE, not receiving anticoagulant therapy												
	i) Higher risk for recurrent DVT/PE	**1**		**2**		**2**		**2**		**2**		**4**	
	ii) Lower risk for recurrent DVT/PE	**1**		**2**		**2**		**2**		**2**		**3**	
	b) Acute DVT/PE	**2**		**2**		**2**		**2**		**2**		**4**	
	c) DVT/PE and established anticoagulant therapy for at least 3 months												
	i) Higher risk for recurrent DVT/PE	**2**		**2**		**2**		**2**		**2**		**4***	
	ii) Lower risk for recurrent DVT/PE	**2**		**2**		**2**		**2**		**2**		**3***	
	d) Family history (*first-degree relatives*)	**1**		**1**		**1**		**1**		**1**		**2**	
	e) Major surgery												
	i) With prolonged immobilization	**1**		**2**		**2**		**2**		**2**		**4**	
	ii) Without prolonged immobilization	**1**		**1**		**1**		**1**		**1**		**2**	
	f) Minor surgery without immobilization	**1**		**1**		**1**		**1**		**1**		**1**	
Depressive disorders		**1***		**1***		**1***		**1***		**1***		**1***	

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Diabetes	a) History of gestational disease	**1**		**1**		**1**		**1**		**1**		**1**	
	b) Nonvascular disease												
	i) Non-insulin dependent	**1**		**2**		**2**		**2**		**2**		**2**	
	ii) Insulin dependent	**1**		**2**		**2**		**2**		**2**		**2**	
	c) Nephropathy/retinopathy/neuropathy‡	**1**		**2**		**2**		**3**		**2**		**3/4***	
	d) Other vascular disease or diabetes of >20 years' duration‡	**1**		**2**		**2**		**3**		**2**		**3/4***	
Dysmenorrhea	Severe	**2**		**1**		**1**		**1**		**1**		**1**	
Endometrial cancer‡		**4**	**2**	**4**	**2**	**1**		**1**		**1**		**1**	
Endometrial hyperplasia		**1**		**1**		**1**		**1**		**1**		**1**	
Endometriosis		**2**		**1**		**1**		**1**		**1**		**1**	
Epilepsy‡	(*see also Drug Interactions*)	**1**		**1**		**1***		**1***		**1***		**1***	
Gallbladder disease	a) Symptomatic												
	i) Treated by cholecystectomy	**1**		**2**		**2**		**2**		**2**		**2**	
	ii) Medically treated	**1**		**2**		**2**		**2**		**2**		**3**	
	iii) Current	**1**		**2**		**2**		**2**		**2**		**3**	
	b) Asymptomatic	**1**		**2**		**2**		**2**		**2**		**2**	
Gestational trophoblastic disease‡	a) Suspected GTD (immediate postevacuation)												
	i) Uterine size first trimester	**1***		**1***		**1***		**1***		**1***		**1***	
	ii) Uterine size second trimester	**2***		**2***		**1***		**1***		**1***		**1***	
	b) Confirmed GTD												
	i) Undetectable/non-pregnant ß-hCG levels	**1***	**1***	**1***	**1***	**1***		**1***		**1***		**1***	
	ii) Decreasing ß-hCG levels	**2***	**1***	**2***	**1***	**1***		**1***		**1***		**1***	
	iii) Persistently elevated ß-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	**2***	**1***	**2***	**1***	**1***		**1***		**1***		**1***	
	iv) Persistently elevated ß-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	**4***	**2***	**4***	**2***	**1***		**1***		**1***		**1***	
Headaches	a) Nonmigraine (mild or severe)	**1**		**1**		**1**		**1**		**1**		**1***	
	b) Migraine												
	i) Without aura (includes menstrual migraine)	**1**		**1**		**1**		**1**		**1**		**2***	
	ii) With aura	**1**		**1**		**1**		**1**		**1**		**4***	
History of bariatric surgery‡	a) Restrictive procedures	**1**		**1**		**1**		**1**		**1**		**1**	
	b) Malabsorptive procedures	**1**		**1**		**1**		**1**		**3**		COCs: **3**	
												P/R: **1**	
History of cholestasis	a) Pregnancy related	**1**		**1**		**1**		**1**		**1**		**2**	
	b) Past COC related	**1**		**2**		**2**		**2**		**2**		**3**	
History of high blood pressure during pregnancy		**1**		**1**		**1**		**1**		**1**		**2**	
History of Pelvic surgery		**1**		**1**		**1**		**1**		**1**		**1**	
HIV	a) High risk for HIV	**1***	**1***	**1***	**1***	**1**		**1**		**1**		**1**	
	b) HIV infection					**1***		**1***		**1***		**1***	
	i) Clinically well receiving ARV therapy	**1**	**1**	**1**	**1**	If on treatment, see Drug Interactions							
	ii) Not clinically well or not receiving ARV therapy‡	**2**	**1**	**2**	**1**	If on treatment, see Drug Interactions							

Key:

1 No restriction (method can be used)	**3** Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	**4** Unacceptable health risk (method not to be used)

Abbreviations: ARV = antiretroviral; C=continuation of contraceptive method; CHC=combined hormonal contraception (pill, patch, and, ring); COC=combined oral contraceptive; Cu-IUD=copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; I=initiation of contraceptive method; LNG-IUD=levonorgestrel-releasing intrauterine device; NA=not applicable; POP=progestin-only pill; P/R=patch/ring; SSRI=selective serotonin reuptake inhibitor; ‡ Condition that exposes a woman to increased risk as a result of pregnancy. *Please see the complete guidance for a clarification to this classification: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a) Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b) Elevated blood pressure levels (*properly taken measurements*)												
	i) Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii) Systolic ≥160 or diastolic ≥100‡	1*		2*		2*		3*		2*		4*	
	c) Vascular disease	1*		2*		2*		3*		2*		4*	
Inflammatory bowel disease	(*Ulcerative colitis, Crohn's disease*)	1		1		1		2		2		2/3*	
Ischemic heart disease‡	Current and history of	1		2	3	2	3	3		2	3	4	
Known thrombogenic mutations‡		1*		2*		2*		2*		2*		4*	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	1		2		2		2		2		2	
	ii) Hepatocellular adenoma‡	1		3		3		3		3		4	
	b) Malignant‡ (hepatoma)	1		3		3		3		3		4	
Malaria		1		1		1		1		1		1	
Multiple risk factors for atherosclerotic cardiovascular disease	(e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1		2		2*		3*		2*		3/4*	
Multiple sclerosis	a) With prolonged immobility	1		1		1		2		1		3	
	b) Without prolonged immobility	1		1		1		2		1		1	
Obesity	a) Body mass index (BMI) ≥30 kg/m^2	1		1		1		1		1		2	
	b) Menarche to <18 years and BMI ≥ 30 kg/m^2	1		1		1		2		1		2	
Ovarian cancer‡		1		1		1		1		1		1	
Parity	a) Nulliparous	2		2		1		1		1		1	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		1		1		1		2		1	
Pelvic inflammatory disease	a) Past												
	i) With subsequent pregnancy	1	1	1	1	1		1		1		1	
	ii) Without subsequent pregnancy	2	2	2	2	1		1		1		1	
	b) Current	4	2*	4	2*	1		1		1		1	
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function												
	i) <6 months	2		2		1		1		1		4	
	ii) ≥6 months	2		2		1		1		1		3	
	b) Moderately or severely impaired cardiac function	2		2		2		2		2		4	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	2*		2*		1*		1*		1*		1*	
	c) Immediate postseptic abortion	4		4		1*		1*		1*		1*	
Postpartum (*nonbreastfeeding women*)	a) <21 days					1		1		1		4	
	b) 21 days to 42 days												
	i) With other risk factors for VTE					1		1		1		3*	
	ii) Without other risk factors for VTE					1		1		1		2	
	c) >42 days					1		1		1		1	
Postpartum (*in breastfeeding or nonbreastfeeding women, including cesarean delivery*)	a) <10 minutes after delivery of the placenta												
	i) Breastfeeding	1*		2*									
	ii) Nonbreastfeeding	1*		1*									
	b) 10 minutes after delivery of the placenta to <4 weeks	2*		2*									
	c) ≥4 weeks	1*		1*									
	d) Postpartum sepsis	4		4									

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Pregnancy		4*		4*		NA*		NA*		NA*		NA*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	2	1	1		2/3*		1		2	
	b) Not on immunosuppressive therapy	1		1		1		2		1		2	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver‡	1		1		1		1		1		1	
Sexually transmitted diseases (STDs)	a) Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1		1		1		1	
	b) Vaginitis (*including trichomonas vaginalis and bacterial vaginosis*)	2	2	2	2	1		1		1		1	
	c) Other factors relating to STDs	2*	2	2*	2	1		1		1		1	
Smoking	a) Age <35	1		1		1		1		1		2	
	b) Age ≥35, <15 cigarettes/day	1		1		1		1		1		3	
	c) Age ≥35, ≥15 cigarettes/day	1		1		1		1		1		4	
Solid organ transplantation‡	a) Complicated	3	2	3	2	2		2		2		4	
	b) Uncomplicated	2		2		2		2		2		2*	
Stroke‡	History of cerebrovascular accident	1		2		2	3	3		2	3	4	
Superficial venous disorders	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial venous thrombosis (acute or history)	1		1		1		1		1		3*	
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	1*	1*	3*		3*		3*	3*	3*		4*	
	b) Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*	
	c) Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*	
	d) None of the above	1*	1*	2*		2*		2*	2*	2*		2*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis‡ (*see also Drug Interactions*)	a) Nonpelvic	1	1	1	1	1*		1*		1*		1*	
	b) Pelvic	4	3	4	3	1*		1*		1*		1*	
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	4*	2*	4*	2*	3*		3*		2*		2*	
Uterine fibroids		2		2		1		1		1		1	
Valvular heart disease	a) Uncomplicated	1		1		1		1		1		2	
	b) Complicated‡	1		1		1		1		1		4	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		1	1	2		2		2		1	
	b) Heavy or prolonged bleeding	2*		1*	2*	2*		2*		2*		1*	
Viral hepatitis	a) Acute or flare	1		1		1		1		1		3/4*	2
	b) Carrier/Chronic	1		1		1		1		1		1	1
Drug Interactions													
Antiretrovirals used for prevention (PrEP) or treatment of HIV	Fosamprenavir (FPV) All other ARVs are 1 or 2 for all methods.	1/2*	1*	1/2*	1*	2*		2*		2*		3*	
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		2*		1*		3*		3*	
	b) Lamotrigine	1		1		1		1		1		3*	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampin or rifabutin therapy	1		1		2*		1*		3*		3*	
SSRIs		1		1		1		1		1		1	
St. John's wort		1		1		2		1		2		2	

Updated in 2020. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condomreduces the risk of STDs and HIV.

CS314239-A

Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives

1) Pregnancy Screen
Review Pregnancy Screen section of Virginia Routine Hormonal Contraceptive Self-screening Questionnaire
If YES to at least one question and is free of pregnancy symptoms, proceed to next step.
If NO to All questions, pregnancy cannot be ruled out – Refer.

Possible Pregnancy → Refer; provide info per protocol if no PCP

Patient is not pregnant

2) Health and History Screen
Evaluate responses on Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire using CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use
1 or 2 (green boxes) = Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes)= Hormonal contraception is contraindicated – Refer.

Contraindicating Conditions/Medications → Refer; provide info per protocol if no PCP

No Contraindicating Conditions/Medications

3) Blood Pressure Screen
Is blood pressure < 140/90?
Note: Pharmacist may choose to take a second reading if initial is high.

BP > 140/90 → Refer; provide info per protocol if no PCP

BP < 140/90

4) Evaluate past use, preference, and current use of birth control.

Not currently on birth control

Patient currently on birth control

5a) Choose Contraception
Initiate contraception for new therapy based on patient preferences, adherence, and history.
Issue prescription for up to 12 months for dispensing at patient's pharmacy of choice (quantity based on professional judgement and patient preference).

5b) Choose Contraception
Continue current form of pills, patch, or ring, if no change necessary. – Or-
Alter therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate.

6) Discuss Initiation Strategy for New Treatment/Change in Treatment (as applicable)
a) Counseling – Regular or Quick Start- Instruct patient she can begin today; use backup method for 7 days.
b) Counseling – Discuss the management and expectations of side effects (bleeding irregularity, etc.)
c) Counseling - Discuss adherence and expectations for follow-up visits.

7a) Inquire of Healthcare Providers, Counsel, Notify Providers
a) If prescribe, notify primary care provider and OB/GYN; counsel patient to seek preventative care per protocol.
b) If no primary care provider, counsel on benefits of relationship and provide information per protocol.

Virginia Algorithm for Pharmacists to Prescribe & Administer Depot Medroxyprogesterone Acetate

1) Pregnancy Screen
Review Pregnancy Screen section of Virginia Routine Hormonal Contraceptive Self-screening Questionnaire
If YES to at least one question and is free of pregnancy symptoms, proceed to next step.
If NO to All questions, pregnancy cannot be ruled out – Refer.

Possible Pregnancy → Refer; provide info per protocol if no PCP

Patient is not pregnant

2) Health and History Screen
Evaluate responses on Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire using CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use
1 or 2 (green boxes) = Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) = Hormonal contraception is contraindicated – Refer.

Contraindicating Conditions/Medications → Refer; provide info per protocol if no PCP

No Contraindicating Conditions/Medications

3) Blood Pressure Screen
Is blood pressure < 140/90?
Note: Pharmacist may choose to take a second reading if initial is high.

BP > 140/90 → Refer; provide info per protocol if no PCP

BP < 140/90

4) Discuss DMPA therapy with patient
a) Address any unexplained vaginal bleeding that worries patient. Refer, when necessary.
b) Counseling- Discuss management and expectations of side effects (bleeding irregularity, etc.)
c) Counseling – Discuss plans for follow-up visits, particularly for q3 month administration DMPA; Stress importance of returning for next injection 11-13 weeks of previous injection. Provide patient with specific calendar date range for next injection.
d) Counseling – Caution with use of DMPA > 2 years (due to loss of bone mineral density). For therapy > 2 years, consultation with primary healthcare provider or OB/GYN is indicated.

First dose of DMPA

q 3 month dose of DMPA

5a) Issue prescription and administer DMPA
Pharmacist shall issue a prescription for depot medroxyprogesterone and administer the medication. Monitor patient for 20 minutes for adverse reaction.
Note: Instruct patient that if this injection is not within 7 days of start of period, then abstain or use backup method for 7 days.

5b) Ongoing administration of DMPA
Pharmacist shall confirm that date of last injection was within 11 weeks.
- If > 13 weeks, then pharmacist must rule out pregnancy (refer to Pregnancy Screening section on *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire*), and instruct patient to abstain or use backup method for 7 days.
- If between 11-13 weeks ago, administer the medication.

7a) Inquire of Healthcare Providers, Counsel, Notify Providers
a) If prescribe, notify primary care provider and OB/GYN; counsel patient to seek preventative care per protocol.
b) If no primary care provider, counsel on benefits of relationship and provide information per protocol.

VIRGINIA ROUTINE HORMONAL CONTRACEPTIVE SELF-SCREENING QUESTIONNAIRE

Name: _____ Today's Date: _____ Weight: _____

Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____

Healthcare Provider's Telephone, Fax, or Email: _____

What was the date of your last women's health clinical visit? _____

Any Allergies to Medications? *Yes / No* If yes, list them here: _____

Pregnancy Screen:

1.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, *AND* have you had no menstrual period since the delivery?	Yes ☐ No☐
2.	Have you had a baby in the last 4 weeks?	Yes ☐ No☐
3.	Did you have a miscarriage or abortion in the last 7 days?	___/___/___
4.	Did your last menstrual period start within the past 7 days?	Yes ☐ No ☐
5.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes ☐ No ☐
6.	Have you been using a reliable contraceptive method consistently and correctly?	Yes ☐ No ☐

If you answered NO to ALL of the questions above, you may stop here and consult with the pharmacist. If you answered YES to at least one of the questions above, please proceed with completing this form.

Additional Information:

7.	Do you think you might be pregnant now?	Yes ☐ No☐
8.	Have you used emergency contraception within the last 5 days?	Yes ☐ No☐
9.	What was the first day of your last menstrual period?	___/___/___
10.	Have you ever been told by a medical professional not to take hormones?	Yes ☐ No ☐
11.	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes ☐ No ☐
12.	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐ No ☐
13.	- If yes, what kind of reaction occurred?	
14.	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes ☐ No ☐
15.	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes ☐ No ☐
16.	- If yes, which one do you use? (List here)	
17.	Do you have a preferred method of birth control that you would like to use? (check box) ☐ A pill that you take daily ☐ A patch that you change weekly ☐ A vaginal ring that you change monthly ☐ An injection that you receive every 3 months	

Medical History

Smoking:

18.	Do you smoke cigarettes or vape nicotine?	Yes ☐ No ☐
19.	-If yes, number or equivalent number of cigarettes per day either smoked or vaped.	_____ /day

Postpartum (nonbreastfeeding women)/Breastfeeding:

20.	Have you given birth within 21 days? If yes, how long ago?	Yes ☐ No ☐
21.	Are you currently breastfeeding?	Yes ☐ No ☐

Diabetes:

22.	Do you have diabetes?	Yes ☐ No ☐

Headaches:

23.	Do you get migraine headaches?	Yes ☐ No ☐

24.	- If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes ☐ No ☐
Hypertension, History of high blood pressure during pregnancy:		
25.	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes ☐ No ☐
Deep venous thrombosis (DVT)/Pulmonary embolism (PE), Ischemic heart disease, Known thrombogenic mutations, Multiple risk factors for atherosclerotic cardiovascular disease, Peripartum cardiomyopathy, Stroke, Valvular heart disease:		
26.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐ No ☐
27.	Have you ever had a blood clot?	Yes ☐ No ☐
28.	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes ☐ No ☐
29.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐ No ☐
History of bariatric surgery:		
30.	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐ No ☐
Breast disease:		
31.	Do you have or have you ever had breast cancer?	Yes ☐ No ☐
Cirrhosis, Gallbladder disease, History of cholestasis, Liver tumors, Viral hepatitis:		
32.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐ No ☐
Rheumatoid arthritis, Systemic lupus erythematosus:		
33.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐ No ☐
Epilepsy, HIV, Tuberculosis, Drug Interactions (Antiretrovirals, Anticonvulsant, Antimicrobial therapy):		
34.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐ No ☐
35.	- If yes, list them here:	
Other information:		
36.	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes ☐ No ☐
37.	- If yes, list them here:	
38.	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes ☐ No ☐

Internal use only

☐ Verified DOB with valid photo ID BP Reading _____/_____

☐ Drug Prescribed:_____

Sig:_____

Pharmacist Name:_____

Pharmacy Name and Address:_____

Pharmacy Phone:_____

☐Patient Referred

Reason(s):_____

Notes:_____

VIRGINIA BOARD OF PHARMACY

Pharmacist Emergency Contraception Statewide Protocol

A pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Self-administered hormonal emergency contraception (EC) provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, or dispensing of a self-administered hormonal EC under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use or standard protocol and shall have completed at least one hour of continuing education specific to the prescribing of EC.

PATIENT INCLUSION CRITERIA

Patients eligible for self-administered hormonal EC under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Emergency Contraception Self-Screening Questionnaire** indicating the last day of unprotected intercourse was within the previous 5 days (120 hours) and who the pharmacist has determined is eligible for a hormonal emergency contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *US Medical Eligibility Criteria for Contraceptive Use, Classifications for Emergency Contraception.*

*Note: A pharmacy may create and use an electronic emergency contraception self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Emergency Contraception Self-Screening Questionnaire.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for EC shall be referred to a healthcare practitioner and may not receive EC under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall 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.

DRUG INCLUSION CRITERIA

The following drug formulations are included in this EC statewide protocol:

Dedicated Approved EC – One Tablet Regimens

Plan B One-Step	1 tablet	1.5mg levonorgestrel	OTC
Levonorgestrel	1 tablet	1.5mg levonorgestrel	OTC
Next Choice One Dose	1 tablet	1.5mg levonorgestrel	OTC
Ella	1 tablet	30mg ulipristal	Rx only

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed.

Oral Contraceptive Pills

Brand	Tablets per dose (2 doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*	Status
Alesse	5 pink tablets	100	0.50	Rx only
Aviane	5 orange tablets	100	0.5	Rx only
Levlen	4 light-orange tablets	120	0.6	Rx only
Levlite	5 pink tablets	100	0.5	Rx only
Levora	4 white tablets	120	0.60	Rx only
Lo/Ovral	4 white tablets	120	0.60	Rx only
Low-Ogestrel	4 white tablets	120	0.60	Rx only
Nordette	4 light-orange tablets	120	0.60	Rx only
Ogestrel	2 white tablets	100	0.50	Rx only
Ovral	2 white tablets	100	0.50	Rx only
Tri-Levlen	4 yellow tablets	100	0.50	Rx only
Triphasil	4 yellow tablets	120	0.50	Rx only
Trivora	4 pink tablets	120	0.50	Rx only
Ovrette	20 yellow tablets	0	0.75	Rx only

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrol, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed. Estrogen containing regimens are not preferred and should be used only when other options are not available.

Anti-nausea Treatment Options for use with EC

Drug	Dose	Timing of Administration	Status
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours	OTC
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Cyclizine hydrochloride	One 50mg tablet	30 minutes before first EC dose; repeat as needed every	OTC

(Marezine)		4-6 hours	

ADDITIONAL PRESCRIBING AND DISPENSING CONSIDERATIONS

- For women who weigh more than 165 lbs, levonorgestrel may be less effective than ulipristal acetate.*
- Levonorgestrel may be preferable for women who need EC due to missed or late pills, patch, or ring.*
- Starting hormonal birth control immediately after taking ulipristal acetate may make it ineffective.*
- For women with prescription insurance coverage, OTC drugs may be covered by the health carrier when prescribed for the patient.*
- Ella may be more effective if it has been more than 72 hours since the last day of unprotected intercourse.
- Pharmacist must counsel the patient on the proper use of the EC and side effects, to include providing written educational materials.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER AND COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a self-administered hormonal EC, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). 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; and,
2. Additionally, 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.

***Per the American Society for Emergency Contraception.**

Virginia Emergency Contraception Self-Screening Questionnaire

Timing is an essential element of the effectiveness of emergency contraception (EC). EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

Patient's Name_____ **Date**_____

Healthcare Provider's Name_____

Healthcare Provider's Telephone or Email address_____

Date of Birth _____ **Age** _____ **Weight** _____

What was the date of you last women's health clinical visit? _____

Any allergies to medications? _____

Number of hours/days since last unprotected intercourse _____

Internal use only

☐ Verified DOB with valid photo ID BP Reading _____/_____

☐ Drug Prescribed: _____

Sig: _____

Pharmacist's Name: _____

Pharmacy's Name and Address: _____

Pharmacy's Phone: _____

☐Patient Referred

Reason(s):_____

Notes:_____

_____

_____

VIRGINIA BOARD OF PHARMACY

Pharmacist Prenatal Vitamin Statewide Protocol

Consistent with the prenatal vitamin manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Prenatal vitamins for which a prescription is required.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering prenatal vitamins under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for prenatal vitamins under this protocol:

- An individual, 18 years of age or older, who is considering pregnancy, attempting to become pregnant, or pregnant.

RECORDKEEPING

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

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 and obstetrician/gynecologist (OB/GYN). 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.

VIRGINIA BOARD OF PHARMACY

Pharmacist Dietary Fluoride Supplement Statewide Protocol

The American Dental Association does not recommend the prescribing of dietary fluoride supplements for persons 18 years of age or older whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services, therefore pharmacists are not currently authorized to initiate treatment with, dispense, or administer dietary fluoride supplements under a pharmacist statewide protocol.

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol to Lower Out-of Pocket Expense

For the purpose of lowering a patient's out-of-pocket health care costs, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Medications 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.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering medications under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and follow any relevant evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for medications under this protocol:

- An individual, 18 years of age or older, whose over-the-counter medication is covered by the patient's health carrier and when the patient's out-of-pocket cost for the prescribed drug is lower than the out-of-pocket cost to purchase the same drug over-the-counter;
- An individual, 18 years of age or older, whose over-the-counter medication would cost more out-of-pocket than a prescribed prescription-only medication that is a therapeutically equivalent drug product[1], as defined in § 54.1-3401, as the over-the-counter medication.

RECORDKEEPING

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

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Drug Control Act, 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.

[1]"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book.", § 54.1-3401.

Agenda Topic: Vaccines included on the immunization schedule published by the Centers for Disease Control and Prevention

Included in agenda package:

- CDC Recommended Adult Immunization Schedule
- Current allowances in law for pharmacists and supervised pharmacy interns to order administer vaccines and additional allowances during COVID-19 public health emergency
    - Staff prepared summary of HHS pediatric vaccine allowance
- *Pharmacist-administered Vaccines*, updated June 2020, APhA/NASPA Survey
- Example and List of Oregon Pharmacy Vaccine Protocol

Action to be taken:

- Discuss subject and offer recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older for vaccines included on the immunization schedule published by the CDC

Recommended Adult Immunization Schedule
for ages 19 years or older

UNITED STATES
2020

How to use the adult immunization schedule

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

2 Assess need for additional recommended vaccinations by medical condition and other indications **(Table 2)**

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

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 College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), and American College of Nurse-Midwives (www.midwife.org).

Vaccines in the Adult Immunization Schedule*

Vaccines	Abbreviations	Trade names
Haemophilus influenzae type b vaccine	Hib	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix®
Hepatitis B vaccine	HepB	Engerix-B® Recombivax HB® Heplisav-B®
Human papillomavirus vaccine	HPV vaccine	Gardasil 9®
Influenza vaccine (inactivated)	IIV	Many brands
Influenza vaccine (live, attenuated)	LAIV	FluMist® Quadrivalent
Influenza vaccine (recombinant)	RIV	Flublok® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R® II
Meningococcal serogroups A, C, W, Y vaccine	MenACWY	Menactra® Menveo®
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
Tetanus and diphtheria toxoids	Td	Tenivac® Tdvax™
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Varicella vaccine	VAR	Varivax®
Zoster vaccine, recombinant	RZV	Shingrix
Zoster vaccine live	ZVL	Zostavax®

*Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Report

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

Injury claims

All vaccines included in the adult immunization schedule except pneumococcal 23-valent polysaccharide (PPSV23) and zoster (RZV, ZVL) vaccines are covered by the Vaccine Injury Compensation Program. Information on how to file a vaccine injury claim is available at www.hrsa.gov/vaccinecompensation.

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 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
- Travel vaccine recommendations: www.cdc.gov/travel
- Recommended Child and Adolescent Immunization Schedule, United States, 2020: www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

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

CS310021-A

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2020

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or **Influenza recombinant** (RIV)	1 dose annually	1 dose annually	1 dose annually	1 dose annually
Influenza live, attenuated (LAIV)	or	or		
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV) *(preferred)*	2 doses	2 doses	2 doses	2 doses
Zoster live (ZVL)	or	or	or	1 dose
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal conjugate (PCV13)	1 dose			65 years and older
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication			1 dose
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			
Hepatitis B (HepB)	2 or 3 doses depending on vaccine			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2020

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count <200	HIV infection CD4 count ≥200	Asplenia, complement deficiencies	End-stage renal disease; or on hemodialysis	Heart or lung disease, alcoholism[1]	Chronic liver disease	Diabetes	Health care personnel[2]	Men who have sex with men
IIV or RIV	1 dose annually										
or										or	
LAIV	NOT RECOMMENDED						PRECAUTION			1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	NOT RECOMMENDED			1 or 2 doses depending on indication							
VAR	NOT RECOMMENDED			2 doses							
RZV *(preferred)*	DELAY				2 doses at age ≥50 years						
or					or						
ZVL	NOT RECOMMENDED				1 dose at age ≥60 years						
HPV	DELAY	3 doses through age 26 years			2 or 3 doses through age 26 years						
PCV13		1 dose									
PPSV23		1, 2, or 3 doses depending on age and indication									
HepA					2 or 3 doses depending on vaccine						
HepB					2 or 3 doses depending on vaccine						
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	PRECAUTION	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[3] recipients only			1 dose						

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended vaccination for adults with an additional risk factor or another indication

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

Delay vaccination until after pregnancy if vaccine is indicated

Not recommended/ contraindicated—vaccine should not be administered

No recommendation/ Not applicable

1. Precaution for LAIV does not apply to alcoholism. **2.** See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. **3.** Hematopoietic stem cell transplant.

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease)**: 1 dose if previously did not receive Hib; if elective splenectomy, 1 dose, preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant** (HSCT): 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

Hepatitis A vaccination

Routine vaccination

- **Not at risk but want protection from hepatitis A** (identification of risk factor not required): 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/5 months between doses 2 and 3])

Special situations

- **At risk for hepatitis A virus infection**: 2-dose series HepA or 3-dose series HepA-HepB as above
  - **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A**
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
  - **Settings for exposure, including** health care settings targeting services to injection or noninjection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

Hepatitis B vaccination

Routine vaccination

- **Not at risk but want protection from hepatitis B** (identification of risk factor not required): 2- or 3-dose series (2-dose series Heplisav-B at least 4 weeks apart [2-dose series HepB only applies when 2 doses of Heplisav-B are used at least 4 weeks apart] or 3-dose series Engerix-B or Recombivax HB at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/8 weeks between doses 2 and 3/16 weeks between doses 1 and 3]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/5 months between doses 2 and 3])

Special situations

- **At risk for hepatitis B virus infection**: 2-dose (Heplisav-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix) as above
  - **Chronic liver disease** (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
  - **HIV infection**
  - **Sexual exposure risk** (e.g., sex partners of hepatitis B surface antigen [HBsAg]-positive persons; sexually active persons not in mutually monogamous relationships; persons seeking evaluation or treatment for a sexually transmitted infection; men who have sex with men)
  - **Current or recent injection drug use**
  - **Percutaneous or mucosal risk for exposure to blood** (e.g., household contacts of HBsAg-positive persons; residents and staff of facilities for developmentally disabled persons; health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids; hemodialysis, peritoneal dialysis, home dialysis, and predialysis patients; persons with diabetes mellitus age younger than 60 years and, at discretion of treating clinician, those age 60 years or older)
  - **Incarcerated persons**
  - **Travel in countries with high or intermediate endemic hepatitis B**
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy (Heplisav-B not currently recommended due to lack of safety data in pregnant women)

Human papillomavirus vaccination

Routine vaccination

- **HPV vaccination recommended for all adults through age 26 years**: 2- or 3-dose series depending on age at initial vaccination or condition:
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2, 6 months (minimum intervals: 4 weeks between doses 1 and 2/12 weeks between doses 2 and 3/5 months between doses 1 and 3; repeat dose if administered too soon)
  - **Age 9 through 14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart**: 1 dose
  - **Age 9 through 14 years at initial vaccination and received 2 doses at least 5 months apart**: HPV vaccination complete, no additional dose needed.
- **If completed valid vaccination series with any HPV vaccine, no additional doses needed**

Shared clinical decision-making

- **Age 27 through 45 years based on shared clinical decision-making**:
  - 2- or 3-dose series as above

Special situations

- **Pregnancy through age 26 years**: HPV vaccination is not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination

Influenza vaccination

Routine vaccination

- **Persons age 6 months or older**: 1 dose any influenza vaccine appropriate for age and health status annually
- For additional guidance, see www.cdc.gov/flu/professionals/index.htm

Special situations

- **Egg allergy, hives only**: 1 dose any influenza vaccine appropriate for age and health status annually
- **Egg allergy more severe than hives** (e.g., angioedema, respiratory distress): 1 dose any influenza vaccine appropriate for age and health status annually in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions
- **LAIV should not be used** in persons with the following conditions or situations:
  - History of severe allergic reaction to any vaccine component (excluding egg) or to a previous dose of any influenza vaccine
  - Immunocompromised due to any cause (including medications and HIV infection)
  - Anatomic or functional asplenia
  - Cochlear implant
  - Cerebrospinal fluid-oropharyngeal communication
  - Close contacts or caregivers of severely immunosuppressed persons who require a protected environment
  - Pregnancy
  - Received influenza antiviral medications within the previous 48 hours
- **History of Guillain-Barré syndrome within 6 weeks of previous dose of influenza vaccine**: Generally should not be vaccinated unless vaccination benefits outweigh risks for those at higher risk for severe complications from influenza

Measles, mumps, and rubella vaccination

Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella**: 1 dose
  - **Evidence of immunity**: Born before 1957 (health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

Special situations

- **Pregnancy with no evidence of immunity to rubella**: MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella**: 1 dose
- **HIV infection with CD4 count ≥200 cells/µL for at least 6 months and no evidence of immunity to measles, mumps, or rubella**: 2-dose series at least 4 weeks apart; MMR contraindicated in HIV infection with CD4 count <200 cells/µL
- **Severe immunocompromising conditions**: MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella**: 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **Health care personnel**:
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella**: 2-dose series at least 4 weeks apart for measles or mumps or at least 1 dose for rubella
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella**: Consider 2-dose series at least 4 weeks apart for measles or mumps or 1 dose for rubella

Meningococcal vaccination

Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use**: 2-dose series MenACWY (Menactra, Menveo) at least 8 weeks apart and revaccinate every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, microbiologists routinely exposed to *Neisseria meningitidis***: 1 dose MenACWY (Menactra, Menveo) and revaccinate every 5 years if risk remains
- **First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) and military recruits**: 1 dose MenACWY (Menactra, Menveo)

Shared clinical decision-making for MenB

- **Adolescents and young adults age 16 through 23 years (age 16 through 18 years preferred) not at increased risk for meningococcal disease**: Based on shared clinical decision-making, 2-dose series MenB-4C at least 1 month apart or 2-dose series MenB-FHbp at 0, 6 months (if dose 2 was administered less than 6 months after dose 1, administer dose 3 at least 4 months after dose 2); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series)

Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, microbiologists routinely exposed to *Neisseria meningitidis***: 2-dose primary series MenB-4C (Bexsero) at least 1 month apart or 3-dose primary series MenB-FHbp (Trumenba) at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series); 1 dose MenB booster 1 year after primary series and revaccinate every 2–3 years if risk remains
- **Pregnancy**: Delay MenB until after pregnancy unless at increased risk and vaccination benefits outweigh potential risks

Pneumococcal vaccination

Routine vaccination

- **Age 65 years or older** (immunocompetent–see www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm?s_cid=mm6846a5_w): 1 dose PPSV23
  - If PPSV23 was administered prior to age 65 years, adminster 1 dose PPSV23 at least 5 years after previous dose

Shared clinical decision-making

- **Age 65 years and older** (immunocompetent): 1 dose PCV13 based on **shared clinical decision-making**
  - If both PCV13 and PPSV23 are to be administered, PCV13 should be administered first
  - PCV13 and PPSV23 should be administered at least 1 year apart
  - PCV13 and PPSV23 should not be administered during the same visit

Special situations

(see www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm?s_cid=mm6846a5_w)

- **Age 19 through 64 years with chronic medical conditions (chronic heart [excluding hypertension], lung, or liver disease, diabetes), alcoholism, or cigarette smoking**: 1 dose PPSV23
- **Age 19 years or older with immunocompromising conditions (congenital or acquired immunodeficiency [including B- and T-lymphocyte deficiency, complement deficiencies, phagocytic disorders, HIV infection], chronic renal failure, nephrotic syndrome, leukemia, lymphoma, Hodgkin disease, generalized malignancy, iatrogenic immunosuppression [e.g., drug or radiation therapy], solid organ transplant, multiple myeloma) or anatomical or functional asplenia (including sickle cell disease and other hemoglobinopathies)**: 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later, then another dose PPSV23 at least 5 years after previous PPSV23; at age 65 years or older, administer 1 dose PPSV23 at least 5 years after most recent PPSV23 (note: only 1 dose PPSV23 recommended at age 65 years or older)
- **Age 19 years or older with cerebrospinal fluid leak or cochlear implant**: 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later; at age 65 years or older, administer another dose PPSV23 at least 5 years after PPSV23 (note: only 1 dose PPSV23 recommended at age 65 years or older)

Tetanus, diphtheria, and pertussis vaccination

Routine vaccination

- **Previously did not receive Tdap at or after age 11 years**: 1 dose Tdap, then Td or Tdap every 10 years

Special situations

- **Previously did not receive primary vaccination series for tetanus, diphtheria, or pertussis**: At least 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks after Tdap and another dose Td or Tdap 6–12 months after last Td or Tdap (Tdap can be substituted for any Td dose, but preferred as first dose); Td or Tdap every 10 years thereafter
- **Pregnancy**: 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- For information on use of Td or Tdap as tetanus prophylaxis in wound management, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm

Varicella vaccination

Routine vaccination

- **No evidence of immunity to varicella**: 2-dose series 4–8 weeks apart if previously did not receive varicella-containing vaccine (VAR or MMRV [measles-mumps-rubella-varicella vaccine] for children); if previously received 1 dose varicella-containing vaccine, 1 dose at least 4 weeks after first dose
  - Evidence of immunity: U.S.-born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella-containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease

Special situations

- **Pregnancy with no evidence of immunity to varicella**: VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility) 1 dose if previously received 1 dose varicella-containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- **Health care personnel with no evidence of immunity to varicella**: 1 dose if previously received 1 dose varicella-containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- **HIV infection with CD4 count ≥200 cells/µL with no evidence of immunity**: Vaccination may be considered (2 doses, administered 3 months apart); VAR contraindicated in HIV infection with CD4 count <200 cells/µL
- **Severe immunocompromising conditions**: VAR contraindicated

Zoster vaccination

Routine vaccination

- **Age 50 years or older**: 2-dose series RZV (Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of ZVL (Zostavax) vaccination (administer RZV at least 2 months after ZVL)
- **Age 60 years or older**: 2-dose series RZV 2–6 months apart (minimum interval: 4 weeks; repeat if administered too soon) or 1 dose ZVL if not previously vaccinated. RZV preferred over ZVL (if previously received ZVL, administer RZV at least 2 months after ZVL)

Special situations

- **Pregnancy**: ZVL contraindicated; consider delaying RZV until after pregnancy if RZV is otherwise indicated
- **Severe immunocompromising conditions (including HIV infection with CD4 count <200 cells/µL)**: ZVL contraindicated; recommended use of RZV under review

Current allowances in law for pharmacists and supervised pharmacy interns to administer vaccines:

1. Pharmacists may administer a vaccine to a person of age pursuant to a patient-specific prescription directing the pharmacist to administer the drug.
2. **54.1-3408 of the Code of Virginia**

   I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

3. **54.1-3408 of the Code of Virginia**

   W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

4. **§ 54.1-3320. Acts restricted to pharmacists.**

   B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

Additional Allowances during COVID-19 Public Health Emergency:

1. HHS Public Readiness and Emergency Preparedness Act (PREP Act) authorizes pharmacists to order and administer and pharmacy interns acting under the supervision of the qualified pharmacist to administer, certain vaccines to patients ages three (3) to eighteen (18) during the federally-declared COVID-19 public health emergency. The purpose of this declaration is to mitigate a potential "decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies."
2. HHS Public Readiness and Emergency Preparedness Act (PREP Act) authorizes pharmacists to order and administer and pharmacy interns acting under the supervision of the qualified pharmacist to administer, to persons ages three or older COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA).

UNITED STATES HHS DECLARATION UNDER PUBLIC READINESS AND EMERGENCY PREPAREDNESS ("PREP") ACT AUTHORIZING PHARMACISTS TO ORDER AND ADMINISTER VACCINES TO PATIENTS AGED THREE THROUGH 18 YEARS DURING THE COVID-19 HEALTH EMERGENCY

Prepared by Board of Pharmacy staff:

On August 19, 2020 the U.S. Department of Health and Human Services issued a declaration authorizing pharmacists "to order and administer," and a "supervised pharmacy intern" "to administer" certain vaccines to patients ages three (3) to eighteen (18) during the federally-declared COVID-19 public health emergency. The purpose of this declaration is to mitigate a potential "decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies."

Comparison of HHS PREP Act allowance for pediatric vaccines to current State law:
Below is a description, based on Virginia Board of Pharmacy staff's review, of the conditions under which pharmacists and pharmacy interns may exercise this authority, and how these conditions appear to differ from existing State law.

• ***Pharmacists may "order" vaccines for patients ages three (3) to eighteen (18).*** This is a new authority. Three provisions exist in State law for pharmacist administration of vaccines.

- 54.1-3408 (I) of the Code of Virginia authorizes pharmacists to administer vaccines to adults pursuant to a Board of Nursing-approved protocol or under the authorization of a prescriber acting on behalf of and in accordance with established protocols of the Department of Health.
- 54.1-3408 (W) of the Code of Virginia authorizes a pharmacist to administer influenza vaccine to minors under the authorization of a prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02.
- Current law authorizes a pharmacist to administer any vaccine to any person pursuant to a patient-specific prescription issued by a prescriber and directing the pharmacist to administer such vaccine.

• ***Pharmacists may order and administer any vaccine found on the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules to patients age (3) to eighteen (18).*** This is partly a new authority. As noted above, current Virginia law limits independent pharmacist ordering of vaccines. However, any vaccine may be administered to a person of any age pursuant to a patient-specific prescription directing the pharmacist to administer such vaccine.

• ***The licensed pharmacist must complete 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.*** This is a new requirement legally, but not operationally. While the State law does not require such training, most employers and liability insurance plans appear to require this training for liability purposes.

• ***The pharmacy intern must complete a practical training program that is approved by the 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.*** This is currently required by the schools of pharmacy, under current accreditation standards, prior the pharmacy intern obtaining required practical experience in a pharmacy setting.

• ***The licensed pharmacist and pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.*** This is currently required for influenza immunizations of minors pursuant to guidelines developed by VDH, pursuant to 54.1-3408(W) of the Code of Virginia. Most employers and liability insurance plans appear to broadly require such certification for liability purposes.

• ***The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.*** This is not currently required under State law.

• ***The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with***

requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine. This is a partly new requirement. Recordkeeping of administration is required, however, notification to the primary care provider is not currently required. While many pharmacies currently report to and review the Virginia Immunization Information System, it is not currently required in law.

- ***The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.*** This is a new requirement.
- ***The HHS declaration does not condition a pharmacist's ability to order or administer a qualifying vaccine to a patient age three (3) to eighteen (18) on the existence of a supervising physician written protocol.*** This is a new requirement.

PHARMACIST-ADMINISTERED VACCINES

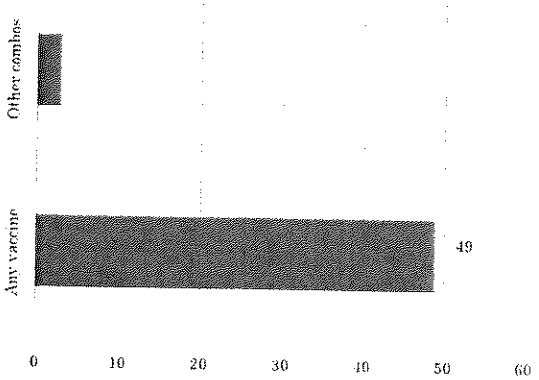
Updated June 2020

Based on APhA/NASPA Survey of State IZ Laws/Rules

APhA NASPA

1

TYPES OF VACCINES AUTHORIZED TO ADMINISTER

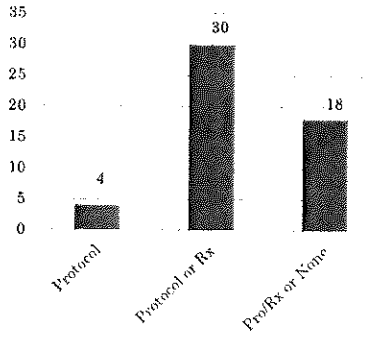


Any vaccine (may require ACIP/CDC)	AL, AK, AZ*, AR, CA, CO, CT, DE*, DC*, FL, GA*, HI, ID, IL, IN*, IA, KS, KY, LA*, MA, ME, MD, MI, MN, MO*, MS, MT, NE, NV, NJ, NM, NC, ND, OH, OK, OR, PA, PR*, RI, SC, SD, TN, TX, UT, VT, VA*, WA, WI, WV
Other combos	NH, NY, WY

* Via Rx for some
• Age requirements applicable to most

2

PRESCRIBER ISSUED PROTOCOLS VS RX



Protocol	FL, KS, MN, NV
Protocol or Rx (depending on age and/or vaccine)	AL, AR, CO, CT, DC, DE, GA,HI, IL, IN, IA, KY, MA, MI, MS, MO, NE, NJ, NY, NC, ND, OH, OK, PA, PR, RI, TN, UT, VT, WA
Protocol/Rx or No Prescriber/Rx Needed (depending on age and/or vaccine)	AK, AZ, CA, ID, LA, ME, MD, MT, NH, NM, OR, SC, SD, TX, VA, WI, WV, WY

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3

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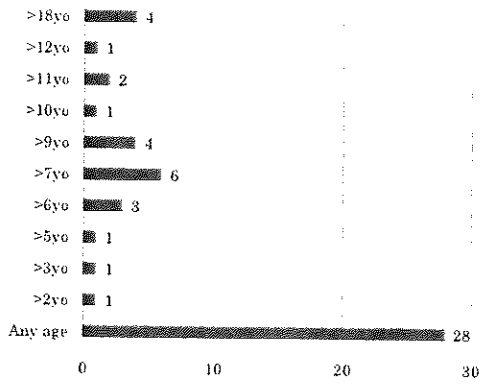
PATIENT-AGE LIMITATIONS



≥18yo	CT, FL, PR*, VT
≥12 yo	DC[L]
≥11 yo	HI[L,*], WV*
≥10yo	IL[L]
≥9yo	MA[L], MD[L], PA[L], RI[L]
≥7yo	AR, ME[L], MT*, NJ*[,L], OH[L], WY[L]
≥6yo	KS[L], MN[L], NC[L,*]
≥5yo	ND[L]
≥3yo	AZ[L]
≥2yo	NY[L]
Any age	AL, AK, CA, CO, DE[D], GA*, ID*, IN*, IA*, KY*, LA*, MI, MS, MO*, NE, NV, NH[L], NM, OK, OR*, SC*, SD, TN, TX*, UT, VA*, WA, WI*

* Via Rx
[L] Limited to certain vaccines
[D] Any age with an adult dose

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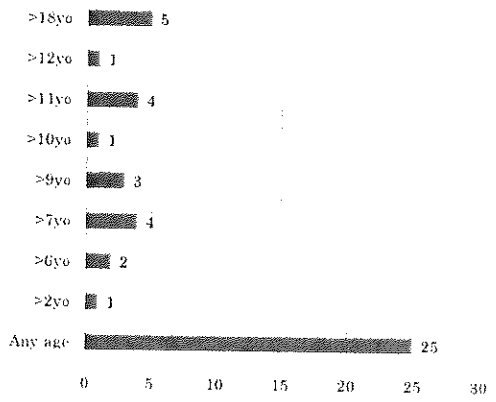
PATIENT-AGE LIMITATIONS VIA RX



≥18yo	CT, ME, MA, PR, VT
≥12yo	DC
≥11yo	HI*, MD, ND, WV
≥10yo	IL*
≥9yo	MA*, PA*, RI*
≥7yo	AR, OH, NJ*, WY[HR]
≥6yo	AZ, NC*
≥2yo	NY*
Any age	AL, AK, CA, CO, DE[D], GA, ID, IN, IA, KY, LA, MI, MS, MO, NE, OK, OR, SC, SD, TN, TX, UT, VA, WA, WI

* Scope varies
[D] Any age with an adult dose
[HR] Rx only for high risk

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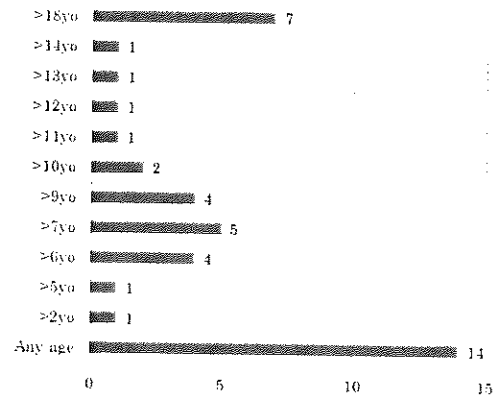
PATIENT-AGE LIMITATIONS VIA PRESCRIBER PROTOCOL



≥18yo	CT, FL, HI, ME, PR*, VT, VA
≥14yo	TX
≥13yo	GA*
≥12yo	DC
≥11yo	IN
≥10yo	IL*, NJ*
≥9yo	KY*, MA, PA*, RI*
≥7yo	AR, MT*, MO*, OH*, TX*
≥6yo	IA*, KS*, MN*, NC*
≥5yo	ND*
≥2yo	NY*
Any age	AL, CA, CO, DE[D], MI, MS, NE, NM, NV, OK, SD, TN, UT, WA

*Scope varies
[D] Any age with an adult dose

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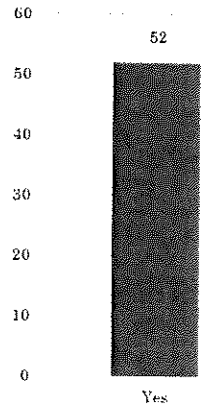
AUTHORITY TO ADMINISTER PNEUMOCOCCAL VACCINE



Yes	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NE, NH, NV , NJ, NM, NC, ND, NY, OH, OK, OR, PA, PR, RI, SC, SD,TN, TX, UT, VT, VA, WA, WV, WI, WY

Various ages and some require RX

Part B Vaccine

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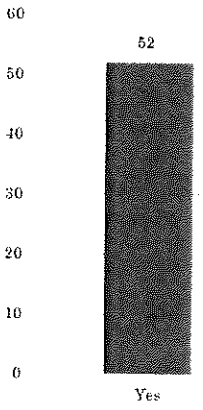
AUTHORITY TO ADMINISTER ZOSTER VACCINE



Yes	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA,KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NE, NH, NY, NV, NJ, NM, NC, ND, OH, OK, OR, PA, PR*, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WV, WY

*Via Rx only

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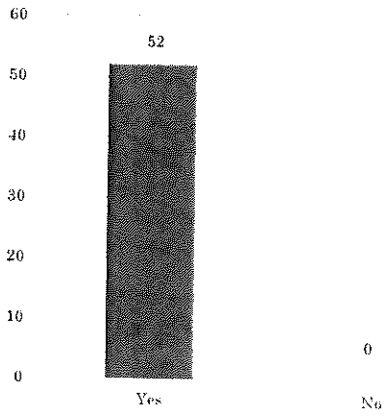
AUTHORITY TO ADMINISTER TD/TDAP VACCINE

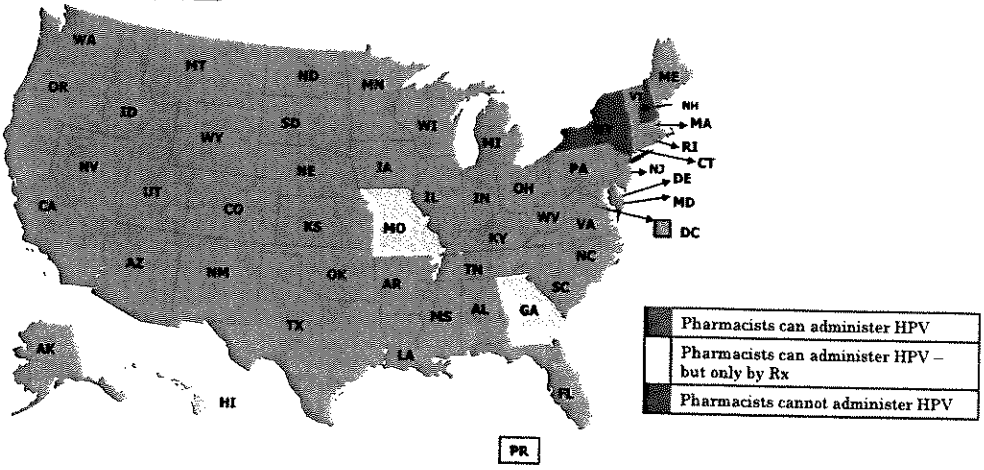


Yes	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA*, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NE, NV, NH, NJ, NM, NY NC, ND, OH, OK, OR, PA, PR*, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

*Via Rx only
Many have age restrictions

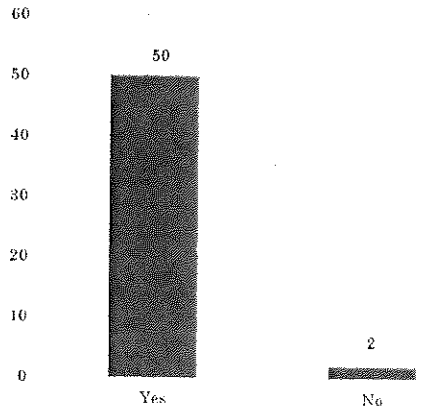
9

AUTHORITY TO ADMINISTER HPV VACCINE



10

AUTHORITY TO ADMINISTER HPV VACCINE



Yes	AL, AK, AZ[A], AR[A], CA, CO, CT[A], DC[A], DE, FL[A], GA[R], HI[A], ID, IL[A], IN, IA[A], KS[A], KY, LA[A], ME[A], MD[A], MA, MI, MN[A], MO[R], MS, MT[A], NC[A], ND, NE, NJ[A], NM, NV, OH[A], OK, OR, PA[A], RI[A], PR[A,R], SC[A], SD, TN, TX[A], UT, VT[A], VA[A], WA, WV, WI, WY[A], DC[A]
No	NH, NY

[R] Via Rx only
[A] Age limitation (may not allow or may require Rx for 11-19)

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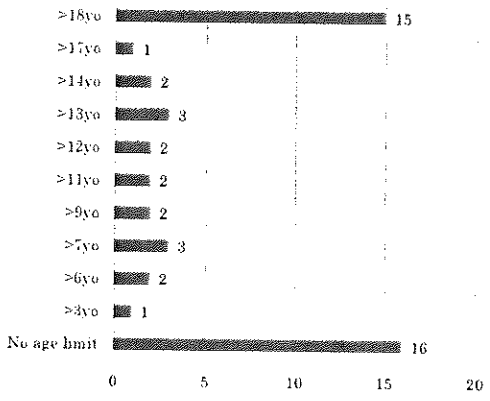
PATIENT-AGE LIMITATIONS FOR HPV VACCINATION



≥18yo	CT, FL, HI*, IA*,ME, MD*, NC, NJ, PA, PR[R], RI, SC*,VA*, VT, WY
≥17yo	LA*
≥14yo	IL,TX*
≥13yo	AZ*, MN, OH*
≥12yo	DC, KS
≥11yo	IN*, ND, WV*
≥9yo	KY, MA
≥7yo	AR, MT,OR
≥6yo	ID, WI
≥3yo	CA
No Age Limit	AL, AK, CO, DE[D],GA[R], MI, MS, MO[R], NE, NV, NM, OK, SD, TN, UT, WA

*Younger ages under prescription/protocol
[R] Requires a prescription [D] Any age with an adult dose

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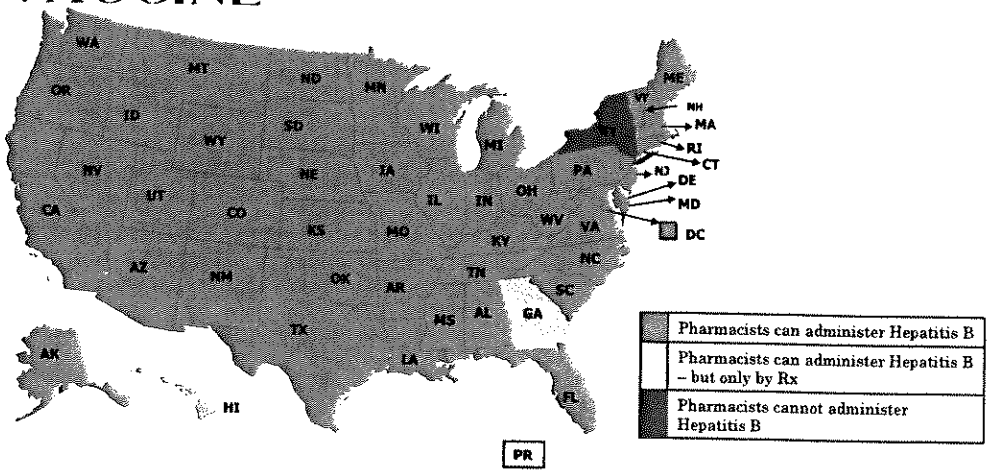
AUTHORITY TO ADMINISTER HEP B VACCINE



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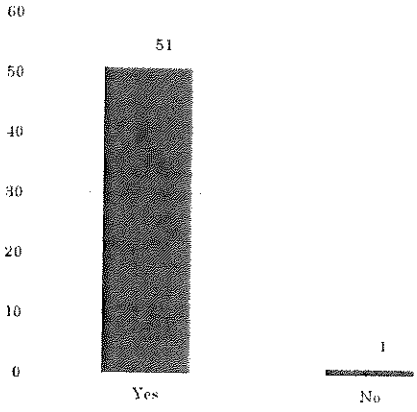
AUTHORITY TO ADMINISTER HEP B VACCINE



Yes	AL, AK, AZ[A], AR[A], CA, CO, CT[A], DC[A], DE, FL[A], GA[R], HI[A], ID, IL[A], IN[R], IA[A], KS, KY, LA[A], ME[A], MD[A], MA, MI, MN[A], MO, MS, MT[A], NH[A], NC[A], ND, NE, NJ[A], NM, NV, OH[A], OK, OR, PA[A], RI[A], PR[A,R], SC[A], SD, TN, TX[A], UT, VT[A], VA[A], WA[A], WV, WI, WY[A], DC
No	NY

[R] Via Rx only
[A] Age limitation (may not allow or may require Rx for 12-18)

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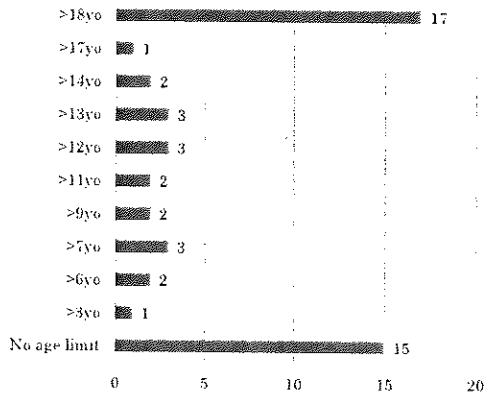
PATIENT-AGE LIMITATIONS FOR HEP B VACCINATION



≥18yo	CT, FL, HI*, IA*, ME, MD*, NC, NJ, NH, PA, PR[R], RI, SC*,VA*, VT, WV*,WY
≥17yo	LA*
≥14yo	IL, TX*
≥13yo	AZ*,MN, OH*
≥12yo	DC, KS, MO*
≥11yo	IN*,ND
≥9yo	KY, MA
≥7yo	AR, MT, OR*
≥6yo	ID, WI
≥3yo	CA*
No Age Limit	AL, AK, CO, DE[D], GA[R], MI, MS, NE, NV, NM, OK, SD, TN, UT, WA

*Younger ages under prescription/protocol
[R] Requires a prescription
[D] Any age with an adult dose

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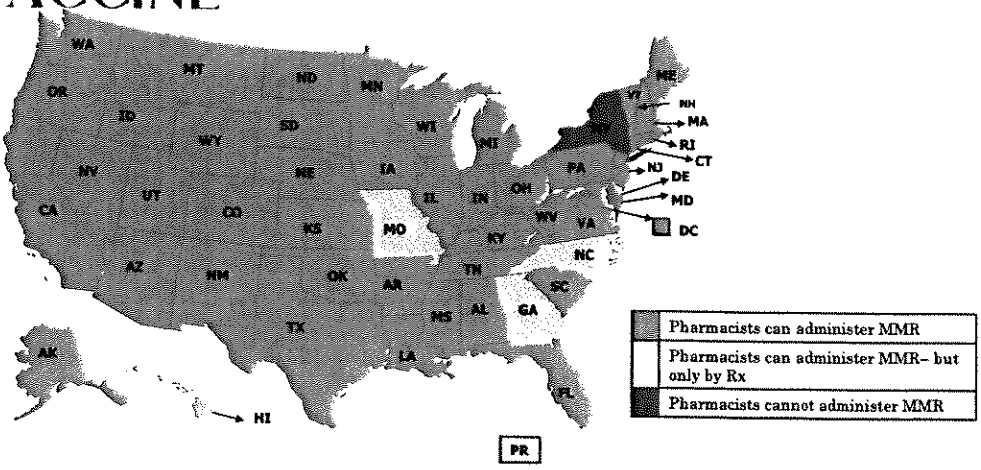
AUTHORITY TO ADMINISTER MMR VACCINE



Pharmacists can administer MMR
Pharmacists can administer MMR– but only by Rx
Pharmacists cannot administer MMR

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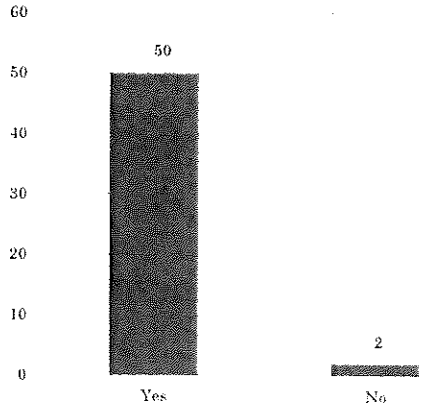
AUTHORITY TO ADMINISTER MMR VACCINE



Yes	AL, AK, AZ[A], AR, CA, CO, CT[A], DE, FL[A], GA[R], HI[A], ID, IL, IN[R], IA[A], KS[A], KY, LA, ME[A], MD[A], MA[A], MI, MN[A], MO[R], MS, MT[A], NE, NH[A], NJ[A], NM, NC[A, R], ND, NV, OH, OK, OR, PA[A], RI[A], PR[A,R], SC[A], SD, TN, TX, UT, VT[A], VA[A], WA, WI, WV[A]
No	DC, NY

[R] Via Rx only
[A] Age limitation (may not allow or may require Rx for certain ages <18)

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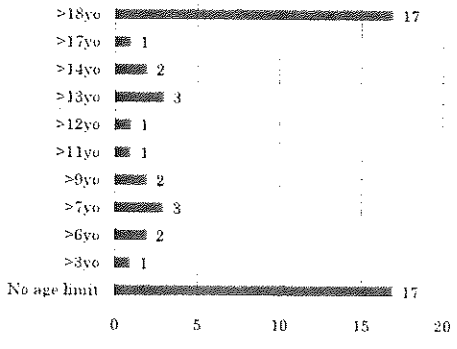
PATIENT-AGE LIMITATIONS FOR MMR VACCINATION



>18yo	CT, FL, HI*, IA*, ME, MD*, NC[R], NH NJ, PA, PR[R], RI, SC*, VA*, VT, WV, WY
>17yo	LA*
>14yo	IL, TX*
>13yo	AZ*, MN, OH*
>12yo	KS
>11yo	ND
>9yo	KY*, MA
>7yo	AR, MT, OR*
>6yo	ID*, WI*
>3yo	CA*
No Age Limit	AL, AK, CO, DE[D], GA[R], IN[R] MI, MS, MO[R], NE, NV, NM, OK, SD, TN, UT, WA

*Younger ages under prescription
[R] Requires a prescription [D] Any age with an adult dose

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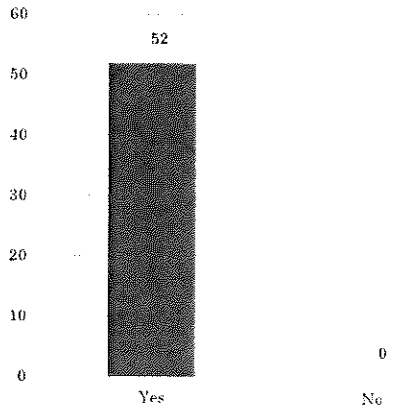
AUTHORITY TO ADMINISTER MENINGOCOCCAL VACCINE



Yes	AL, AK, AZ[A], AR, CA, CO, CT[A], DC[A], DE, FL[A], GA[R], HI[A], ID[A], IL[A], IA[A], IN, KS[A], KY[A], LA[A], ME[A], MA[A], MD[A], MI, MN[A], MO[A], MS, MT[A], NH, NC[A], ND, NE, NJ[A], NM, NY[A], NV, OH[A], OK, OR, PA[A], PR[R,A], RI[A], SC[A], SD, TN, TX[A], UT, VT[A], VA[A], WA, WV, WI, WY[A]

[R] Via Rx only
[A] Age limitations (may not allow or may require Rx for 11-18)

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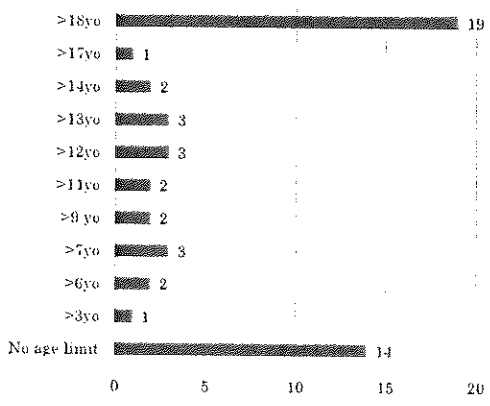
PATIENT-AGE LIMITATIONS FOR MENINGOCOCCAL VACCINATION



≥18yo	CT, FL, GA*, HI*, IA*, ME, MD*, NH, NJ, NY, NC, PA, RI, PR[R], SC* VT, VA*, WV*, WY
≥17yo	LA*
≥14yo	IL, TX*
≥13yo	AZ*, MN, OH*
≥12yo	DC, KS, MO*
≥11yo	IN*, ND
≥9yo	KY*, MA
≥7yo	AR, MT, OR
≥6yo	ID, WI*
≥3yo	CA
No Age Limit	AL, AK, CO, DE[D], MI, MS, NE, NV, NM, OK, SD, TN, UT, WA

*May allow for younger ages under prescription
[R] Via Rx only
[D] Any age with an adult dose

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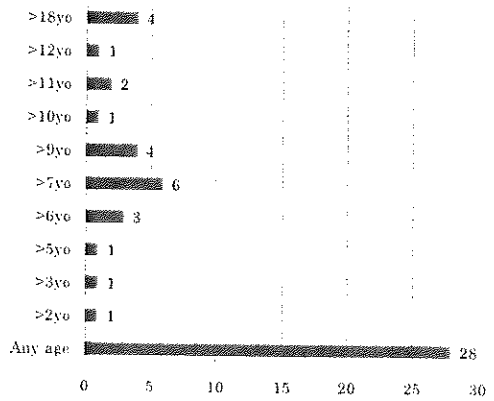
INFLUENZA - AGE OF ADMINISTRATION AUTHORIZED BY ANY PROVISION



≥18yo	CT, FL, PR, VT
≥12yo	DC
≥11yo	HI*, WV*
≥10yo	IL
≥9yo	MD, MA, PA, RI
≥7yo	AR, ME, MT, NJ*, OH, WY
≥6yo	KS, MN, NC
≥5yo	ND
≥3yo	AZ
≥2yo	NY
Any age	AL, AK, CA*, CO, DE[D], GA*, ID*, IN*, IA*, KY*, LA*, MI, MS, MO*, NE, NH, NM, NV, OK, OR*, SC*, SD, TN, TX*, UT, VA*, WA, WI*

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* Requires Prescription
[D] Any age with an adult dose

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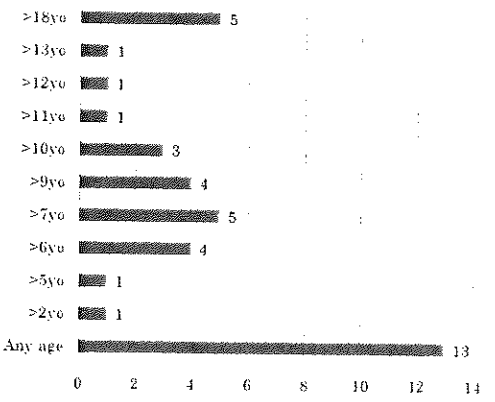
INFLUENZA - AGE OF ADMINISTRATION AUTHORIZED BY PROTOCOL



≥18yo	CT, FL, HI, PR, VT
≥13yo	GA
≥12 yo	DC
≥11yo	IN
≥10yo	IL, NJ, NC
≥9yo	KY, MA, PA, RI
≥7yo	AR, MT, MO, OH, TX
≥6yo	IA, KS, MN, WI
≥5yo	ND
≥2yo	NY
Any age	AL, CA, CO, DE[D], MI, MS, NE, NV, OK, SD, TN, UT, WA

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[D] Any age with an adult dose

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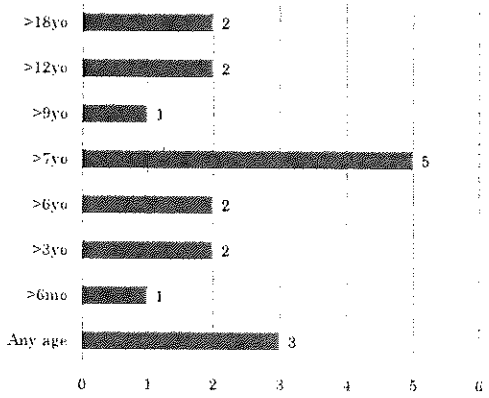
INFLUENZA - PHARMACISTS STATE AUTHORIZED



18 States

≥18yo	SD, WV
≥12yo	MT, SC
≥9yo	MD
≥7yo	LA, ME, OR, TX, WY
≥6yo	ID, WI
≥3yo	AZ, CA
≥6mo	VA
Any age	AK, NH, NM

Note: Authority comes from statute and/or regulation from BOP or Public Health

MAY STUDENT INTERNS ADMINISTER VACCINES?

Number of states/territories allowing	**51***
States/territories not verified	**1 (PR)**
Criteria common among states	**•Student must be trained (complete Certificate Training Program) •Operating under supervision of trained pharmacist**

MAY PHARMACY TECHNICIANS ADMINISTER VACCINES?

Number of states/territories allowing	**6 (IA(pilot), ID, IN, RI, UT, WA (guidance document in development)**
States/territories not verified	**1 (PR)**
Criteria common among states	**•Technician must be trained (complete Certificate Training Program/CPR) •Operating under supervision of trained pharmacist**

Updated June 2020 | Based on APhA/NASPA Survey of State IZ Laws/Rules

25

25

PHARMACIST-ADMINISTERED VACCINES

Updated June 2020

Based on APhA/NASPA Survey of State IZ Laws/Rules

APhA NASPA

26

Pharmacy Protocol

***Haemophilus influenzae* type b (Hib) Conjugate Vaccines and Combination Vaccines (ActHIB®[1], PedvaxHIB®[3], HIBERIX®[2])**	
Last Reviewed	24 August 2020
Last Revised	24 August 2020
This order expires	August 31, 2022

Table of contents

1. What's new

No changes.

2. Oregon immunization model standing order

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Screen clients for contraindications.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for IM injection.

F. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the vastus lateralis or deltoid muscle and use proper IM administration technique.

G. Administer a 0.5-mL dose, IM, of Hib-containing vaccine to patients ≥7 years of age according to high-risk indication.

H. Hib-containing vaccines can be given with all other routinely recommended vaccines.

I. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Immunizing pharmacist Date

3. Vaccine schedule for *Haemophilus influenzae* type b vaccines

N/A

4. Licensed *Haemophilus influenzae* type b vaccines

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
ActHIB®[1] (PRP-T)	Hib	0.5-mL single-dose vials	6 weeks – 5 years	None
HIBERIX®[2] (PRP-T)	Hib		6 weeks – 4 years	
PedvaxHIB®[3] (PRP-OMP)	Hib		6 weeks – 5 years	

5. Recommendations for use

Routinely Recommended Use

N/A

Catch-Up for Healthy Children

N/A

Catch-Up for Persons at High-Risk[4]

High-Risk Group	Vaccine Guidance
Patients aged ≥7 years undergoing elective splenectomy	If unimmunized, 1 dose prior to procedure.
Asplenic patients 7 years of age or older	If unimmunized, 1 dose.
HIV-infected children 7-18 years of age	If unimmunized, 1 dose.
HIV-infected persons ≥19 years of age	Hib immunization is not recommended.
Hematopoietic stem cell transplantation (HSCT)	3 doses beginning 6–12 months after HSCT regardless of prior Hib vaccine history

6. Contraindications[5]

A. Severe allergic reaction to any component of the vaccine, including latex (ActHIB®[1], PedvaxHIB®[3]).

Vaccine	Contains
Hib (ActHIB®[1])	Sodium chloride, formaldehyde, sucrose

Hib (HIBERIX®[2])	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB®[3])	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride

7. Warnings and precautions

N/A

8. Other considerations

In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.[1-3]

9. Side effects and adverse reactions

Hib, single-antigen (ActHib®, HIBERIX®, PedvaxHIB®)[1-3]	
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 49%
Severe pain, induration or swelling at injection site	Uncommon, up to 4%
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever.	Very common, up to 70%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 6%

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
All[1-3]	2°– 8°C	Protect from light. Do not freeze.	HIBERIX®[2] – discard if the diluent has been frozen.

11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html. VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.

Event and interval from vaccination
A. Shoulder Injury Related to Vaccine Administration (7 days)
B. Vasovagal syncope (7 days)
C. Any acute complication or sequelae (including death) of above events (interval - not

applicable)
D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert).

12. References

1. ActHIB® package insert. 17 May 2019. Available at www.fda.gov/media/74395/download. Accessed 30 July 2020.
2. HIBERIX® package insert. April 2018. Available at www.fda.gov/media/77017/download. Accessed 30 July 2020.
3. PedvaxHIB® package insert. No date. Available at www.fda.gov/media/80438/download. Accessed 30 July 2020.
4. Briere EC, Rubin L, Moro P, et al. Prevention and control of *Haemophilus influenzae* type b disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63(RR-1). Available at: www.cdc.gov/mmwr/PDF/rr/rr6301.pdf. Accessed 30 July 2020.
5. CDC. Vaccine Excipient Table. February 2020. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 30 July 2020.
6. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 30 July 2020.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: standing orders

13. Appendix

Not applicable.

Immunization Provider Information

Oregon Immunization Program
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/)

notifications

OHA COVID-19 Updates: Visit our COVID-19 page (https://govstatus.egov.com/OR-OHA-COVID-19) for Oregon updates and community resources, or visit our healthcare partner resources page. (/oha/PH/DISEASESCONDITIONS/DISEASESAZ/Pages/COVID-19.aspx)

notifications

Wildfires in Oregon: Get wildfire resources and news (https://wildfire.oregon.gov/) or visit OHA's wildfires and smoke (/oha/PH/PREPAREDNESS/PREPARE/Pages/PrepareForWildfire.aspx) page to learn what you can do to reduce the health effects of wildfire smoke.

Pharmacy Protocols

For Immunization Providers (/oha/PH/PREVENTIONWEL

Vaccines for Children (VFC) (/oha/PH/PREVENTIONWEL

Maternal Immunization Toolkit (/oha/PH/PREVENTIONWEL

Provider Resources (/oha/PH/PREVENTIONWEL

Provider Training (/oha/PH/PREVENTIONWEL

For Local Health Departments (/oha/PH/PREVENTIONWEL

Model Standing Orders for Immunizations (/oha/PH/PREVENTIONWEL

For Pharmacists (/oha/PH/PREVENTIONWEL

Pharmacy Protocols (/oha/PH/PREVENTIONWEL

ALERT IIS (/oha/PH/PREVENTIONWEL

IQIP

Oregon Pharmacy Protocols for Immunization

Note to pharmacists:
The following Pharmacy Protocols for Immunization are reviewed yearly. Generally, updates are made as new recommendations are published by the Advisory Committee on Immunization Practices (ACIP).

An **Interim protocol** is published when clinical guidance is needed but the Advisory Committee on Immunization Practices recommendations haven't yet been published in the MMWR. The interim protocol will be replaced with a final protocol once the recommendations are published.

Protocols

Please read through all the protocols carefully. If you decide to change any part of them, your changes must be submitted in writing to Amanda Timmons and approved by the OHA Immunization Program.

If you have any questions about these revised protocols, please call Amanda Timmons at (971) 673-0312.

Please read the Disclaimer
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Pages/stdgc

NOTE: These are PDF files that require Adobe Reader software to be read and printed.

Vaccine/biologic

Guidelines for managing adverse events
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Adverse Events E-kit Checklist and Report Form
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents
Anaphylaxis (optional)
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents
Urticaria (optional
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents
Syncope (optional)
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Cholera (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/D

Haemophilus influenzae type b
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Hepatitis A &Twinrix
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Hepatitis B
Pediatric Formulation
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents
Adult Formulation
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Human papillomavirus vaccine
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Influenza (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/I
2020-21)

Influenza (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/I
(LAIV 2020-21)

Japanese Encephalitis
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Meningococcal A, C, W, Y and B
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

MMR/MMRV (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCE

Pneumococcal Vaccines
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Polio (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Docu

Polio for Travelers
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Rabies (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Do
(inactivated)

Shingrix (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/D

Tdap and Combo Vaccines
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents
Use of Tdap in Persons ≥7 years of Age
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Typhoid (/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/D

Varicella-containing vaccines
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Yellow fever
(/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents

Agenda Topic: Tobacco cessation

Included in agenda package:

- Article, *Pharmacists May Help Patients Quit Smoking, Notes Surgeon General's Report*
  - Pharmacy Today article, June 2020
- Resource information from the National Alliance of State Pharmacy Associations (NASPA)
- Oregon Tobacco Cessation Protocol – NRT and Non-NRT
- California Nicotine Replacement Protocol

Action to be taken:

- Discuss subject and offer recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older for drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy

Pharmacists May Help Patients Quit Smoking, Notes Surgeon General's Report

Pharmacists can play an important role in helping patients quit smoking, as highlighted in the Surgeon General's 2020 report on smoking cessation. The report advises pharmacists to recommend the use of both prescription and over-the-counter medications, when appropriate. In addition, the report notes that authorizing pharmacists to prescribe cessation therapies and allowing them to bill for interventions could increase the number of successes.

According to the American Pharmacists Association, pharmacists in Colorado, Idaho, Indiana, and New Mexico are currently authorized to prescribe all cessation medications. Pharmacists can also provide behavior counseling resources and should continually support and follow up with patients to help prevent relapses. Additional information is available in an article published in the June 2020 issue of *Pharmacy Today*.

Pharmacists highlighted in Surgeon General smoking cessation report

In January, the Surgeon General released the first report on smoking cessation in 30 years. The report updates the latest findings on smoking cessation in the United States and highlights the important role pharmacists play in cessation efforts.

"One of the most striking aspects of the report, compared to prior reports, is the extent of emphasis on pharmacists," said Karen Hudmon, BSPharm, DrPH, professor of pharmacy practice at Purdue University College of Pharmacy in West Lafayette, IN. "It's been slow progress, but our profession has made major strides over the past 2 decades to advance our role in tobacco cessation."

Progress and challenges

About 34 million American adults currently smoke cigarettes, and 16 million are living with a smoking-related disease. But according to the report, cigarette smoking among adults is at 14%—an all-time low. Nearly 70% of adults who smoke say they want to quit, and more than 50% try each year. Three out of five adults who have ever smoked cigarettes have successfully quit.

Despite this progress, smoking remains the leading cause of preventable disease, disability, and death in the country. It also poses significant financial and economic burden on individuals and society, contributing to more than $170 billion of health care spending annually.

The report found that fewer than 1 in 10 adults successfully quit smoking every year. This, in part, may be due to ineffective methods—less than one-third of individuals attempting to quit use behavioral counseling or FDA-approved cessation medications.

"There are two parts to smoking; thus there are two parts to quitting," said Hudmon. "There's the behavioral aspect, the habits and routines associated with smoking, which we address with programs that help retrain the way a smoker thinks. Then, there's the addiction to nicotine, which we treat with medications."

Both interventions, especially when combined, significantly increase patients' likelihood of quitting successfully. But many often try to quit without assistance. Even when patients do use medications such as nicotine replacement therapy, some find limited success.

Insufficient self-treatment is partly to blame, said Robin Corelli, PharmD, professor of clinical pharmacy at the University of California San Francisco School of Pharmacy. "Medicines like the nicotine gum and lozenge should be dosed every 1 to 2 hours while awake during the initial 4 to 6 weeks of treatment. Time and time again, people compromise their treatment by underdosing or discontinuing medications too soon."

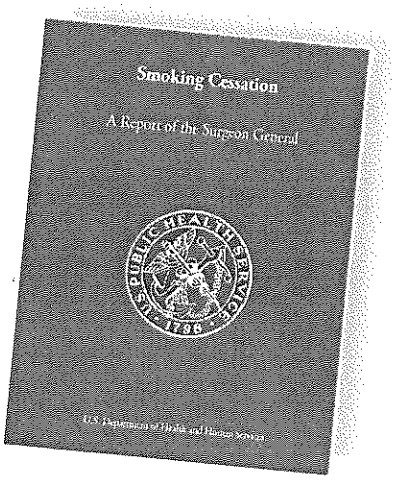
Patients may also not know all of their options. While cessation advice from providers has increased over the years, the report notes that more than 40% of adult smokers still don't receive advice to quit from a health professional.

A 'call to action' for pharmacists

This is where pharmacists can step in, said Corelli, whose research and practice focus on community pharmacists' role in disease prevention and treatment, including tobacco cessation. "It's a call to action for us that we're cited in the report multiple times as a viable provider and an important resource to tackle this significant public health problem," she said.

For Corelli, this means building interventions into the pharmacy workflow. Pharmacists and pharmacy technicians—whom she dubbed "the secret sauce," as they are often the patient's first contact—should always ask patients if they smoke, especially if they take medications that interact with tobacco. "Once you ask, the logical extension is to advise them to quit and assess their readiness to quit," she said.

The key is to come from a space of caring, said Corelli. "You're not shaming someone. You recognize it's that person's choice, and if and when they're ready to quit, hopefully they will perceive you as a resource."



Pharmacists should recommend medications when appropriate, said Hudmon, "including nonprescription products (the nicotine patch, lozenge, and gum) and prescription products (varenicline, bupropion SR, and the nicotine inhaler and nasal spray)."

The report notes that authorizing pharmacists to prescribe cessation therapies, and allowing them to bill for interventions, could help boost success. In Colorado, Idaho, Indiana, and New Mexico, pharmacists can now prescribe all cessation medications, with efforts underway in other states.

Pharmacists can also provide behavior counseling resources and refer patients to the tobacco quitline (1-800-QUIT-NOW), said Hudmon. They should continually support and follow up with patients to help prevent relapses.

Other major conclusions

The report also highlights the need for actions at the population and health-system levels. These include mass media campaigns, comprehensive smoke-free policies and statewide tobacco control programs, raising cigarette prices, and requiring pictorial health warnings.

Comprehensive insurance coverage for cessation treatments can also boost patient access and success rates, while being cost-effective. Disparities influenced by socioeconomic status, age, race/ethnicity, sexual orientation, gender identity, and more also need to be addressed.

The report emphasizes that there is currently insufficient evidence that e-cigarette use increases smoking cessation, and the products may pose serious health risks. Clinicians should steer interventions toward treatments backed by solid evidence.

Aina Abell, assistant editor

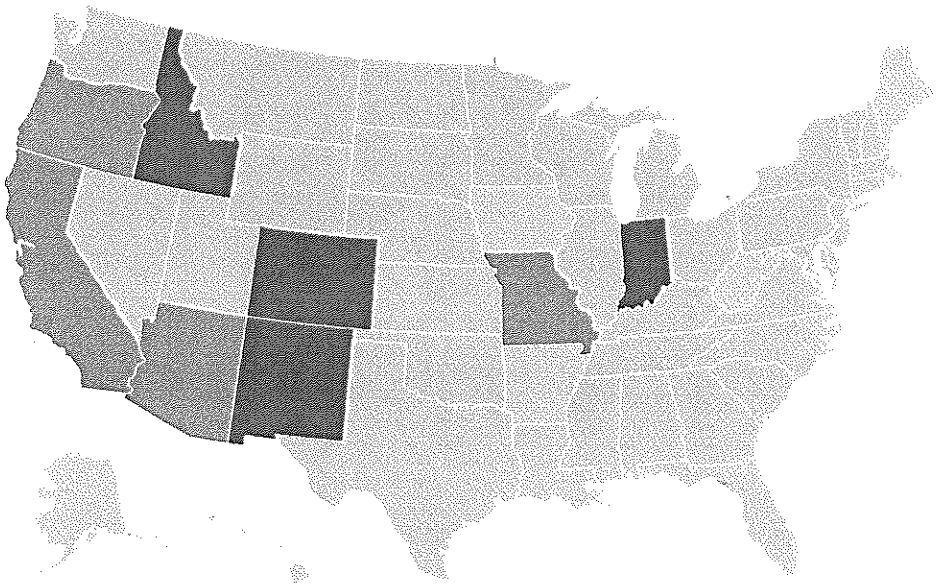
Resources

Pharmacist Prescribing: Tobacco Cessation Aids

POSTED ON NOVEMBER 22, 2019

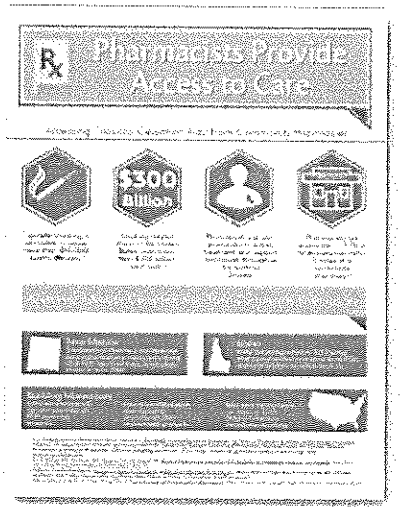
Currently, there are 12 states with statutes or regulations addressing pharmacist prescribing of tobacco cessation aids (without a CPA or local standing order).

Tobacco Cessation Prescribing Map



Updated
8.5.19 – hover over state to view details

(https://naspa.us/resource/tobacco-cessation-infographic/)Advocacy Resources



- Pharmacist-provided tobacco cessation services fact sheet (https://naspa.us/wp-content/uploads/2018/04/Tobacco-Cessation-Facts.pdf)
- Pharmacist prescribing tobacco cessation infographic (https://naspa.us/resource/tobacco-cessation-infographic/)
- Pharmacist prescriptive authority for smoking cessation medications in the United States (https://www.japha.org/article/S1544-3191(18)30001-3/fulltext)
  - Includes FAQs helpful for advocacy!

NASPA Members log-in for more!

- **Outside Support**
  - CMCS Bulletin on the Value of Pharmacist Prescribing (https://naspa.us/resource/cmcs-bulletin-value-pharmacist-prescribing/)
  - ASTHO: Access to Tobacco Cessation Medication through Pharmacists (https://naspa.us/wp-content/uploads/2018/04/Tobacco-Cessation-Via-Pharmacists-ASTHO.pdf)

News

- Pharmacists Authorized to Prescribe Tobacco Cessation Therapy in More States (https://naspa.us/2017/06/pharmacists-authorized-to-prescribe-tobacco-cessation-therapy-in-more-states/)

- **Video:** 'We're Passionate About It': Pharmacists Help Coloradans Quit Smoking (https://denver.cbslocal.com/2018/10/10/colorado-pharmacists-quit-smoking-pharmacy/) (CBS Denver; October 10, 2018)

CPE Opportunities from State Pharmacy Associations:

- Furnishing Nicotine Replacement Therapy: Smoking Cessation Training Program for Pharmacists (https://cpha.com/ce-events/on-demand-courses/furnishing-nicotine-replacement-therapy/) (California)
- Tobacco Cessation Training Course (https://www.papharmacists.com/page/TobaccoCessation2) (Pennsylvania)
- Tobacco Cessation Certificate: Pharmacists as Tobacco Cessation Counselors (http://www.wsparx.org/default.asp?page=36&hhSearchTerms=%252522tobacco%252522) (Washington)

Other State Pharmacy Association Resources:

- Smoking Cessation Toolkit: Clinical Training Resources/ Continuing Education (https://www.papharmacists.com/page/SCClinical?) (Pennsylvania)
- Nicotine Cessation Counseling: Home Study Continuing Education (https://www.npharm.org//Files/Newsandevents/NicotineCPE_Flyer.pdf) (Nebraska)
- Nicotine Cessation Counseling Toolkit (https://www.npharm.org/store_product.asp?prodid=34) (Nebraska)

Other Resources

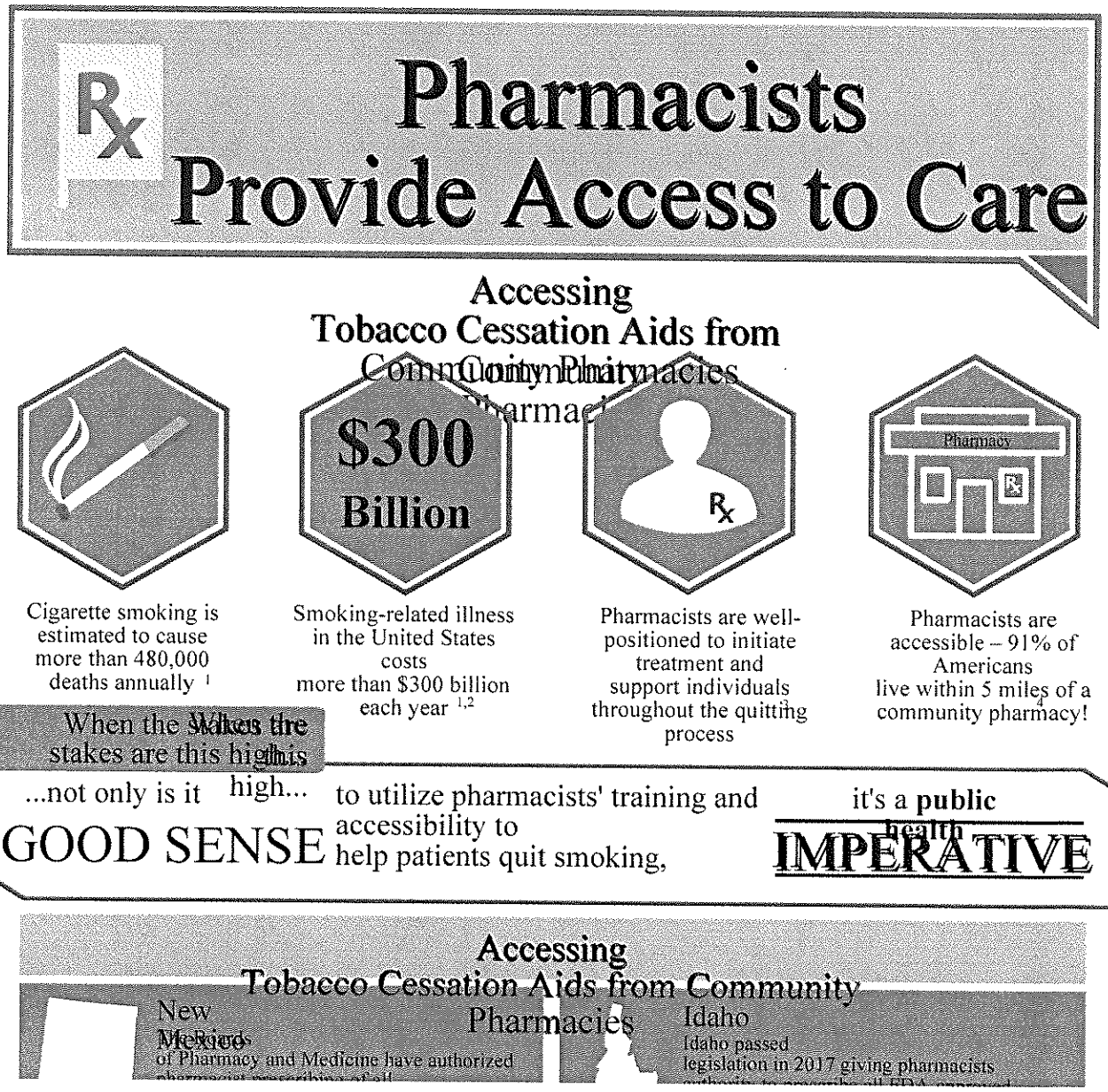
- Tobacco Cessation Change Package (https://millionhearts.hhs.gov/tools-protocols/action-guides/tobacco-change-package/index.html) – Million Hearts has posted the Tobacco Cessation Change Package, a quality improvement tool created by the Centers for Disease Control and Prevention (CDC) that presents a list of process improvements that clinicians can implement as they seek to deliver optimal treatment to patients who use tobacco;and gives clinical teams a practical resource to increase the reach and effectiveness of tobacco cessation interventions and to incorporate these interventions into the clinical workflow.
- Pharmacists: Help Your Patients Quit Smoking (https://www.cdc.gov/tobacco/campaign/tips/partners/health/pharmacist/index.html) – The CDC has compiled a plethora of resources to help pharmacists help patients to quit smoking.
- Smokefree.gov (https://smokefree.gov/) – This website offers a range of resources for patients and providers alike.
- Practice Guidance for Expanding Pharmacy-Based Tobacco Cessation Services Within the Appointment-Based Model (https://www.pharmacist.com/sites/default/files/files/Practice_Guidance_Tobacco_Cessation.pdf) – This practice resource, developed by APhA, outlines opportunities for pharmacists to leverage the appointment based model to provide and expand tobacco cessation services in community pharmacies.

Click Here to Go to the Pharmacist Prescribing Resource Page
(http://www.naspa.us/swp)

Resources

Pharmacist Prescribing Tobacco Cessation: Infographic

POSTED ON JULY 23, 2018



1. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm
2. Xu X, Bishop EE, Kennedy SM, Simpson SA, Pechacek TF. Annual Healthcare Spending Attributable to Cigarette Smoking: An Update. American Journal of Preventive Medicine 2014;48(3):326-33.
3. Tobacco Control Network. Access to Tobacco Cessation Medication through Pharmacists. Association of State and Territorial Health Officials (ASTHO). 2017. http://www.astho.org/Prevention/Tobacco/Tobacco-Cessation-Via-Pharmacists/
4. National Association of Chain Drug Stores. Face-to-face with community pharmacies. http://www.nacds.org/pdfs/about/rximpact-leavebehind.pdf.

Pharmacist Prescribing of Tobacco Cessation Aids:

1 MYTH

Tobacco cessation aids are **too dangerous** for pharmacists to prescribe

FACT

In 2016, FDA removed the Boxed Warning from Chantix (varenicline) and Zyban (bupropion). Pharmacists have [1] been safely prescribing these medications in New Mexico since 2004.

2 MYTH

Pharmacists aren't **properly trained** to prescribe medications.

FACT

Pharmacists have a four-year, doctoral-level degree with extensive coursework in pharmacology, clinical patient care, drug selection and more. [2]

And there are many resources available for all healthcare providers who need a refresher in tobacco cessation counseling. [3]

3 MYTH

Only physicians can effectively help patients quit smoking.

FACT

In a study including over 1,400 participants, researchers showed that pharmacist-provided smoking cessation [4] interventions have quit rates on par with other healthcare professionals.

4 MYTH

Allowing pharmacists to prescribe **only NRT products** is good enough.

FACT

The EAGLES study showed that tobacco users taking varenicline were 12% more likely to quit smoking compared to those who used a nicotine replacement [5] product.

1. U.S. Department of Health and Human Services. FDA Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings. https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm. Accessed 6.13.18.
2. New Mexico tobacco prescribing law
3. Many resources available. Here is one compilation from the CDC: https://www.cdc.gov/tobacco/campaign/tips/partners/health/hcp/index.html
4. Shen X, et al. Quitting patterns and predictors of success among participants in a tobacco cessation program provided by pharmacists in New Mexico. J Manag Care Pharm. 2014;20(6):579-87.
5. Anthenelli RM, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomized, placebo-controlled clinical trial. *Lancet*. 2016;387(10037):2507-20.
6. Based on data from the Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

4.5M

If 12% doesn't sound like much, consider that if all smokers tried to quit smoking, a 12% increase in the success rate would mean 4,536,000 more people would To

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. 2-4)
- Utilize the standardized Tobacco Cessation Assessment and Treatment Care Pathway (pg. 5-6)

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

Name_____Date of Birth_____Age____ *Today's Date* _____

Today's BP_____/_____mmHg (*must be taken by a RPH)

Do you have health insurance? ***Yes / No*** Name of insurance provider _____

PCP/Health Care Provider's Name_____

List of medicine you take _____

_____

_____

Any allergies to medicines? ***Yes / No*** If yes, list them here _____

Any food allergies (ex. menthol/soy) _____

_____

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 heart beat 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

Stop here if patient and pharmacist are considering nicotine replacement therapy.

KEEP GOING

If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) continue to answer the questions below.

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 (Zyvox®)?	□ 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_____

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 or fax: 800-483-3114)
- ☐ BP Reading: ____/____ *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
(fax or electronic notification to the Quit Line is acceptable)

_____

Notes:

Tobacco Cessation Assessment & Treatment Care Pathway

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** Oregon Quit Line 1-800-QUIT-NOW
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
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
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

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

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
	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		

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 - Refer if patient still wants bupropion. - If patient wants varenicline, continue to depression screening step 8.	Refer to PCP if patient wants bupropion; NRT* can be considered

8) The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	Score < 3 on PHQ2. Review Suicide Screening in step 9.	Score ≥ 3 on PHQ. → Refer Avoid bupropion and varenicline, refer to PCP for treatment. NRT* can be offered.	Refer to PCP; NRT* can be considered
9) Suicide Screening	Score of 0 on suicide screening. May prescribe bupropion or varenicline.	Score ≥ 1 on suicide screening. → Refer **Immediate** referral to PCP.	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.	0.5mg daily for 3 days then 0.5mg twice daily for 3 days then 1mg twice daily for 12 to 24 weeks (may use Starter Pack).
Consider combining with Nicotine patch or Nicotine lozenge or Nicotine gum for increased efficacy.*	Quit day after day 7 or alternatively quit date up to 35 days after initiation of varenicline.
For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.	Generally not use in combination with other smoking cessation medications.

***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 up to 30 days
- Maximum duration = 12 weeks
- Maximum frequency = 2x in rolling 12 months

TREATMENT CARE PLAN:

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

DEVICES AND SUPPLIES

PRESCRIPTIVE AUTHORITY - OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may prescribe and dispense an FDA-approved drug or device, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis

➢ Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe the following devices and supplies:

- Diabetic blood sugar testing supplies;
- Injection supplies
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies; and
- Ostomy products and supplies

Approved: 10/2018
Reviewed: 7/2019
Modified: 10/2019

California

§1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

(A) Review the patient's current tobacco use and past quit attempts.

(B) Ask the patient the following screening questions:

(i) Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)

(ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)

(iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)

(iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)

(v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

(vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

(C) When a nicotine replacement product is furnished:

(i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.

(ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.

(D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy's or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

NICOTINE REPLACEMENT THERAPY MEDICATIONS FOR SMOKING CESSATION

Rx for Change

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY					COMBINATION NRT
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	
PRODUCT	**Nicorette[1], Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge,[1] Nicorette Mini Lozenge,[1] Generic** OTC 2 mg, 4 mg cherry, mint	**NicoDerm CQ[1], Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	**Nicotrol NS[2]** Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	**Nicotrol Inhaler[2]** Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	**Combinations with demonstrated efficacy** Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
PRECAUTIONS	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
DOSING	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum: 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum: 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing, initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	*Reserve for patients smoking ≥10 cigarettes/day* **Long-acting NRT**: to prevent onset of severe withdrawal symptoms ▪ **Nicotine patch** 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks PLUS **Short-acting NRT** used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ **Nicotine gum (2 mg)** 1 piece q 1–2 hours as needed *OR* ▪ **Nicotine lozenge (2 mg)** 1 lozenge q 1–2 hours as needed *OR* ▪ **Nicotine nasal spray** 1 spray in each nostril q 1–2 hours as needed *OR* ▪ **Nicotine inhaler** 1 cartridge q 1–2 hours as needed

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Combination therapy is more costly than monotherapy ▪ See disadvantages listed for individual agents

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

Authority: Sections 4005, 4052(a)(10) and 4052.9, Business and Professions Code. Reference: Sections 4052(a)(10) and §4052.9, Business and Professions Code.

Agenda Topic: Tuberculin purified protein derivative for tuberculosis testing

Included in agenda package:

- Kentucky Tuberculin Skin Testing One-Step Protocol
- Kentucky Tuberculin Skin Testing Two-Step Protocol: For Initial Testing in Adults who will be Undergoing Annual Testing

Action to be taken:

- Discuss subject and offer recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older for drugs approved by the U.S. Food and Drug Administration for tuberculin purified protein derivative for tuberculosis testing

TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL
v2

Approved 12/11/2019

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration and interpretation of the Mantoux Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration and interpretation of TST under this protocol, the pharmacist(s) must successfully complete training and follow procedures as specified by the US Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education, completion of Module 3 of the CDC Core Curriculum on Tuberculosis: Targeted testing and the diagnosis of latent tuberculosis infection and tuberculosis disease[2], or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date of Training: _____

Inclusion Criteria

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration and interpretation of TST to adults ages ≥ 18 years of age who:

- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance or insurance purposes

Exclusion Criteria

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last 28 days
- History of positive TST
- History of documented previous bacilli Calmette-Guerin (BCG) vaccination
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.

[2] CDC Core Curriculum on Tuberculosis. Available at https://www.cdc.gov/tb/education/corecurr/pdf/chapter3.pdf.

MEDICATIONS

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The Mantoux tuberculin skin test (TST) is the standard method of determining whether a person is infected with *Mycobacterium tuberculosis*. This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined below and in the ATS/CDC Guideline.[1]

Relevant Medical and Social History

- Past medical history, including vaccination history
- Current medications
- Allergies and hypersensitivities
- Current living environment
- History of TST and reactions to TST

Contraindications and Precautions (Refer to Exclusion Criteria)

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last 28 days
- History of positive TST
- History of documented previous bacilli Calmette-Guerin (BCG) vaccination
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix A for detailed procedures).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix B). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred toa healthcare provider for treatment and further advised regarding isolation precautions.

EDUCATION REQUIREMENTS

Individuals receiving TST will receive education regarding:

- Need to return in 48-72 hours for interpretation of the TST
- Result of the TST
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred to a health care provider for treatment and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription record with each person who receives a TST under this protocol including:

1. Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and Documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of test and result must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as requirement of employment.

NOTIFICATION AND REFERRAL

Pharmacist shall ask all persons receiving TST under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the test performed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive a TST under this protocol provided all other applicable requirements of the protocol are met.

Guidance provided by 902 KAR 20:205 indicates **all positive results** must be sent to the local health department within one (1) business day and, if available, the individual's primary care provider for follow-up.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of individuals receiving TST under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

Appendix A: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[3]

Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

Scoring: ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§

_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.§
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ Removes needle guard.
_____ Inserts needle into the vial.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
_____ Removes needle from vial.
_____ Returns antigen vial to the refrigerator immediately after filling.

3. TST administration site selected and cleaned

_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
_____ Cleans the site with antiseptic swab using circular motion from center to outside.
_____ Allows site to dry thoroughly before administering antigen.

4. Needle inserted properly to administer antigen

_____ Rests arm on firm, well-lit surface.
_____ Stretches skin slightly.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Advances needle until entire bevel is under the first layer of skin.
_____ Releases stretched skin.
_____ Injects entire dose slowly.
_____ Forms wheal, as liquid is injected.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Discards used gauze or cotton ball according to local standard precautions.
_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Uses appropriate hand hygiene methods after placing TST.

5. Explanation to the client regarding care instructions for the injection site

_____ The wheal (bump) is normal and will remain about 10 minutes.
_____ Do not touch wheal; avoid scratching.
_____ Avoid pressure or bandage on injection site.
_____ Rare local discomfort and irritation does not require treatment.
_____ May wash with soap and water (without pressure) after 1 hour.
_____ No lotions or liquids on site, except for light washing, as above.
_____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site. **SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

[3] Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.

Appendix F. (*Continued*) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
_____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
_____ Uses well-lit area.
_____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

_____ Palpates with arm bent at elbow at a 90° angle.
_____ Lightly sweeps 2-inch diameter from injection site in four directions.
_____ Uses zigzag featherlike touch.
_____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

_____ Holds palm over injection site.
_____ Cleanse site with antiseptic swab using circular motion from center to outside.
_____ Uses fingertips to find margins of the induration.
_____ Marks the induration by placing small dots on both sides of the induration.
_____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
_____ Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

_____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
_____ Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

_____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
_____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

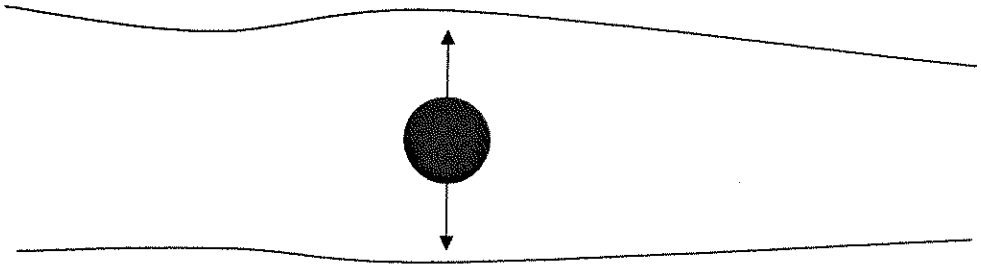
Appendix B: Interpretation of the Tuberculin Skin Test

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

Classification of the Tuberculin Skin Test Reaction (Table 8: page 1390)

Induration of >5mm	Induration of >10mm	Induration of >15mm
Positive if certain factors present: • HIV positive • Recent contact with active TB patient • Individuals with fibrotic changes on chest radiograph consistent with prior TB • Individuals with organ transplants • Individuals who are immunosuppressed for other reasons	Positive if certain factors present: • Recent immigrants (<5years) from high prevalence country • Injection drug users • Residents and employees of high-risk congregant settings • Mycobacteriology lab personnel • Persons with clinical conditions that place them at high risk	• Positive for any individual, including persons with no known risk factors for TB testing • However, targeted skin testing programs should only be conducted among high-risk groups

A negative TST result does not exclude LTBI or active TB disease.



Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

Sample Risk Assessment

http://www.cdc.gov/tb/publications/ltbi/appendixa.htm

Appendix C: Kentucky Department for Public Health TB Risk Assessment Forms (Example of TB-4 TB Risk Assessment Form (Rev. July 2018); TB-4a Instructions for TB Risk Assessment; TB-4b Additional Instructions) *Please check the Kentucky Department for Public Health website for updates to TB Risk Assessment forms under Clinical Service Guide Forms and Teaching Sheets: https://chfs.ky.gov/agencies/dph/dpqi/hcab/Pages/ccsguide.aspx*

INSERT LOGO HERE

Kentucky Department For Public Health
Tuberculosis (TB) Risk Assessment

Patient name (L,F,M): _____ DOB: _____ Race: ____ Sex: ____ SSN: _____

Address: _____ City, State, Zip: _____

Home/Work #: _____ Cell# _____ Patient Pregnant: ____ No ____ Yes; If Yes, LMP _____

Language: _____ Country of Origin: _____ Year arrived in US: _____ Interpreter needed: ____No ____ Yes

Allergies: _____ Current Medications: _____

I. Screen for Active TB Symptoms (Check all that apply)

___None (Skip to Section II, "Screen for TB Infection Risk")
___Cough for ≥ 3 weeks → Productive: ___YES ___NO
___Hemoptysis
___Fever, unexplained
___Unexplained weight loss
___Poor appetite
___Night sweats
___Fatigue

Evaluate these symptoms in context

Pediatric Patients (≤ 5 years of age):
___Wheezing
___Failure to thrive
___Decreased activity, playfulness and/or energy
___Lymph node swelling
___Personality changes

II. Screen for TB Infection Risk *(Check all that apply)*

Individuals with an increased risk for acquiring latent TB infection (LTBI) or for progression to active disease once infected should have a TST. Screening for persons with a history of LTBI should be individualized.

A. Assess Risk for Acquiring LTBI. The Patient:
___ is a current high risk contact of a person known or suspected to have TB disease.
___ has been in another country for - 3 or more months where TB is common, and has been in the US for ≤ 5 years
___ is a resident or an employee of a high TB risk congregate setting
___ is a healthcare worker who serves high-risk patients
___ is medically underserved
___ has been homeless within the past two years
___ is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories
___ injects illicit drugs or uses crack cocaine
___ is a member of a group identified by the health department to be at an increased risk for TB infection
___ needs baseline/annual screening approved by the health department

B. Assess Risk for Developing TB Disease if Infected The Patient...
___ is HIV positive
___ has risk for HIV infection, but HIV status is unknown
___ was recently infected with *Mycobacterium tuberculosis*
___ has certain clinical conditions, placing them at higher risk for TB disease: _____
___ injects illicit drugs (determine HIV status): _____
___ has a history of inadequately treated TB
___ is >10% below ideal body weight
___ is on immunosuppressive therapy (this includes treatment for rheumatoid arthritis with drugs such as REMICADE, HUMIRA, etc.)

History of BCG / TB Skin Test / BAMT / TB Treatment:

History of prior BCG: ___NO ___YES → Year: _____
History of prior (+) TST or (+) BAMT: ____NO ___YES
Date (+) TST / (+) BAMT _____ TST: ____mm
CXR Date: _____ CXR result: ___ABN ___WNL
Dx: ___LTBI ___Disease
Tx Start: _____ Tx End: _____
Rx: _____
Completed: ___NO ___YES
Location of Tx: _____

III. Finding(s) *(Check all that apply)*

___ Previous Treatment for LTBI and/or TB disease
___ No risk factors for TB infection
___ Risk(s) for infection and/or progression to disease
___ Possible TB suspect
___ Previous (+) TST or (+) BAMT, no prior treatment

IV. Action(s) *(Check all that apply)*

___ Issued screening letter ___ Issued sputum containers
___ Referred for CXR ___ Referred for medical evaluation
___ Administered the Mantoux TB Skin Test
___ Draw BAMT / Interferon-gamma Release Assay ((IGRA)
___ Other: _____

TST Brand/Lot #_____ TST Brand/Lot#_____

Arm: ___Left ___Right	Arm: ___Left ___Right
Date/Time _____	Date/Time _____
Induration_____mm	Induration_____mm

___BAMT ___T-SPOT.*TB* **___QFT-TB-Gold-Plus**

Date/Time drawn: _____

Result: ___Pos ___Neg ___Borderline/Indeterminate

Screener's signature: _____
Screener's name (print): _____
Screener's title: _____
Date: _____ Phone #: _____
Comments: _____

- I hereby authorize the doctors, nurses, or nurse practitioners of the _____Department for Public Health to administer a Tuberculin Skin Test (TST) or draw blood from me or my child named above for a Blood Assay for *Mycobacterium tuberculosis* (BAMT) test.
- I agree that the results of this test may be shared with other health care providers.
- I understand that:
  - this information will be used by health care providers for care and for surveillance /statistical purposes only.
  - this information will be kept confidential

X _____ Date: _____

IMPORTANT: A decision to test is a decision to treat. Given the high rates of false positive TB skin test results, the Kentucky TB Prevention and Control Program discourages administration of the Mantoux TST to persons who are at a low risk for TB infection.

TB-4 (7/2018)

Kentucky
UNBRIDLED SPIRIT

Kentucky Department For Public Health
Instructions for the TB Risk Assessment

Purpose of Form
The TB Risk Form is a tool to assess and document a patient's TB symptoms and/or risk factors. Completing this form will also help in determining the need for further medical testing and evaluation.

Directions for Completing the Form
Print clearly and complete this form according to the instructions provided below.

I. Screen for Presence of TB Symptoms

- Screen the patient for symptoms of active TB disease
- All symptomatic individuals who have not had a positive tuberculin skin test (TST) in the past should: (1) receive a TST or a Blood Assay for *Mycobacterium tuberculosis* (BAMT or Interferon Gamma Release Assay [IGRA]); (2) have their sputum collected; and (3) be referred for an immediate chest x-ray and medical evaluation regardless of the TST or BAMT result.
- If the patient does not have symptoms of active TB disease, go to Section II and assess risk for LTBI and/or disease.
- *Symptoms of active TB disease are more subtle in children.* Children with symptoms of active TB disease should receive a TST, CXR and immediate medical evaluation by medical personnel knowledgeable about pediatric TB.

II. Screen for TB Infection Risk (In subsections A and B, check all the risk factors that apply.)

Section II has 2 sections. Section A: "Assess Risk for Acquiring LTBI", Section B: "Assess Risk for Developing TB Disease if infected".

- If a patient has one or more risk factors for LTBI as listed in sections A or B, then go to Section III and administer the TST or BAMT.
- If a patient does not have risk factors for LTBI, do not administer the TST or BAMT. Go to Section III and place a check next to "No Risk *Factors for TB Infection.*"
- If the patient's school, employment, etc. requires a TB screening, place a check next "Issued Screening Letter" (Section IV) and provide that document to the patient.

A. Assess Risk for Acquiring LTBI -- The following are definitions of select categories of persons at risk for LTBI

- *Person is a current close contact of another individual known or suspected to have TB disease --*
  Person is part of a current TB contact investigation
- *Person is a resident/employee of high TB risk congregate settings-*
  These settings are correctional facilities, nursing homes, and long-term care institutions for the elderly, mentally ill, and persons with AIDS.
- *Person is a health care worker who serves high-risk clients --*
  Screen for the individual risk factors for TB infection, unless screening efforts are part of an ongoing facility infection control program approved by local health department.
- *Person is medically underserved –*
  Person does not have a regular health care provider, and has not received medical care within the last 2 years.
- *Person is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories –*
  Child has foreign-born parents, or child's parents/caretakers are at high risk for acquiring TB infection.
- *Person is a member of a group identified by a local health department to be at an increased risk for TB infection --*
  Identification of a group is based on local epidemiologic data showing an increase in the number of persons with TB disease or TB infection in the given group
- *Person needs baseline/annual screening approved by health department –*
  Screening program that is approved by the local health dept. for facilities or individuals at an increased risk for LTBI

B. Assess Risk for Developing TB Disease if Infected - The following are definitions of select categories of persons at risk for TB disease if infected

- *Person's HIV Status is unknown but has risk for HIV infection*
  Offer HIV test. Proceed with the TB Skin Test or BAMT, even if the patient refuses the HIV test.
- *Person with clinical conditions that place them at high risk --*
  Conditions include substance abuse, chest x-ray findings that suggest previous TB, diabetes mellitus, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, leukemia, lymphoma, hematologic and reticuloendothelial diseases, end stage renal disease, smoker, intestinal bypass or gastrectomy, and chronic malabsorption syndromes.
- *Person is on immunosuppressive therapy –*
  Person is taking ≥ 15 mg/day of prednisone for ≥ 1 month; person is receiving treatment for rheumatoid arthritis with medications such as REMICADE, Enbrel, or HUMIRA and/or person needs baseline evaluation prior to start of arthritis treatment with the medications cited here.

III. Finding(s) (Check all findings that apply.)

In this section, indicate findings from the assessments in all previous sections.

IV. Action(s) (Check all actions that apply.)

- Indicate the action(s) to take as a result of the findings in Section III
- If administering a TST or BAMT, provide all requested data.
- Write other pertinent patient information next to "Comments"

Additional Follow-up to the TST or BAMT

- If the patient's TST reaction or BAMT result is interpreted as positive or if she/he has symptoms for TB disease, refer the patient immediately for a chest x-ray.
- If a person has a history of a positive TST or a positive BAMT and is currently asymptomatic, then refer him/her for a chest x-ray if the following two conditions apply: 1) patient is a candidate for LTBI treatment and 2) patient is willing to adhere to the treatment.

Additional Guidelines for Tuberculosis (TB) Risk Assessments, Form TB-4

Since 2007, Local Health Departments (LHDs) have had more activity for "**Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**," http://www.cdc.gov/MMWR/preview/MMWRhtml/rr4906a1.htm. The TB Risk Assessment Form, TB-4, was developed to aid Local Health Departments in conducting TB risk assessments with targeted testing for those Kentuckians with increased risk for latent TB infection (LTBI).

As noted in the CDC guideline, "Targeted tuberculin testing for LTBI is a strategic component of tuberculosis (TB) control that identifies persons at high risk for developing TB who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB. Following that principle, targeted tuberculin testing programs should be conducted only among groups at high risk and discouraged in those at low risk. Infected persons who are considered to be at high risk for developing active TB should be offered treatment of LTBI irrespective of age."

The overall goal of these TB risk assessments at LHDs is to increase the percentage of tuberculin skin tests (TSTs) or blood assays for *Mycobacterium tuberculosis* (BAMTs) that are administered to individuals at increased risk for LTBI and to decrease the percentage of TSTs or BAMTs that are administered to individuals who have no risk factors for LTBI.

LHDs should use the TB risk assessment for all patients presenting for TB screenings, including those individuals identified in contact investigations. The TB Risk assessment form is an ideal tool for educating patients about the signs and symptoms of active TB, the risk factors for developing LTBI, and the risk factors for rapid progression of LTBI to active TB.

The TB risk assessment process also more easily enables LHD staff to determine the cut-off values for reading a TST when a TST is used for screening. A "Report of Tuberculosis Screening," Form TB-3, can be completed for those patients who need documentation of the results of TB screening for their employers or other groups.

*The Kentucky TB Program recognizes that the LHD may choose to collaborate with other organizations for the management and treatment of LTBI or other TB-related occupational health services. In these instances, a written agreement should be initiated between the two agencies to clearly identify the roles of each organization and define a payment schedule for any TB-related services provided by the LHD.

TUBERCULIN SKIN TESTING TWO-STEP PROTOCOL:
FOR INITIAL TESTING IN ADULTS WHO WILL BE UNDERGOING ANNUAL TESTING

v2

PURPOSE **Approved 12/11/2019**

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration and interpretation of the Mantoux Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control. The two-step testing will help in reducing the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration and interpretation of TST under this protocol, the pharmacist(s) must successfully complete training and follow procedures as specified by the US Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education, completion of Module 3 of the CDC Core Curriculum on Tuberculosis: Targeted testing and the diagnosis of latent tuberculosis infection and tuberculosis disease[2], or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date of Training: _____

Inclusion Criteria

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration and interpretation of TST to adults ages $\geq$ 18 years of age who are receiving initial TB skin testing and will be receiving an annual TST for employment purposes.

Exclusion Criteria

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last 28 days

[1]Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm**.

[2] CDC Core Curriculum on Tuberculosis. Available at https://www.cdc.gov/tb/education/corecurr/pdf/chapter3.pdf.

- History of positive TST
- History of documented previous bacilli Calmette-Guerin (BCG) vaccination

MEDICATIONS

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The Mantoux tuberculin skin test (TST) is the standard method of determining whether a person is infected with *Mycobacterium tuberculosis*. This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined below and in the ATS/CDC Guideline.[1] In addition, the need for periodic retesting and individual risk factors for occupational exposures will be used to determine the need for two-step testing.

Relevant Medical and Social History

- Past medical history, including vaccination history
- Current medications
- Allergies and hypersensitivities
- Current living environment
- History of TST and reactions to TST

Contraindications and Precautions

- Allergy to any component of the TST or those individuals with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale

elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix A for detailed procedures).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix B). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred to a healthcare providerfor treatment and further advised regarding isolation precautions.

An initial positive reaction is considered a TB infection and a second TST is not required. An initial negative reaction requires a retest 1-3 weeks after the initial TST. Upon retesting, a negative reaction suggests the patient does not have a TB infection, in which case TST can be repeated annually. However, a positive reaction after retesting is considered a boosted reaction due to a TB infection that occurred a long time ago. In this case, the patient has a latent TB infection and referral is required such that treatment considerations can be made (see Appendix D)[2].

EDUCATION REQUIREMENTS

Individuals receiving TST will receive education regarding:

- Need to return in 48-72 hours for interpretation of the TST
- Result of the TST
- Need for a second TST in 1-3 weeks if the initial result is negative
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred to a healthcare provider for treatment and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription record with each person who receives a TST under this protocol including:

1. Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and Documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of test and result must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as requirement of employment.

NOTIFICATION AND REFERRAL

Pharmacist shall ask all persons receiving TST under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the test performed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive a TST under this protocol provided all other applicable requirements of the protocol are met.

Guidance provided by 902 KAR 20:205 indicates **all positive results** must be sent to the local health department within one (1) business day and, if available, the individual's primary care provider for follow-up.

[If directed by the authorizing prescriber the pharmacist(s), shall provide written notification via fax or other secure electronic means to the authorizing prescriber of individuals receiving TST under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Signature

Pharmacist Name

Date

Pharmacist Signature

Appendix A: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[3]

Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

Scoring: ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

1. Preliminary

- _____ Uses appropriate hand hygiene methods before starting.
- _____ Screens patient for contraindications (severe adverse reactions to previous TST).*
- _____ Uses well-lit area.

2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§

- _____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
- _____ Checks label and expiration date on vial.
- _____ Marks opening date on multidose vial.
- _____ Fills immediately after vial removed from refrigeration.
- _____ Cleans vial stopper with antiseptic swab.
- _____ Twists needle onto syringe to ensure tight fit.
- _____ Removes needle guard.
- _____ Inserts needle into the vial.
- _____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
- _____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
- _____ Removes needle from vial.
- _____ Returns antigen vial to the refrigerator immediately after filling.

3. TST administration site selected and cleaned

- _____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
- _____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
- _____ Cleans the site with antiseptic swab using circular motion from center to outside.
- _____ Allows site to dry thoroughly before administering antigen.

4. Needle inserted properly to administer antigen

- _____ Rests arm on firm, well-lit surface.
- _____ Stretches skin slightly.††
- _____ Holds needle bevel-up and tip at 5°–15° angle to skin.
- _____ Inserts needle in first layer of skin with tip visible beneath skin.
- _____ Advances needle until entire bevel is under the first layer of skin.
- _____ Releases stretched skin.
- _____ Injects entire dose slowly.
- _____ Forms wheal, as liquid is injected.
- _____ Removes needle without pressing area.
- _____ Activates safety feature of device per manufacturer's recommendations, if applicable.
- _____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
- _____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
- _____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
- _____ Discards used gauze or cotton ball according to local standard precautions.
- _____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
- _____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
- _____ Uses appropriate hand hygiene methods after placing TST.

5. Explanation to the client regarding care instructions for the injection site

- _____ The wheal (bump) is normal and will remain about 10 minutes.
- _____ Do not touch wheal; avoid scratching.
- _____ Avoid pressure or bandage on injection site.
- _____ Rare local discomfort and irritation does not require treatment.
- _____ May wash with soap and water (without pressure) after 1 hour.
- _____ No lotions or liquids on site, except for light washing, as above.
- _____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site. **SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

[3] Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.

Appendix A: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[3]

Appendix F. *(Continued)* Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

Scoring: ✓ or Y - Yes X or N - No NA - Not Applicable

1. Preliminary

- ..... Uses appropriate hand hygiene methods before starting.
- _____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
- ..... Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
- ..... Uses well-lit area.
- _____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

- ..... Palpates with arm bent at elbow at a 90° angle.
- _____ Lightly sweeps 2-inch diameter from injection site in four directions.
- ..... Uses zigzag featherlike touch.
- _____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

- _____ Holds palm over injection site.
- ..... Cleanse site with antiseptic swab using circular motion from center to outside.
- _____ Uses fingertips to find margins of the induration.
- ..... Marks the induration by placing small dots on both sides of the induration.
- _____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
- ..... Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

- _____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
- ..... Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

- ..... Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
- _____ Correctly records results in mm, only a single measured induration in mm should be recorded.

Trainee's measurement ..... mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.

† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).

§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9 -13 mm to be considered correct.

3 Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.

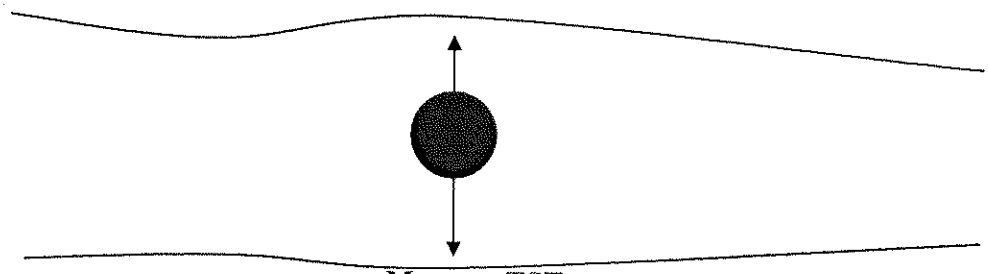
Appendix B: Interpretation of the Tuberculin Skin Test

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

Classification of the Tuberculin Skin Test Reaction (Table 8: page 1390)

Induration of ≥5mm	Induration of ≥10mm	Induration of ≥15mm
Positive if certain factors present: • HIV positive • Recent contact with active TB patient • Individuals with fibrotic changes on chest radiograph consistent with prior TB • Individuals with organ transplants • Individuals who are immunosuppressed for other reasons	Positive if certain factors present: • Recent immigrants (<5years) from high prevalence country • Injection drug users • Residents and employees of high-risk congregant settings • Mycobacteriology lab personnel • Persons with clinical conditions that place them at high risk	• Positive for any individual, including persons with no known risk factors for TB testing • However, targeted skin testing programs should only be conducted among high-risk groups

A negative TST result does not exclude LTBI or active TB disease.



Measure TSTs Transversely

Appendix C: Kentucky Department for Public Health TB Risk Assessment Forms (Example of TB-4 TB Risk Assessment Form (Rev. July 2018); TB-4a Instructions for TB Risk Assessment; TB-4b Additional Instructions) *Please check the Kentucky Department for Public Health website for updates to TB Risk Assessment forms under Clinical Service Guide Forms and Teaching Sheets: https://chfs.ky.gov/agencies/dph/dpqi/hcab/Pages/ccsguide.aspx*

INSERT LOGO HERE

Kentucky Department For Public Health
Tuberculosis (TB) Risk Assessment

Patient name (L,F,M): _____ DOB: _____ Race: _____ Sex: _____ SSN: _____

Address: _____ City, State, Zip: _____

Home/Work #: _____ Cell# _____ Patient Pregnant: _____ No _____ Yes; If Yes, LMP _____

Language: _____ Country of Origin: _____ Year arrived in US: _____ Interpreter needed: _____ No _____ Yes

Allergies: _____ Current Medications: _____

I. Screen for Active TB Symptoms (Check all that apply)

____None (Skip to Section II, "Screen for TB Infection Risk")
____Cough for ≥ 3 weeks → Productive: ___YES ___NO
____Hemoptysis
____Fever, unexplained
____Unexplained weight loss
____Poor appetite
____Night sweats
____Fatigue
Evaluate these symptoms in context

Pediatric Patients (≤ 5 years of age):
____Wheezing
____Failure to thrive
____Decreased activity, playfulness and/or energy
____Lymph node swelling
____Personality changes

II. Screen for TB Infection Risk *(Check all that apply)*

Individuals with an increased risk for acquiring latent TB infection (LTBI) or for progression to active disease once infected should have a TST. Screening for persons with a history of LTBI should be individualized.

A. Assess Risk for Acquiring LTBI. The Patient:
____ is a current high risk contact of a person known or suspected to have TB disease.
____ has been in another country for - 3 or more months where TB is common, and has been in the US for ≤ 5 years
____ is a resident or an employee of a high TB risk congregate setting
____ is a healthcare worker who serves high-risk patients
____ is medically underserved
____ has been homeless within the past two years
____ is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories
____ injects illicit drugs or uses crack cocaine
____ is a member of a group identified by the health department to be at an increased risk for TB infection
____ needs baseline/annual screening approved by the health department

B. Assess Risk for Developing TB Disease if Infected The Patient...
____ is HIV positive
____ has risk for HIV infection, but HIV status is unknown
____ was recently infected with *Mycobacterium tuberculosis*
____ has certain clinical conditions, placing them at higher risk for TB disease: _____
____ injects illicit drugs (determine HIV status): _____
____ has a history of inadequately treated TB
____ is >10% below ideal body weight
____ is on immunosuppressive therapy (this includes treatment for rheumatoid arthritis with drugs such as REMICADE, HUMIRA, etc.)

History of BCG / TB Skin Test / BAMT / TB Treatment:

History of prior BCG: ___NO ___YES → Year: _____
History of prior (+) TST or (+) BAMT: ____NO ___YES
Date (+) TST / (+) BAMT _____ TST: _____mm
CXR Date: _____ CXR result: ___ABN ___WNL
Dx: ___LTBI ___Disease
Tx Start: _____ Tx End: _____
Rx: _____
Completed: ___NO ___YES
Location of Tx: _____

III. Finding(s) *(Check all that apply)*

____ Previous Treatment for LTBI and/or TB disease
____ No risk factors for TB infection
____ Risk(s) for infection and/or progression to disease
____ Possible TB suspect
____ Previous (+) TST or (+) BAMT, no prior treatment

IV. Action(s) *(Check all that apply)*

____ Issued screening letter ____ Issued sputum containers
____ Referred for CXR ____ Referred for medical evaluation
____ Administered the Mantoux TB Skin Test
____ Draw BAMT / Interferon-gamma Release Assay ((IGRA)
____ Other: _____

TST Brand/Lot #_____ TST Brand/Lot#_____

Arm: ___Left ___Right	Arm: ___Left ___Right
Date/Time _____	Date/Time _____
Induration_____mm	Induration_____mm

____BAMT ____T-SPOT.*TB* **____QFT-TB-Gold-Plus**

Date/Time drawn: _____

Result: ___Pos ___Neg ___Borderline/Indeterminate

Screener's signature: _____
Screener's name (print): _____
Screener's title: _____
Date: _____ Phone #: _____
Comments: _____

- I hereby authorize the doctors, nurses, or nurse practitioners of the _____ Department for Public Health to administer a Tuberculin Skin Test (TST) or draw blood from me or my child named above for a Blood Assay for *Mycobacterium tuberculosis* (BAMT) test.
- I agree that the results of this test may be shared with other health care providers.
- I understand that:
  - this information will be used by health care providers for care and for surveillance /statistical purposes only.
  - this information will be kept confidential

X _____ Date: _____

IMPORTANT: A decision to test is a decision to treat. Given the high rates of false positive TB skin test results, the Kentucky TB Prevention and Control Program discourages administration of the Mantoux TST to persons who are at a low risk for TB infection.

TB-4 (7/2018)

Kentucky Department For Public Health
Instructions for the TB Risk Assessment

Purpose of Form
The TB Risk Form is a tool to assess and document a patient's TB symptoms and/or risk factors. Completing this form will also help in determining the need for further medical testing and evaluation.

Directions for Completing the Form
Print clearly and complete this form according to the instructions provided below.

I. Screen for Presence of TB Symptoms

- Screen the patient for symptoms of active TB disease
- All symptomatic individuals who have not had a positive tuberculin skin test (TST) in the past should: (1) receive a TST or a Blood Assay for *Mycobacterium tuberculosis* (BAMT or Interferon Gamma Release Assay [IGRA]); (2) have their sputum collected; and (3) be referred for an immediate chest x-ray and medical evaluation regardless of the TST or BAMT result.
- If the patient does not have symptoms of active TB disease, go to Section II and assess risk for LTBI and/or disease.
- *Symptoms of active TB disease are more subtle in children.* Children with symptoms of active TB disease should receive a TST, CXR and immediate medical evaluation by medical personnel knowledgeable about pediatric TB.

II. Screen for TB Infection Risk (In subsections A and B, check all the risk factors that apply.)

Section II has 2 sections. Section A: "Assess Risk for Acquiring LTBI", Section B: "Assess Risk for Developing TB Disease if infected".

- If a patient has one or more risk factors for LTBI as listed in sections A or B, then go to Section III and administer the TST or BAMT.
- If a patient does not have risk factors for LTBI, do not administer the TST or BAMT. Go to Section III and place a check next to "No Risk *Factors for TB Infection.*"
- If the patient's school, employment, etc. requires a TB screening, place a check next "Issued Screening Letter" (Section IV) and provide that document to the patient.

A. Assess Risk for Acquiring LTBI -- The following are definitions of select categories of persons at risk for LTBI

- *Person is a current close contact of another individual known or suspected to have TB disease* --
  Person is part of a current TB contact investigation
- *Person is a resident/employee of high TB risk congregate settings*-
  These settings are correctional facilities, nursing homes, and long-term care institutions for the elderly, mentally ill, and persons with AIDS.
- *Person is a health care worker who serves high-risk clients* --
  Screen for the individual risk factors for TB infection, unless screening efforts are part of an ongoing facility infection control program approved by local health department.
- *Person is medically underserved* –
  Person does not have a regular health care provider, and has not received medical care within the last 2 years.
- *Person is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories* –
  Child has foreign-born parents, or child's parents/caretakers are at high risk for acquiring TB infection.
- *Person is a member of a group identified by a local health department to be at an increased risk for TB infection* --
  Identification of a group is based on local epidemiologic data showing an increase in the number of persons with TB disease or TB infection in the given group
- *Person needs baseline/annual screening approved by health department* –
  Screening program that is approved by the local health dept. for facilities or individuals at an increased risk for LTBI

B. Assess Risk for Developing TB Disease if Infected - The following are definitions of select categories of persons at risk for TB disease if infected

- *Person's HIV Status is unknown but has risk for HIV infection*
  Offer HIV test. Proceed with the TB Skin Test or BAMT, even if the patient refuses the HIV test.
- *Person with clinical conditions that place them at high risk* --
  Conditions include substance abuse, chest x-ray findings that suggest previous TB, diabetes mellitus, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, leukemia, lymphoma, hematologic and reticuloendothelial diseases, end stage renal disease, smoker, intestinal bypass or gastrectomy, and chronic malabsorption syndromes.
- *Person is on immunosuppressive therapy* –
  Person is taking $\geq$ 15 mg/day of prednisone for $\geq$ 1 month; person is receiving treatment for rheumatoid arthritis with medications such as REMICADE, Enbrel, or HUMIRA and/or person needs baseline evaluation prior to start of arthritis treatment with the medications cited here.

III. Finding(s) (Check all findings that apply.)

In this section, indicate findings from the assessments in all previous sections.

IV. Action(s) (Check all actions that apply.)

- Indicate the action(s) to take as a result of the findings in Section III
- If administering a TST or BAMT, provide all requested data.
- Write other pertinent patient information next to "Comments"

Additional Follow-up to the TST or BAMT

- If the patient's TST reaction or BAMT result is interpreted as positive or if she/he has symptoms for TB disease, refer the patient immediately for a chest x-ray.
- If a person has a history of a positive TST or a positive BAMT and is currently asymptomatic, then refer him/her for a chest x-ray if the following two conditions apply: 1) patient is a candidate for LTBI treatment and 2) patient is willing to adhere to the treatment.

Additional Guidelines for Tuberculosis (TB) Risk Assessments, Form TB-4

Since 2007, Local Health Departments (LHDs) have had more activity for "**Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**," http://www.cdc.gov/MMWR/preview/MMWRhtml/rr4906a1.htm. The TB Risk Assessment Form, TB-4, was developed to aid Local Health Departments in conducting TB risk assessments with targeted testing for those Kentuckians with increased risk for latent TB infection (LTBI).

As noted in the CDC guideline, "Targeted tuberculin testing for LTBI is a strategic component of tuberculosis (TB) control that identifies persons at high risk for developing TB who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB. Following that principle, targeted tuberculin testing programs should be conducted only among groups at high risk and discouraged in those at low risk. Infected persons who are considered to be at high risk for developing active TB should be offered treatment of LTBI irrespective of age."

The overall goal of these TB risk assessments at LHDs is to increase the percentage of tuberculin skin tests (TSTs) or blood assays for *Mycobacterium tuberculosis* (BAMTs) that are administered to individuals at increased risk for LTBI and to decrease the percentage of TSTs or BAMTs that are administered to individuals who have no risk factors for LTBI.

LHDs should use the TB risk assessment for all patients presenting for TB screenings, including those individuals identified in contact investigations. The TB Risk assessment form is an ideal tool for educating patients about the signs and symptoms of active TB, the risk factors for developing LTBI, and the risk factors for rapid progression of LTBI to active TB.

The TB risk assessment process also more easily enables LHD staff to determine the cut-off values for reading a TST when a TST is used for screening. A "Report of Tuberculosis Screening," Form TB-3, can be completed for those patients who need documentation of the results of TB screening for their employers or other groups.

*The Kentucky TB Program recognizes that the LHD may choose to collaborate with other organizations for the management and treatment of LTBI or other TB-related occupational health services. In these instances, a written agreement should be initiated between the two agencies to clearly identify the roles of each organization and define a payment schedule for any TB-related services provided by the LHD.

Appendix D: Booster Phenomenon and Two-step TST Testing (Chapter 3, page 58-59)[2]

Figure 3.5
The TST Booster Phenomenon

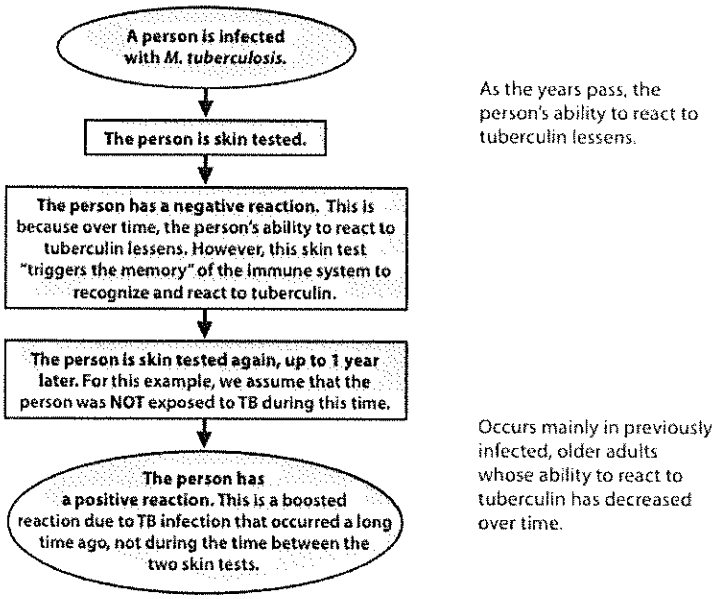
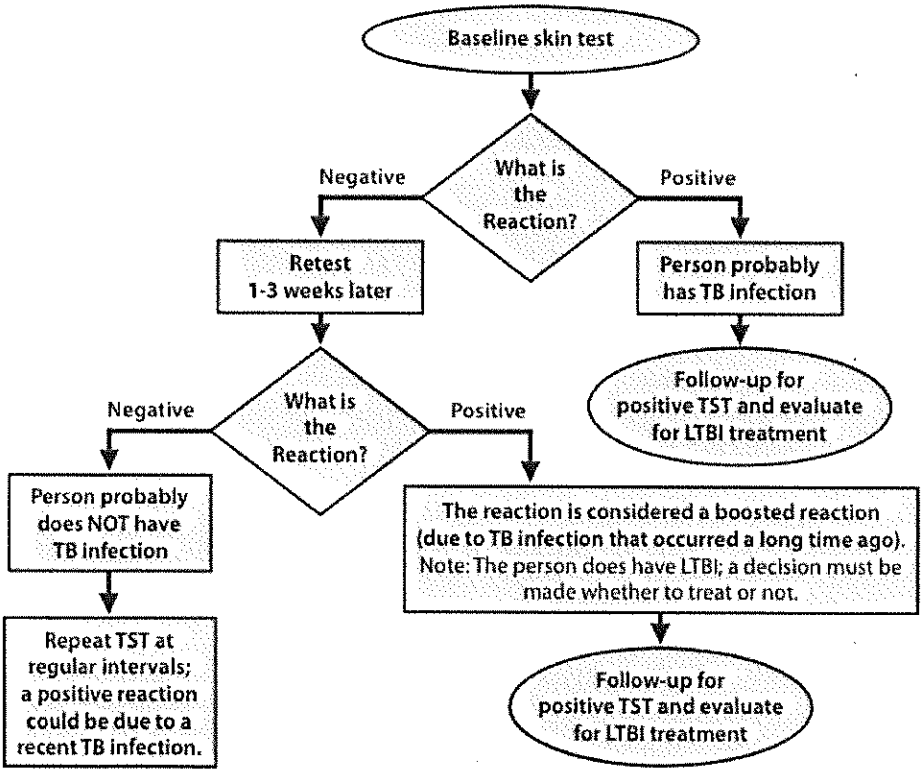


Figure 3.6
Two-Step TST Testing



Agenda Topic: Controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria

Included in agenda package:

- Example of protocol used in Idaho for treatment of Influenza
- Kentucky Acute Influenza Infection: Antiviral Therapy Protocol
- Example of protocol used in Idaho for treatment of Strep Throat
- Kentucky Acute Group A Streptococcal Pharyngitis Infection Protocol

Action to be taken:

- Discuss subject and offer recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older for drugs approved by the U.S. Food and Drug Administration for controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria

Pharmacist Prescribing Treatment of Influenza
Service Outline

Background:
To allow for timely and accessible treatment, Idaho pharmacists are authorized to prescribe treatment for low-risk patients with influenza in accordance with the clinical guidelines of the Infectious Disease Society of America.

Pharmacist Training:
To prescribe treatment for influenza to an eligible individual, a pharmacist must have completed the following:

- Review this *Pharmacist Prescribing Treatment of Influenza.*

Patient Eligibility:
Individuals potentially eligible to be issued a prescription for influenza include:

- Patients six years of age or older exhibiting signs of influenza-like illness for 48 hours or less and who test positive on a CLIA-waived test indicated for influenza.

Exclusion Criteria:
The following patients must be referred to a primary care physician or another healthcare provider:

- Patients exhibiting signs of influenza-like illness for greater than 48 hours
- Patients who report they are pregnant or breastfeeding
- Patients who report they are immunocompromised by medication or condition
- Patients who have one or more of the following:
    - Systolic hypotension <100 mmHg
    - Tachypnea >25 breaths per minute (>20 breaths per minute for patients <18 years)
    - Tachycardia >100 beats per minute (>119 beats/min for patients <18 years)
    - Oxygenation <90% via pulse oximetry
    - Body temperature >103° F (>102° F for patients <18 years)
- Patients who report any of the following:
    - History of renal dysfunction
    - History of allergic reaction to any previous antiviral therapy
    - History of psychologic side effects from any previous neuraminidase therapy
    - Use of antiviral therapy in past four weeks

Procedure:

1. Patient Intake

- A pharmacy staff member should explain the cost of the service to the patient. There is a $35 service fee if a rapid influenza test is administered.
- Ask the patient to complete the *Intake Form* and return it to the In-Window when completed.
- **The *Influenza Treatment Intake Form* must be completed each time a new prescription is issued.**

2. Delivery of Care

- The pharmacist must review the answers provided on the *Intake Form* and assess if the patient meets any of the exclusion criteria for receiving prescription treatment. If they meet any of the exclusion criteria, the patient must be referred to a primary care physician or another healthcare provider. OTC product recommendations may be made for symptom management.
- The physical assessment must be performed in a private area.
- The patient's blood pressure, pulse, breathing rate, oxygenation, and body temperature must be documented on the intake form.
- The physical readings must be assessed by the pharmacist, and if the patient meets any of the exclusion criteria, antiviral treatment must not be prescribed.
- Inform the patient that he/she will receive a follow-up call from the pharmacist at 48 hours.
- The medications listed below are indicated for treatment of influenza:

Table 1: Treatment for Influenza per IDSA and CDC guidelines

Medication	Children 15 – 23 kg	Children 24 – 40 kg	Children > 40 kg	Age 13 and older
Oseltamivir (Tamiflu)	45 mg twice daily for 5 days	60 mg twice daily for 5 days	75 mg twice daily for 5 days	75 mg twice daily for 5 days

Table2: Treatment for Influenza with Baloxavir (Ages 12 and older)

Medication	**Weight 40kg – 80 kg**	**Weight 80 kg and higher**
Baloxavir	**40 mg as a single dose**	**80 mg as a single dose**

- **If provided by patient, the patient's primary care provider must be contacted with result of service using the *PCP Notification* form.**

Billing—Prescription:

The pharmacy staff must process the prescription in the pharmacy dispensing system. The *Intake Form* should be used as the prescription hardcopy. This must be filed with other prescriptions per normal filing procedures.

Billing—Service:

- The service must be billed each time a new prescription is issued, including when issuing a new prescription for an established patient.
- The pharmacy staff must process the prescribing service in the pharmacy dispensing system. This must be filed with other prescriptions per normal filing procedures.

	Service resulting in a rapid flu test administered	Service resulting in a no flu test and/or Referral
NDC#	55555-5556-92	55555-5556-93
Name	Influenza Test Administered	Influenza Prescribing Referral
Qty	1	1
Cash Price	$35	$0

Reordering Testing Supplies

- If a test kit needs to be ordered, the store must email [redacted] with the test kit that is required. To order the Influenza A&B test kit, request that pharmacy procurement order:

  Sofia Influenza A&B Test Kit (Item #[redacted]

- Pharmacy procurement will order the test supplies on behalf of the store. Stores are not able to directly order the test kits from the supplier.

Influenza Treatment | Intake Form

Patient Information

Name: _____ Today's Date: _____

Address: _____ Phone #: _____

City: _____ State: _____ Zip: _____ DOB: _____ Sex: □ Female □ Male

Primary Care Physician: _____ Allergies: _____

Insurance Information - *Please Provide Card(s) to Pharmacy*

Prescribing services may or may not be covered by your insurance. We will verify all eligibility under your plan and attempt to collect payment from your insurance for all services. If we are unable to confirm eligibility or coverage, you may still opt to receive these services at our pharmacy and pay for it yourself or your insurance may cover prescribing services at your physician's office. Your insurance may reimburse you for out-of-pocket expenses for covered services if you submit receipts and documentation. You are responsible for payment for products or services you receive that are not paid for by your plan. Please provide your insurance information below.

Prescription Insurance Name: _____

Cardholder ID #: _____

RX Group #: _____

Rx Bin #: _____ Rx PCN #: _____

Relationship of Patient to Cardholder: _____

Medical Insurance Name: _____

Insurance Address: _____

Cardholder Name: _____

Cardholder ID #: _____

Cardholder DOB: _____

Group #: _____

Relationship of Patient to Cardholder: _____

If patient is under 13, please enter weight:

Weight: _____ (1 kg = 2.2 lbs)

Current Symptoms

- ☐ Fever
- ☐ Cough
- ☐ Sore throat
- ☐ Headache
- ☐ Nasal Congestion
- ☐ Fatigue
- ☐ Muscle/Body Aches
- ☐ Other _____

Patient History

	Yes	No
1. Have flu-like symptoms been present for more than two days?		
2. Have you received an antiviral in the past 30 days?		
3. Are you pregnant or breastfeeding?		
4. Do you have a condition that affects your immune system (e.g., cancer, leukemia, HIV, active shingles, etc.)?		
5. Do you take medications that affect the immune system (e.g., prednisone, oral steroids, anticancer or antiviral drugs, etc.)?		
6. Do you have a history of kidney dysfunction?		
7. History of allergic reaction to any previous antiviral therapy?		
8. History of psychologic side effects from any previous antiviral therapy?		

FOR PHARMACY USE ONLY

Patient Screening

	Yes	No
1. Is the patient 6 years or older?		
2. Are the patient's Current Symptoms consistent with flu-like illness?		
3. Are the responses to questions 1 – 8 on the Patient History marked as "no"?		

If the answers to questions above are yes, the pharmacist may exercise professional discretion in performing the physical assessment listed below.

Physical Assessment

Assessment	Patient Value	Acceptable Range for Prescribing
Blood Pressure		Systolic BP greater than 100 mmHg
Breathing Rate		Less than 25 breaths per minute *Less than 20 for patient <18 years*
Pulse		Less than 100 beats per minute *Less than 119 for patients <18 years*
Oxygenation		Greater than 90%
Body Temperature		Less than 103°F *Less than 102°F for patients <18 years*

If all assessment values are within the acceptable range, the pharmacist may perform the rapid influenza test. If the rapid influenza test is positive, the pharmacist may prescribe appropriate product to treat the patient's influenza. The pharmacist must ensure the service is provided in a manner consistent with the service outline.

Rapid Influenza Test Result: ☐ Positive (Prescribe treatment) ☐ Negative (Refer)

Prescription Information

Patient Name: _____ Patient DOB: _____

Prescription Name and Strength: _____ Rx Date: _____

SIG: _____ Quantity: _____

Prescriber: _____

Prescriber Address: _____

Patient Follow-up (Due at 48 hours)

Follow-up Call Attempt 1: _____ Follow-up Call Attempt 2: _____ Follow-up Call Attempt 3: _____	Yes	No
Was the patient reached for follow up, as required, after being prescribed the medication?		
If yes, is the patient still experiencing symptoms?		
If yes, what symptoms?		
If yes, are the symptoms: ☐ Improving ☐ Worsening ☐ The same		
If the patient is still experiencing symptoms recommend that the patient be seen by a Primary Care Provider.		
Notes on Follow-up:		

Date form faxed to provider: _____

ACUTE INFLUENZA INFECTION: ANTIVIRAL THERAPY PROTOCOL v3

Approved 7/29/2020

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antiviral therapies to treat acute influenza infection. The purpose of this protocol is to ensure appropriate and timely antiviral therapy for individuals with influenza following diagnostic confirmation via CLIA-waived point-of-care Rapid Influenza Diagnostic Test (RIDT) or CLIA-waived real-time Polymerase Chain Reaction (PCR) test.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating influenza testing and dispensing of antiviral therapy under this protocol, pharmacist(s) must have received education and training in point-of-care RIDT testing techniques from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy. Additionally, pharmacist(s) must maintain knowledge of the Centers for Disease Control and Prevention (CDC)'s current recommendations for the use of antiviral drugs in the treatment of influenza.[1]

Provider of Training: _____

Date Training Completed: _____

CRITERIA

Pharmacists authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection will treat individuals according to annual guidance from the CDC.[1]

Inclusion criteria:

Any individual who presents to the pharmacy during influenza season, when known influenza viruses are circulating in the community, and meets **ALL** of the following criteria:

- Age 5 years or older (with consent of a parent/guardian if < 18 years old)
- Complaint of **ANY** sign/symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis)
- Reported symptom onset < 48 hours before time of presentation
- Positive influenza virus result via CLIA-waived point-of-care RIDT or PCR

Exclusion criteria:

Any individual who meets **any** of the following criteria:

- Age < 5 years
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)

[1] *https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm*

- Long-term aspirin therapy in individuals younger than 19 years of age
- Antiviral agent for influenza prescribed currently or within the previous 2 weeks
- Any condition requiring home oxygen therapy
- Known hypersensitivity to- all antiviral therapies for influenza and to any common component of the products.
- Receipt of FluMist within past 2 weeks
- Clinically unstable based on the clinical judgment of the pharmacist or any of the following criteria:
    - Acutely altered mental status
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
    - Pulse >125 beats/min
    - Respiratory rate >30 breaths/min
    - Temperature >103 °F taken orally

All individuals who request influenza testing but do not qualify for antiviral therapy dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate.

MEDICATIONS

This protocol authorizes pharmacists to initiate the dispensing of the following antiviral agents. The pharmacist may dispense any dosage form deemed appropriate for the individual.

Oral Oseltamivir dosing:

- **Adults:** 75 mg twice a day x 5 days
- **Children** (current weight determined using pharmacy's scale) x 5 days:
    - **15 kg or less:** 30 mg twice a day
    - **>15 to 23 kg**: 45 mg twice a day
    - **>23 to 40 kg**: 60 mg twice a day
    - **> 40 kg**: 75 mg twice a day

Oral baloxavir dosing:

- **Adults and Children 12 and older:**
    - **40 to less than 80kg:** single dose of 40 mg
    - **80 kg or more:** single dose of 80mg

Inhaled Zanamivir dosing:

- **Adults**: 10mg (two 5mg inhalations) twice a day x 5 days
- **Children** (7 years or older): 10mg (two 5mg inhalations) twice a day x 5 days

PROCEDURES FOR INITIATION OF THERAPY

Antiviral therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Relevant Medical and Social History

- Past medical history
- Current medications
- Allergies and hypersensitivities
- Onset and duration of flu-like symptoms
- Positive RIDT or PCR

Contraindications and Precautions

- Know hypersensitivity to oseltamivir, zanamivir or baloxavir
- Underlying respiratory disease or asthma (zanamivir)
- Severe renal dysfunction (est. CrCl < 30 ml/min, oseltamavir)
- Fructose/sorbitol intolerance (oseltamivir)
- Weight under 40kg (baloxavir)
- Under 7 years of age (zanamavir)
- Under 12 years of age (baloxavir)
- Under five years of age

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

No additional follow-up monitoring or laboratory tests will be required. Pharmacist will follow-up within 36-72 hours for evaluation of therapy, adverse effects, and need for referral for additional medical intervention.

EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on influenza vaccination and education on appropriate self-care, including symptom control, hygiene, and infection control measures.

Individuals receiving antiviral therapies under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Telephone follow-up by a pharmacist within 36 to 72 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, onset of new symptoms, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:
    - Significant deterioration in condition or new evidence of clinical instability
    - Onset of symptoms inconsistent with influenza or indicative of serious complications from influenza
    - Medication adverse effects severe enough to warrant discontinuation of therapy

Individuals who test negative for influenza via point-of-care testing will be counseled on the risk of a false-negative test result and will be counseled on selfcare or referred to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Referral will be made when the pharmacist has high suspicion of a false-negative result (i.e. when influenza activity in the community is high and person has clear signs and symptoms of influenza infection), determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

DOCUMENTATION

Pharmacist(s) will document via prescription record each individual who is tested for influenza under this protocol, including:

- Documentation of the presenting signs and symptoms that warranted influenza testing
- Documentation of parental consent for individuals under age 18
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care RIDT or PCR used to determine influenza status
- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual received and expressed understanding of the education required by this protocol

NOTIFICATION

Pharmacist(s) shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual or parent/guardian identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, influenza test results, medication dispensed, and follow-up plan, within 2 business days.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving antiviral therapy under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date all parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than 60 days.

Pharmacist Prescribing for Strep Throat
Service Outline

Background:
To allow for timely and accessible treatment, Idaho pharmacists are authorized to prescribe treatment for low-risk, symptomatic patients with strep throat in accordance with the clinical guidelines of the Infectious Disease Society of America.

Pharmacist Training:
To prescribe treatment for strep throat to an eligible individual, a pharmacist must have completed the following:

- Review this *Pharmacist Prescribing for Strep Throat Service Outline.*
- Review the *Pharmacist Prescriptive Authority Protocol for Group A Streptococcal Pharyngitis (Strep Throat)* issued by the Idaho Board of Pharmacy.

Patient Eligibility:
Individuals potentially eligible to be issued a prescription for streptococcal pharyngitis include:

- Symptomatic patients between age 6 and 45 who score 2 or higher on the Centor Score and then test positive on a CLIA-waived test indicated for group A streptococcal pharyngitis.

Exclusion Criteria:
The following patients must be referred to a primary care physician or another healthcare provider:

- Patients younger than 6 years of age or older than 45 years of age
- Patients who received antibiotic therapy within the previous 30 days
- Patients who report they are pregnant or breastfeeding
- Patients who report they are immunocompromised by medication or condition
- Adult patients who have one or more of the following:
    - Systolic hypotension <100 mmHg
    - Tachypnea >25 breaths per minute (>20 breaths per minute for patients <18 years)
    - Tachycardia >100 beats per minute (>119 beats/min for patients <18 years)
    - Oxygenation <90% via pulse oximetry
    - Body temperature >103° F (>102° F for patients <18 years)

Procedure:

1. Patient Intake

- A pharmacy staff member should explain the cost of the service to the patient. There is a $35 service fee if a rapid strep test is administered.
- Ask the patient to complete the *Intake Form* and return it to the In-Window when completed.
- **The *Strep Throat Intake Form* must be completed each time a new prescription is issued.**

2. Delivery of Care

- The pharmacist must review the answers provided on the *Intake Form* and assess if the patient meets any of the exclusion criteria for receiving prescription treatment. If they meet any of the exclusion criteria, he/she must be referred to a primary care physician or another healthcare provider. OTC products may be recommended for symptom management.
- The physical assessment must be performed in a private area.
- The patient's blood pressure, pulse, breathing rate, oxygenation, and body temperature must be documented on the intake form under the physical service section.
- In performing the physical assessment, the pharmacist must ensure the Centor score for the patient is 2 or greater. The Centor score is used in assessing whether patients are appropriate for rapid strep testing. The table for calculating the Centor Score is displayed below:

Table 1: Calculating Centor Score

Exudate or swelling on tonsils	No (0)	Yes (+1)
Patient Age	15 – 45 years old (0)	6 – 14 years old (+1)
Swollen/tender anterior cervical lymph nodes	No (0)	Yes (+1)
Temperature >100.4°F	No (0)	Yes (+1)
Cough	Cough present (0)	Cough absent (+1)
TOTAL SCORE		

- The physical readings must be assessed by the pharmacist, A rapid strep test may be performed only for patients with physical readings in the appropriate range.
- If treatment can be prescribed, the medication prescribed must consider patient allergies, local community resistance prevalence, availability, and cost.
- Inform the patient that he/she will receive a follow-up call from the pharmacist at 48 hours.

- In choosing an appropriate therapy, the medications listed below are indicated for treatment of strep throat:

Table 1: Treatment for Strep Throat from IDSA Guidelines

Medication	Dosage	Duration
First Line Therapies		
Amoxicillin	≥20 kg: 1 g (500 mg x 2) once daily <20 kg: 50 mg/kg once daily	10 days
Penicillin V	Age 12 and older: 500 mg twice daily	10 days
Second Line Therapies or Individuals with Penicillin Allergy		
Cephalexin	≥25 kg: 500 mg twice daily <25 kg: 20 mg/kg twice daily	10 days
Clindamycin	≥43 kg: 300 mg three times a day <43 kg: 7 mg/kg three times a day	10 days
Azithromycin	Adults ≥18: Take 500 mg once on day 1, then 250 mg once daily on days 2 – 5. Age <18: 12 mg/kg once daily	5 days

- **If provided by patient, the patient's primary care provider should be contacted with result of service with *PCP Notification* form.**

Billing—Prescription:

The pharmacy staff must process the prescription in the pharmacy dispensing system. The *Strep Throat Intake Form* must be scanned in as an additional document with the service. This must be filed with other prescriptions according to the prescription number.

Billing—Service:

- The service must be billed each time a new prescription is issued, including when issuing a new prescription for an established patient.
- The pharmacy staff must process the prescribing service in the pharmacy dispensing system This must be filed with other prescriptions according to the prescription number.

	Service resulting in a positive rapid strep test	Service resulting in negative rapid strep test	Service resulting in no strep test/referral
NDC#	55555-5556-90	55555-5556-91	55555-5556-96
Name	Strep Throat test administered	Strep Throat Prescribing Referral	Strep Referral No Test
Qty	1	1	1
Cash Price	$35	$35	$0

Reordering Testing Supplies

- If a test kit needs to be ordered, the store must email [redacted] with the test kit that is required. To order the Strep A+ test kit, request that pharmacy procurement order:

  Sofia Strep A+ Test Kit (Item [redacted]

- Pharmacy procurement will order the test supplies on behalf of the store. Stores are not able to directly order the test kits from the supplier.

Strep Throat | Intake Form

Patient Information

Name: _____ Today's Date: _____

Address: _____ Phone #: _____

City: _____ State: _____ Zip: _____ DOB: _____ Sex: □ Female □ Male

Primary Care Physician: _____ Allergies: _____

Insurance Information - *Please Provide Card(s) to Pharmacy*

Prescribing services may or may not be covered by your insurance. We will verify all eligibility under your plan and attempt to collect payment from your insurance for all services. If we are unable to confirm eligibility or coverage, you may still opt to receive these services at our pharmacy and pay for it yourself or your insurance may cover prescribing services at your physician's office. Your insurance may reimburse you for out-of-pocket expenses for covered services if you submit receipts and documentation. You are responsible for payment for products or services you receive that are not paid for by your plan. Please provide your insurance information below.

Prescription Insurance Name: _____

Cardholder ID #: _____

RX Group #: _____

Rx Bin #: _____ Rx PCN #: _____

Relationship of Patient to Cardholder: _____

Medical Insurance Name: _____

Insurance Address: _____

Cardholder Name: _____

Cardholder ID #: _____

Cardholder DOB: _____

Group #: _____

Relationship of Patient to Cardholder: _____

Weight: _____

1 kg = 2.2 lbs

Current Symptoms

- □ Fever (_____°F if measured)
- □ Sore throat/Painful swallowing
- □ Redness in throat (sometimes with white patches)
- □ Headache
- □ Body aches
- □ Cough
- □ Other _____

Patient History

	Yes	No
1. Have you received an antibiotic in the past 30 days?		
2. Are you pregnant or breastfeeding?		
3. Do you have a condition that affects your immune system (e.g., cancer, leukemia, HIV, active shingles, etc.)?		
4. Do you take medications that affect the immune system (e.g., prednisone, oral steroids, anticancer or antiviral drugs, etc.)?		
5. Do you have a history of kidney problems?		

FOR PHARMACY USE ONLY

Patient Screening

	Yes	No
1. Is the patient between the age of 6 and 45?		
2. Are the responses to questions 1 – 5 above marked as "no"?		

If the answer to both questions above are yes, the pharmacist may exercise professional discretion in performing the physical assessment listed below.

Physical Assessment

Calculate the Centor Score for the patient by using the table directly below.

Exudate or swelling on tonsils	No (0)	Yes (+1)
Patient Age	15 – 45 years old (0)	6 – 14 years old (+1)
Swollen/tender anterior cervical lymph nodes	No (0)	Yes (+1)
Temperature >100.4°F	No (0)	Yes (+1)
Cough	Cough present (0)	Cough absent (+1)
TOTAL SCORE*		

***Patients must score 2 or greater on the Centor Score to be eligible to receive a rapid strep test.**

Assessment	Patient Value	Acceptable Range for Prescribing
Blood Pressure		Systolic BP greater than 100 mmHg
Breathing Rate		Less than 25 breaths per minute *Less than 20 for patient <18 years*
Pulse		Less than 100 beats per minute *Less than 119 for patients <18 years*
Oxygenation		Greater than 90%
Body Temperature		Less than 103°F *Less than 102°F for patients <18 years*

If all assessment values are within the acceptable range, the pharmacist may perform the rapid strep test. If the rapid strep test is positive, the pharmacist may prescribe appropriate product to treat the patient's strep throat. The pharmacist must ensure the service is provided in a manner consistent with the service outline.

Rapid Strep Test Result: □ Positive (Prescribe treatment) □ Negative (Refer)

Prescription Information

Patient Name: _____ Patient DOB: _____

Prescription Name and Strength: _____ Rx Date: _____

SIG: _____ Quantity: _____

Prescriber: _____

Prescriber Address: _____

Patient Follow-up (Due at 48 hours)

Follow-up Call Attempt 1: _____ Follow-up Call Attempt 2: _____ Follow-up Call Attempt 3: _____	Yes	No
Was the patient reached for follow up, as required, after being prescribed the medication?		
If yes, is the patient still experiencing symptoms?		
If yes, what symptoms?		
If yes, are the symptoms: ☐ Improving ☐ Worsening ☐ The same		
If the patient is still experiencing symptoms, recommend that the patient be seen by a Primary Care Provider.		
Notes on Follow-up:		

Date form faxed to provider: _____

ACUTE GROUP A STREPTOCOCCAL PHARYNGITIS INFECTION PROTOCOL
v2
Approved 7/29/2020

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotics to treat acute Group A streptococcal (GAS) pharyngitis infection. The purpose of this protocol is to ensure appropriate and timely antibiotic therapy for individuals with streptococcal pharyngitis following diagnostic confirmation via CLIA-waived point-of-care Rapid Antigen Detection Test (RADT) or CLIA-waived real-time Polymerase Chain Reaction (PCR) test.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating testing and dispensing antibiotics under this protocol, pharmacist(s) must have received education and training in point-of-care RADT techniques from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy. Additionally, pharmacist(s) must maintain knowledge of the Infectious Disease Society of America (IDSA)'s current guidelines for the treatment of GAS pharyngitis.[1]

Provider of Training: _____

Date Training Completed: _____

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute GAS infection will treat individuals according to current IDSA guidelines.[1]

Inclusion criteria:
Any individual who presents to the pharmacy and meets **ALL** of the following inclusion criteria:

- Age 5 years or older (with consent of a parent/guardian if < 18 years old)
- Complaint of any sign or symptom consistent with GAS pharyngitis (sore throat, pain on swallowing, fever, headache, swollen or tender cervical lymph nodes, inflamed or swollen tonsils or uvula)
- Positive GAS result via CLIA-waived point-of-care RADT or PCR

Exclusion criteria:
Any individual who meets **ANY** of the following criteria:

- Age < 5 years old
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)

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[1] *Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America.* Available online at http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_By_Organ_System-81567/Lower/Upper_Respiratory/Streptococcal_Pharyngitis/

- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis
- Other antibiotic therapy prescribed for sore throat or upper respiratory infection within the previous 30 days
- Clinically unstable based on the clinical judgment of the pharmacist or any of the following criteria:
    - Acute altered mental status
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
    - Pulse >125 beats/min
    - Respiratory rate >30 breaths/min
    - Temperature >103 °F (taken orally)
- Presenting with overt viral features, such as: rhinorrhea, cough, oral ulcers, and/or hoarseness

Individuals who do not qualify for RADT or PCR under this protocol will be referred to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Individuals who do not qualify for antibiotic dispensing following RADT or PCR will be referred for additional evaluation when the pharmacist has high suspicion of a false-negative result, determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of one of the following medication regimens to an individual meeting criteria:

First-line Treatment (unless contraindicated due to history of penicillin allergy)

1. **Amoxicillin PO 25mg/kg (max = 500 mg) twice daily for 10 days or 50 mg/kg (max 1000 mg) once daily for 10 days**

Second-line Treatment (for those with mild allergic reactions e.g. rash to penicillin)

2. **Cephalexin PO 20 mg/kg/dose (max 500 mg/dose) twice daily for 10 days**

Third-line Treatments (for those with mild allergies to penicillin and cephalosporins or severe reactions e.g. anaphylaxis to penicillin)

3a. Azithromycin PO 12 mg/kg (max 500 mg) once daily for 5 days

3b. Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days

3c. Clarithromycin PO 7.5 mg/kg/dose (max 250 mg/dose) twice daily for 10 days

Adjunctive therapy may be useful for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis and should be considered as an adjunct to an appropriate antibiotics.

Acetaminophen PO; follow OTC dosing recommendations
Ibuprofen PO; follow OTC dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform RADT to determine between acute GAS and viral pharyngitis

- If positive, continue to evaluate with protocol
- If negative,
  - Adult: no back up throat culture needed for adults
  - Children and adolescents (<18 y/o): back up throat culture must be done, thus referral to primary care provider or urgent treatment center is required

Antbiotic therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Assess for Relevant Medical and Social History

- Patient demographics and weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current Medications
- Medication allergies and hypersensitivities

Evaluate for Contraindications and Precautions

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin

Selection of antibiotic regimen will follow the ordered preference listed above. A lower-ranked regimen will only be prescribed if the individual or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen. The pharmacist will assess reported drug allergies for validity by reviewing the individual's pharmacy record and documenting the reported reaction. In any case where amoxicillin is not the selected regimen, the pharmacist will document the clinical reasoning for the selection.

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications

- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per IDSA guidelines people with acute GAS pharyngitis should stay home from work, school, or daycare until they are afebrile and until 24 hours after starting appropriate antibiotic therapy

Individuals receiving antibiotics under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document via prescription record each person who is tested for GAS under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care RADT or PCR used to determine GAS status
- Documentation that the individual (or caregiver) received the education required by this protocol
- Documentation of clinical follow up as appropriate

NOTIFICATION

Pharmacist(s) shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary careprovider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, GAS test results, medication dispensed, and follow-up plan, within 2 business days.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving medications under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than 60 days.

Agenda Topic: 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

Included in agenda package:

- Excerpt from California SB 159, passed in 2019
- Colorado HB 20-1061, passed in 2020
- Oregon HIV Post-Exposure Prophylaxis (PEP) Protocol

Action to be taken:

- Discuss subject and offer recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older for drugs approved by the U.S. Food and Drug Administration for 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

Senate Bill No. 159

CHAPTER 532

An act to amend Section 4052 of, and to add Sections 4052.02 and 4052.03 to, the Business and Professions Code, to add Section 1342.74 to the Health and Safety Code, to add Section 10123.1933 to the Insurance Code, and to amend Section 14132.968 of the Welfare and Institutions Code, relating to HIV prevention.

[Approved by Governor October 7, 2019. Filed with Secretary of State October 7, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

SB 159, Wiener. HIV: preexposure and postexposure prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of these requirements a crime. Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as furnishing emergency contraceptives, hormonal contraceptives, and naloxone hydrochloride, pursuant to standardized procedures.

This bill would authorize a pharmacist to furnish preexposure prophylaxis and postexposure prophylaxis in specified amounts and would require a pharmacist to furnish those drugs if certain conditions are met, including that the pharmacist determines the patient meets the clinical criteria for preexposure prophylaxis or postexposure prophylaxis consistent with federal guidelines. The bill would require a pharmacist, before furnishing preexposure prophylaxis or postexposure prophylaxis, to complete a training program approved by the board. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services pursuant to a schedule of benefits, including pharmacist services, which are subject to approval by the federal Centers for Medicare and Medicaid Services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

This bill would expand the Medi-Cal schedule of benefits to include preexposure prophylaxis and postexposure prophylaxis as pharmacist services, as specified.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers

by the Department of Insurance. Existing law authorizes health care service plans and health insurers that cover prescription drugs to utilize reasonable medical management practices, including prior authorization and step therapy, consistent with applicable law. For combination antiretroviral drug treatments medically necessary for the prevention of AIDS/HIV, existing law prohibits plans and insurers, until January 1, 2023, from having utilization management policies or procedures that rely on a multitablet drug regimen instead of a single-tablet drug regimen, except as specified.

This bill would additionally prohibit plans and insurers from subjecting antiretroviral drugs, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except that if the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, the bill would instead require the plan or insurer to cover at least one of the therapeutically equivalent versions without prior authorization or step therapy. The bill would also prohibit plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit, a pharmacy provider from providing preexposure prophylaxis or postexposure prophylaxis, except as specified. The bill would prohibit plans and insurers from covering preexposure prophylaxis that has been furnished by a pharmacist in excess of specified amounts. Because a willful violation of these provisions by a health care service plan would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the

HOUSE BILL 20-1061

BY REPRESENTATIVE(S) Valdez A. and Herod, Arndt, Benavidez, Bird, Buckner, Buentello, Caraveo, Coleman, Esgar, Exum, Froelich, Gonzales-Gutierrez, Gray, Hooton, Jaquez Lewis, Kipp, Lontine, Melton, Michaelson Jenet, Mullica, Roberts, Singer, Sirota, Tipper, Titone, Weissman, Woodrow, Duran, Snyder, Young;
also SENATOR(S) Moreno and Priola, Bridges, Crowder, Donovan, Fenberg, Fields, Hansen, Lee, Pettersen, Rodriguez, Smallwood, Story, Todd, Williams A., Winter, Zenzinger, Garcia.

CONCERNING PHARMACISTS' ABILITY TO PROVIDE HIV INFECTION PREVENTION MEDICATIONS TO PATIENTS, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, 10-16-102, **add** (27.5), (38.5), (50.5), and (50.7) as follows:

10-16-102. Definitions. As used in this article 16, unless the context otherwise requires:

(27.5) "FDA" MEANS THE FOOD AND DRUG ADMINISTRATION IN THE

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OR ANY SUCCESSOR ENTITY.

(38.5) "HIV INFECTION PREVENTION DRUG" MEANS PREEXPOSURE PROPHYLAXIS, POST-EXPOSURE PROPHYLAXIS, OR OTHER DRUGS APPROVED BY THE FDA FOR THE PREVENTION OF HIV INFECTION.

(50.5) "POST-EXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES, AS DEFINED IN SECTION 12-280-125.7.

(50.7) "PREEXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES, AS DEFINED IN SECTION 12-280-125.7.

SECTION 2. In Colorado Revised Statutes, 10-16-104, **add** (18)(e) as follows:

10-16-104. Mandatory coverage provisions - definitions - rules. (18) **Preventive health care services.** (e) (I) A CARRIER SHALL REIMBURSE A PHARMACIST EMPLOYED BY AN IN-NETWORK PHARMACY FOR PRESCRIBING AND DISPENSING HIV INFECTION PREVENTION DRUGS TO A COVERED PERSON. A CARRIER SHALL PROVIDE A PHARMACIST WHO PRESCRIBES AND DISPENSES HIV INFECTION PREVENTION DRUGS TO A COVERED PERSON PURSUANT TO SECTION 12-280-125.7 AN ADEQUATE CONSULTATIVE FEE, OR, IF MEDICAL BILLING IS NOT AVAILABLE, AN ENHANCED DISPENSING FEE, THAT IS EQUIVALENT OR THAT IS PROVIDED TO A PHYSICIAN OR ADVANCED PRACTICE NURSE.

(II) THIS SUBSECTION (18)(e) DOES NOT APPLY TO AN INTEGRATED HEALTH CARE DELIVERY SYSTEM THAT DISPENSES A MAJORITY OF PRESCRIPTION DRUGS THROUGH INTEGRATED PHARMACIES.

SECTION 3. In Colorado Revised Statutes, **add** 10-16-152 as follows:

10-16-152. HIV prevention medication - limitations on carriers - step therapy - prior authorization. A CARRIER SHALL NOT REQUIRE A

COVERED PERSON TO UNDERGO STEP THERAPY OR TO RECEIVE PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION PREVENTION DRUG.

SECTION 4. In Colorado Revised Statutes, 12-280-103, **amend** (39)(c)(II)(C) and (39)(d); and **add** (39)(e) as follows:

12-280-103. Definitions - rules. As used in this article 280, unless the context otherwise requires or the term is otherwise defined in another part of this article 280:

(39) "Practice of pharmacy" means:

(c) The provision of a therapeutic interchange selection or a therapeutically equivalent selection to a patient if, during the patient's stay at a nursing care facility or a long-term acute care hospital licensed under part 1 of article 3 of title 25, the selection has been approved for the patient:

(II) By one of the following health care providers:

(C) An advanced practice nurse prescriber licensed as a professional nurse under section 12-255-110, registered as an advanced practice nurse under section 12-255-111, and authorized to prescribe controlled substances or prescription drugs pursuant to section 12-255-112, if the advanced practice nurse prescriber has developed an articulated plan to maintain ongoing collaboration with physicians and other health care professionals; ~~and~~

(d) The dispensing of chronic maintenance drugs pursuant to section 12-280-125.5 and board rules adopted in accordance with that section; AND

(e) PURSUANT TO A STANDING ORDER OR TO A STATEWIDE DRUG THERAPY PROTOCOL DEVELOPED PURSUANT TO SECTION 12-280-125.7, THE PRESCRIBING AND DISPENSING OF POST-EXPOSURE PROPHYLAXIS, AS DEFINED IN SECTION 12-280-125.7 (1)(d), FOR NONOCCUPATIONAL EXPOSURE TO HIV INFECTION AND PREEXPOSURE PROPHYLAXIS, AS DEFINED IN SECTION 12-280-125.7 (1)(e), AND THE ORDERING OF LAB TESTS IN CONJUNCTION WITH PRESCRIBING OR DISPENSING THE DRUGS.

SECTION 5. In Colorado Revised Statutes, **add** 12-280-125.7 as follows:

12-280-125.7. Pharmacists' authority to prescribe and dispense HIV infection prevention drugs - definitions - rules. (1) AS USED IN THIS SECTION:

(a) "CDC" MEANS THE FEDERAL CENTERS FOR DISEASE CONTROL AND PREVENTION IN THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OR ANY SUCCESSOR ENTITY.

(b) "CDC GUIDELINES" MEANS THE CDC GUIDELINES FOR PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION AND THE "UPDATED GUIDELINES FOR ANTIRETROVIRAL POST-EXPOSURE PROPHYLAXIS AFTER SEXUAL, INJECTION DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE TO HIV", AND ANY ANALOGOUS SUBSEQUENT GUIDELINES PUBLISHED BY THE CDC.

(c) "HIV INFECTION PREVENTION DRUG" MEANS PREEXPOSURE PROPHYLAXIS, POST-EXPOSURE PROPHYLAXIS, OR OTHER DRUGS APPROVED BY THE FDA FOR THE PREVENTION OF HIV INFECTION.

(d) "POST-EXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES.

(e) "PREEXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES.

(f) "PRESCRIBER" MEANS:

(I) A PHYSICIAN OR PHYSICIAN ASSISTANT LICENSED PURSUANT TO ARTICLE 240 OF THIS TITLE 12; OR

(II) AN ADVANCED PRACTICE NURSE, AS DEFINED IN SECTION 12-255-104 (1), WITH PRESCRIPTIVE AUTHORITY PURSUANT TO SECTION 12-255-112.

(g) "STANDING ORDER" MEANS A PRESCRIPTION ORDER WRITTEN BY

A PRESCRIBER THAT IS NOT SPECIFIC TO AND DOES NOT IDENTIFY A PARTICULAR PATIENT.

(2) A PHARMACIST MAY PRESCRIBE AND DISPENSE HIV INFECTION PREVENTION DRUGS IN ACCORDANCE WITH A STANDING ORDER PURSUANT TO SECTION 25-1-130 OR A STATEWIDE DRUG THERAPY PROTOCOL DEVELOPED PURSUANT TO SUBSECTION (5) OF THIS SECTION.

(3) BEFORE PRESCRIBING OR DISPENSING HIV INFECTION PREVENTION DRUGS TO A PATIENT, A PHARMACIST MUST:

(a) HOLD A CURRENT LICENSE TO PRACTICE IN COLORADO;

(b) BE ENGAGED IN THE PRACTICE OF PHARMACY;

(c) HAVE EARNED A DOCTORATE OF PHARMACY DEGREE OR COMPLETED AT LEAST FIVE YEARS OF EXPERIENCE AS A LICENSED PHARMACIST;

(d) CARRY ADEQUATE PROFESSIONAL LIABILITY INSURANCE AS DETERMINED BY THE BOARD; AND

(e) COMPLETE A TRAINING PROGRAM ACCREDITED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION, OR ITS SUCCESSOR ENTITY, PURSUANT TO THE PROTOCOL DEVELOPED BY THE BOARD.

(4) THE BOARD SHALL PROMULGATE RULES NECESSARY TO IMPLEMENT THIS SECTION, INCLUDING RULES THAT ESTABLISH PROTOCOLS FOR PRESCRIBING AND DISPENSING PREEXPOSURE PROPHYLAXIS AND POST-EXPOSURE PROPHYLAXIS.

(5) (a) ON OR BEFORE SIX MONTHS AFTER THE EFFECTIVE DATE OF THIS SECTION, THE STATE BOARD OF PHARMACY, THE COLORADO MEDICAL BOARD, AND THE STATE BOARD OF NURSING SHALL, IN COLLABORATION WITH THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, AND AS DESCRIBED IN SECTION 12-280-601 (1)(b), DEVELOP STATEWIDE DRUG THERAPY PROTOCOLS FOR PHARMACISTS TO PRESCRIBE AND DISPENSE HIV INFECTION PREVENTION DRUGS.

(b) IF THE STATE BOARD OF PHARMACY, THE COLORADO MEDICAL

BOARD, AND THE STATE BOARD OF NURSING ARE NOT ABLE TO AGREE IN THE TIME PERIOD REQUIRED BY SUBSECTION (5)(a) OF THIS SECTION TO STATEWIDE DRUG THERAPY PROTOCOLS FOR PHARMACISTS TO PRESCRIBE AND DISPENSE HIV INFECTION PREVENTION DRUGS, THE STATE BOARD OF PHARMACY SHALL COLLABORATE WITH THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT TO DEVELOP AND IMPLEMENT STATEWIDE DRUG THERAPY PROTOCOLS BY JANUARY 1, 2021.

(c) IN DEVELOPING THE STATEWIDE DRUG THERAPY PROTOCOLS, THE APPLICABLE BOARDS AND THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT SHALL CONSIDER PHYSICIAN REFERRALS; LAB TESTING, INCLUDING PREEXPOSURE AND POST-EXPOSURE PRESCRIBING TESTS, AND APPROPRIATE REFERRALS PURSUANT TO CDC GUIDELINES; COUNSELING PURSUANT TO CDC GUIDELINES; AND PATIENT FOLLOW-UP CARE AND COUNSELING.

SECTION 6. In Colorado Revised Statutes, **add** 25-1-130 as follows:

25-1-130. Standing order - post-exposure prophylaxis - definition. (1) ON OR BEFORE AUGUST 1, 2020, AND UNTIL A STATEWIDE DRUG THERAPY PROTOCOL IS IMPLEMENTED PURSUANT TO SECTION 12-280-125.7, THE DEPARTMENT SHALL IMPLEMENT AND MAINTAIN A STANDING ORDER FOR POST-EXPOSURE PROPHYLAXIS SO THAT PHARMACISTS MAY PRESCRIBE AND DISPENSE POST-EXPOSURE PROPHYLAXIS PURSUANT TO SECTION 12-280-125.7.

(2) AS USED IN THIS SECTION "POST-EXPOSURE PROPHYLAXIS" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-125.7.

SECTION 7. Appropriation. For the 2020-21 state fiscal year, $13,347 is appropriated to the department of regulatory agencies for use by the division of insurance. This appropriation is from the division of insurance cash fund created in section 10-1-103 (3), C.R.S., and is based on an assumption that the division will require an additional 0.2 FTE. To implement this act, the division may use this appropriation for personal services.

SECTION 8. Safety clause. The general assembly hereby finds,

determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.

KC Becker
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Leroy M. Garcia
PRESIDENT OF
THE SENATE

Robin Jones
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

APPROVED July 13, 2020 at 1:45 pm
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

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 post-exposure prophylaxis (PEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PEP Patient Intake Form (pg. 2-3)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 4-6)

PHARMACIST TRAINING/EDUCATION:

- Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(confidential-protected health information)

Name_____Date of Birth_____ Age_____ Today's Date_____

Health Care Provider's Name_____

Do you have health insurance? *Yes / No* Name of Insurance Provider_____

Any allergies to Medications? *Yes / No* If yes, list them here _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like this vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®/Motrin®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____	□ Yes □ No □ Not sure

Signature_____ Date_____

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

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg (Truvada®)
  Sig: Take one tablet by mouth once daily in combination with Isentress® for 30 days
  Quantity: #30
  Refills: none

AND

- Drug: raltegravir 400mg (Isentress®)
  Sig: Take one tablet by mouth twice daily in combination with Truvada® for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____ Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

Patient Referred

☐Hepatitis B Vaccination administered:

Lot:_____Expiration Date:_____ / Dose ___ of 3

Notes:_____

_____

_____

_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)-Assessment and Treatment Care Pathway

Name_____ Date of Birth_____ Today's Date_____

1. Is the patient less than 13 years old?		Notes: According to the CDC PEP treatment guidelines, Truvada® plus Isentress® is a preferred regimen for individuals 13 years and older.
Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic	No: Go to #2	
2. Is the patient known to be HIV-positive?		Notes:
Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	No: Go to #3. Conduct 4th generation HIV fingerstick test if available (optional).	
3. What time did the exposure occur?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
☐≤72 hours ago: go to #4	☐>72 hours ago: PEP not recommended. Refer patient to local primary care provider, infectious disease specialist, or public health department.	
4. Was the patient a survivor of sexual assault?		Notes:
Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #5) and then refer the patient to the emergency department for a sexual assault workup.**	No: Go to #5	
5. Was the exposure from a source person known to be HIV-positive?		
Yes: Go to #6	No: Go to #7	
6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:		Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.
Please check any/all that apply: ☐Blood ☐Semen ☐Vaginal secretions ☐Rectal secretions ☐Breast milk ☐Any body fluid that is visibly contaminated with blood If any boxes are checked, go to #9.	Please check any/all that apply (*Note: only applicable if not visibly contaminated with blood*): ☐Urine ☐Nasal Secretions ☐Saliva ☐Sweat ☐Tears ☐None of the above Go to #7	
7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?		Notes: This type of exposure puts the patient at a high risk for HIV acquisition
Yes: Go to #9	No: Go to #8	
8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?		Notes: Consider calling the HIV PEPline (888) 448-4911 for guidance.
Yes: Please check all that apply and go to #9: ☐Was the source person known to be HIV-positive? ☐Were there cuts/openings/sores/ulcers on the oral mucosa? ☐Was blood present? ☐Has this happened more than once without PEP treatment? ☐None of the above	No: Use clinical judgment. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.	

9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?		Notes: Connection to care is critical for future recommended follow-up.
Yes: Go to #10	No: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.	
10. Does the patient have history of known Hepatitis B infection (latent or active)?		Notes: Tenofovir disoproxil fumurate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.
Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.	No. Go to #11	
11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No Verify vaccine records or AlertIIS. Dates:		
Yes: Go to #13	No: Go to #12	
12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13. ☐Vaccine administered Lot:_____ Exp:_____ Signature:_____		
13. Does the patient have known chronic kidney disease or reduced renal function?		Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min
Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.	No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.	

Recommended regimen:	
Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days PLUS Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days	Notes: • There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time. • Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such. • Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com • If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

Counseling points:

Truvada®:

- Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset. Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.

Isentress®:

- Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset. If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.

Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.

Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.

Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

Pharmacist mandatory follow-up:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____ Date_____

Pharmacy Name
Address of Pharmacy
Pharmacy Phone Number

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are the medications and directions you have been prescribed, some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Medications: You must start these within 72 hours of your exposure

- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **AND**
- Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

Key Points

- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - HIV antigen/antibody 4th generation
   - Hepatitis B surface antigen and surface antibody
   - Hepatitis C antibody
   - Treponema pallidum antibody
   - Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Pharmacy Name
Pharmacy Address
Pharmacy Phone Number

Dear Provider,

Your patient _____ (name, DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.
- This regimen was initiated on _____ (Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada and Isentress are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- HIV ag/ab (4th gen) test
- Hepatitis B surface antigen and surface antibody
- Hepatitis C ab
- Comprehensive metabolic panel
- Treponema pallidum ab as appropriate
- Pregnancy test as appropriate
- STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- HIV ag/ab (4th gen) test
- Hepatitis C ab

If you have further questions, please contact the prescribing pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

Agenda Topic: Drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription

Action to be taken:

- Discuss subject and offer recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older for drugs approved by the U.S. Food and Drug Administration for drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription