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 Work Group Meeting

August 16, 2021 In-person Meeting (no virtual component)

10AM

TOPIC	**PAGES**
Call to Order: Kris Ratliff, DPh, Work Group Chairman	
• Welcome & Introductions	1
• Approval of Agenda	
Call for Public Comment: The work group will receive public comment at this time. The work group will not receive comment on any board regulation process for which a public comment period has closed or any pending disciplinary matters.	
Agenda Items	
• Review charge of work group as described in the fourth enactment clause of HB 2079	2-4
• Overview of pharmacist educational/training standards, VCU School of Pharmacy	5-11
• Excerpts from DRAFT Virginia's Pharmacist Workforce: 2020 Report	12-21
• Provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including:	
o Drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy, and;	22-32
o Controlled substances, devices, controlled paraphernalia, and supplies and equipment 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, urinary tract infection, and group A Streptococcus bacteria	33-61
Adjourn	

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

Work Group Members

1. Kris Ratliff, DPh, Workgroup Chairman, Board of Pharmacy Member
2. Sarah Melton, PharmD, Board of Pharmacy Member
3. Jake Miller, DO, Board of Medicine Member
4. Brenda Stokes, MD, Board of Medicine Member
5. Laurie Forlano, DO, MPH, Deputy Director, Office of Epidemiology, VDH
6. Will Hockaday, Tobacco Control Program/Outreach Coordinator, VDH
7. Kristin Collins, MPH, Policy Analyst, Office of Epidemiology, VDH
8. Stephanie Wheawill, PharmD, Division of Pharmacy Services Director, VDH
9. Kelly Goode, PharmD, BCPS, FAPhA, FCCP, VCU School of Pharmacy
10. Iain Pritchard, PharmD, BCACP, Shenandoah University, Bernard J. Dunn School of Pharmacy
11. Dr. Zahra Raza, VCU, School of Medicine
12. John R. Lucas, DO, Edward Via College of Osteopathic Medicine
13. Michelle Thomas, PharmD, CDE, BCACP, Virginia Pharmacists Association
14. Wendy Klein, MD, Medical Society of Virginia

history | pdf

CHAPTER 214

An Act to amend and reenact §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia, relating to pharmacists; initiation of treatment; certain drugs and devices.

[H 2079]

Approved March 18, 2021

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia are amended and reenacted as follows:

§ 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 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.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"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; (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, *devices, or controlled paraphernalia* 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.

§ 54.1-3303.1. 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, *controlled paraphernalia, and other supplies and equipment* 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~~ *Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter,* covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, *device, controlled paraphernalia, or other supplies or equipment;*

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

8. Tuberculin purified protein derivative for tuberculosis testing; and

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

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.

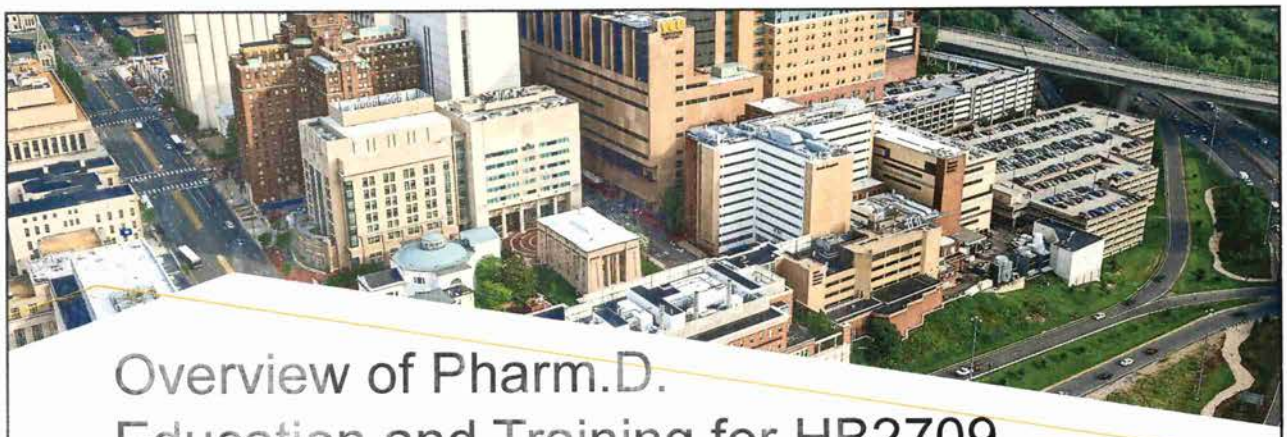
C. A pharmacist who administers a vaccination pursuant to subdivision A 7 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2021. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to recommend protocols to the Board of Pharmacy for review and implementation. No pharmacist shall initiate treatment with or dispense or administer such drug, device, controlled paraphernalia, or supply or equipment until such protocols have been adopted. Such protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment pursuant to § 54.1-3303.1 of the Code of Virginia, as amended by this act.

3. That the Board of Pharmacy, in collaboration with the Board of Medicine, shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulation shall include authorization for a pharmacist to initiate treatment with or dispense or administer drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1 of the Code of Virginia, as amended by this act, in accordance with protocols adopted by the Board of Pharmacy. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to develop recommendations and propose language for inclusion in such regulations.

4. That the Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine as well as 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 of Pharmacy may deem appropriate to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment 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, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety and report its recommendations to the Governor and the Chairmen of the Joint Commission on Health Care, the House Committee on Health, Welfare and Institutions, and the Senate Committee on Education and Health by November 1, 2021.

Legislative Information System



Overview of Pharm.D. Education and Training for HB2709

Jean-Venable "Kelly" R. Goode, Pharm.D., BCPS, FAPhA
Professor and Director, PGY1 Community-Based Pharmacy Residency Program
Email: jrgoode@vcu.edu Phone: (804) 828-3865

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

Educational Outcomes

- Standard 1: Foundational Knowledge
- Standard 2: Essentials for Practice and Care
- Standard 3: Approach to Practice and Care
- Standard 4: Personal and Professional Development

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Standard 2: Essentials for Practice and Care

- Patient-centered care
- Medication use systems management
- Health and wellness
- Population-based care

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Standard 3: Approach to Practice and Care

- Problem-solving
- Education
- Patient advocacy
- Interprofessional collaboration
- Cultural sensitivity
- Communication

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VCU Pharm.D. Curriculum (P1 Year)

Fall Semester 2019 | Course | Credit Hours		Spring Semester 2020 | Course | Credit Hours	
IPEC 501 Foundations of Interprofessional Practice	1.0	MEDC 553 Clinical Therapeutics Module: Introduction to Medicinal Chemistry*	1.0
MEDC 527 Basic Pharmaceutical Principles for the Practicing Pharmacist	3.0	PHTX 606 Clinical Therapeutics Module: Introduction to Pharmacology (Pharmacy)*	1.0
MEDC 533 Pharmacognosy	2.0	PHAR 529 Clinical Therapeutics Module: Introduction to Special Populations*	2.0
PCEU 501 Pharmaceutical Calculations	1.0	PCEU 508 Pharmacokinetics	3.0
PCEU 507 Pharmaceutics and Biopharmaceutics I	3.0	PCEU 509 Pharmaceutics and Biopharmaceutics II	3.0
PHAR 509 Evidence-based Pharmacy I: Introduction to Pharmacy Information Skills*	1.5	PHAR 513 Contemporary Pharmacy Practice	2.0
PHAR 523 Foundations I	1.5	PHAR 524 Foundations II	1.5
PHAR 545 The U.S. Health Care System	2.0	PHAR 526 Community Pharmacy Practice Management I	2.0
PHAR 652 Health Promotion and Communication in Pharmacy Practice	2.5	PHAR 530 Introductory Pharmacy Practice Experience: Community Practice	4.0
PHAR 515 Continuous Professional Development I	continues	PHAR 515 Continuous Professional Development I	1.0
TOTAL CREDIT HOURS	17.5	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		Spring Semester 2021 | Course | Credit Hours	
MEDC 543 Clinical Chemistry for the Pharmacist	1.0	IPEC 502: Interprofessional Quality Improvement and Patient Safety	1.0
PHAR 534 Foundations III	1.5	MEDC 542 Biotechnology-Derived Therapeutic Agents*	1.0
PHAR 541 Patient Assessment Skills for Pharmacy Practice	2.0	PCEU 615 Applied Pharmacokinetics	2.5
PHAR 544 Clinical Therapeutics Module: Cardiovascular*	4.5	PHAR 535 Foundations IV	1.5
PHAR 555 Clinical Therapeutics Module: Endocrinology*	2.5	PHAR 566 Evidence-based Pharmacy III: Drug Literature Evaluation	2.0
PHAR 603 Clinical Therapeutics Module: Respiratory/Immunology*	3.0	PHAR 604 Clinical Therapeutics Module: Infectious Diseases*	4.5
PHAR 565 Evidence-based Pharmacy II: Research Methods and Statistics*	2.5	PHAR 606 Clinical Therapeutics Module: Nephrology/Urology*	2.0
PHAR 546 Pharmacy-based Immunization Delivery	1.5	PHAR 532 Introductory Pharmacy Practice Experience: Hospital Practice	3.0
PHAR 615 Continuous Professional Development II	continues	PHAR 615 Continuous Professional Development II	1.0
TOTAL CREDIT HOURS	18.5	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

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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:
  - CLIA-waived laboratory testing
  - Infectious diseases
    - UTI's
    - Strep
    - Influenza
  - Tobacco Cessation
    - Motivational Interviewing

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

- Pharmacists regularly dispense and make dosing recommendations for the medications being discussed today
  - Additional guidance or training is not needed
- Treatment for Influenza, group A Streptoccocus and urinary tract infection
  - Additional guidance for treating to guidelines or training on assessing symptoms may be appropriate
- Tobacco cessation is largely based on tobacco use and patient preference
  - Additional guidance or training on assessing tobacco dependence and patient preferences may be appropriate.

VCU School of Pharmacy

THANK YOU!

VCU School of Pharmacy

Virginia's Pharmacist Workforce: 2020

Healthcare Workforce Data Center

February 2021

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-597-4213, 804-527-4466 (fax)
E-mail: ***HWDC@dhp.virginia.gov***

Follow us on Tumblr: ***www.vahwdc.tumblr.com***
Get a copy of this report from:
http://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/ProfessionReports/

14,771 Pharmacists voluntarily participated in this survey. *Without their effort, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for your ongoing cooperation.*

Thank You!

Virginia Department of Health Professions

David E. Brown, DC
Director

Barbara Allison-Bryan, MD
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Elizabeth Carter, PhD
Director

Yetty Shobo, PhD
Deputy Director

Laura Jackson, MSHSA
Operations Manager

Rajana Siva, MBA
Data Analyst

Christopher Coyle, BSc
Research Assistant

The Board of Pharmacy

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Kristopher S. Ratliff
Marion

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Executive Director

Caroline D. Juran

The Pharmacist Workforce: At a Glance:

The Workforce

Licensees:	16,205
Virginia's Workforce:	8,827
FTEs:	7,142

Survey Response Rate

All Licensees:	91%
Renewing Practitioners:	97%

Demographics

Female:	66%
Diversity Index:	53%
Median Age:	44

Background

Rural Childhood:	32%
HS Degree in VA:	48%
Prof. Degree in VA:	49%

Education

Baccalaureate:	32%
Pharm.D./Professional:	68%

Finances

Median Inc.:	$120k-$130k
Health Benefits:	70%
Under 40 w/ Ed debt:	72%

Current Employment

Employed in Prof.: 91%
Hold 1 Full-time Job: 72%
Satisfied?: 87%

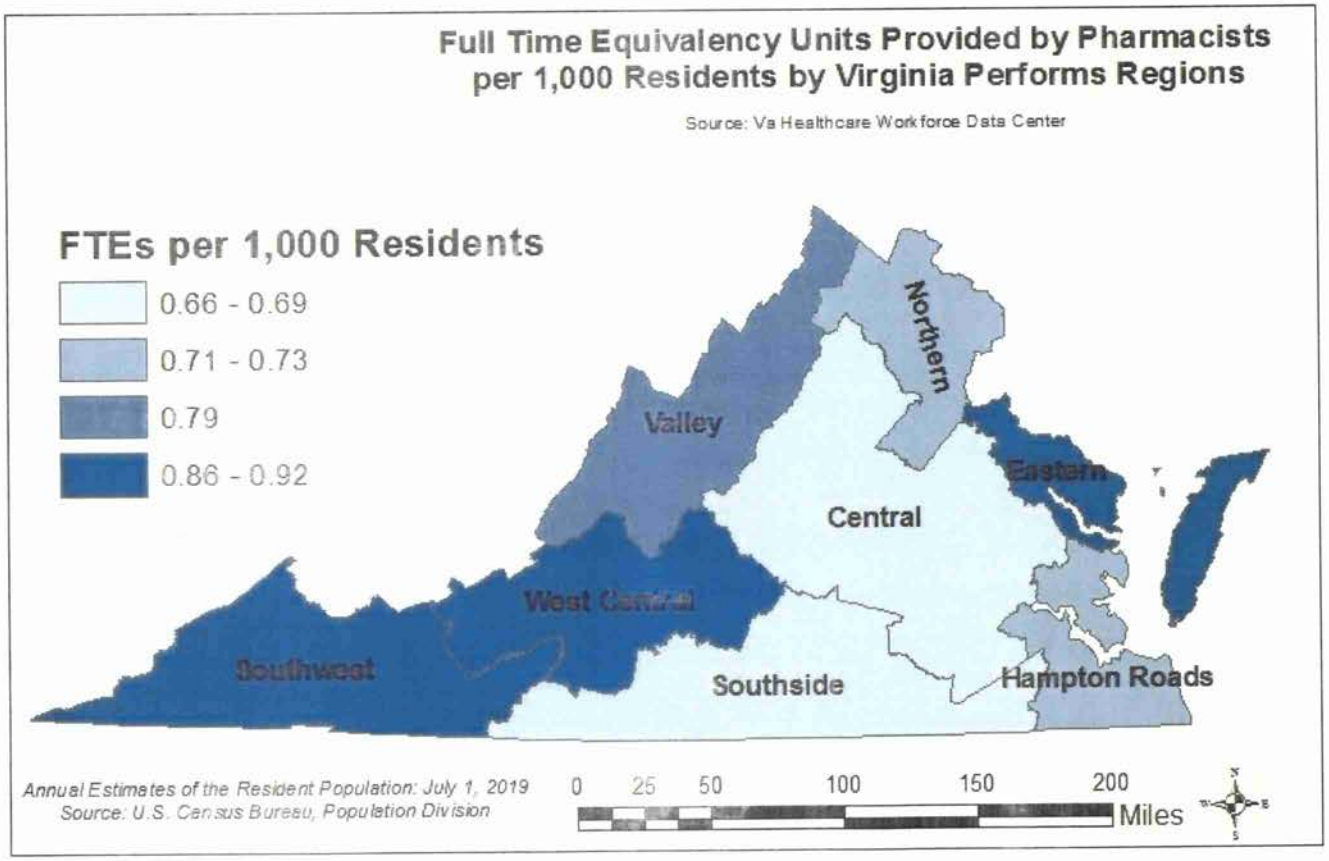
Job Turnover

Switched Jobs in 2020: 4%
Employed over 2 yrs: 63%

Primary Roles

Patient Care: 74%
Administration: 8%
Education: 1%

Source: Va. Healthcare Workforce Data Center



Results in Brief

A total of 14,771 pharmacists voluntarily took part in the 2020 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 16,205 pharmacists who are licensed in the state and 97% of renewing practitioners. The HWDC estimates that 8,827 pharmacists participated in Virginia's workforce during the survey period and they provided 7,142 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 68% of Virginia's pharmacist workforce have earned a doctorate or other professional degree as their highest educational attainment. Further, 42% 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 $120,000 and $130,000.

Nine out of every ten pharmacists are currently employed in the profession, with 72% holding one full-time position. Over the past year, 3% of pharmacists were involuntarily unemployed, while another 4% were underemployed. The typical pharmacist earned between $120,000 and $130,000 in 2020. Around 87% of all pharmacists are satisfied with their current employment situation, including 47% who indicated that they are "very satisfied".

About 90% of all pharmacists work in the private sector, including 64% 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 2045.

Summary of Trends

The total number of licensed pharmacists has grown by 27% since 2013. Of these, the number working in the state workforce has also increased but the increase of 12% is modest by comparison. However, the 4% increase in FTE provided in state 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 53% in 2020. The percentage of pharmacists who are female also continued inching up by about one percent nearly every other year, from 62% in 2013 to 66% in 2020. Median age has been relatively stable between 44 to 45 years in the past eight surveys. Even the percent under age 40, which increased from 37% in 2013 to 40% in 2016, has stayed at 40% in the past four years.

Educational attainment continues to increase among the pharmacist workforce. In 2013, only 51% had a pharmacy doctorate compared to 68% in 2020. Not surprisingly, the percent reporting educational debt has also increased annually from 35% in 2013 to 42% in 2020. Further, the median educational debt, which increased from $90K-$100K in 2013 to $110K-$120K in 2018, is now $120K-$130K.

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 2020, when the survey took place, was 2%. Median income has been stable at $120K to $130K between 2016 and 2020 after increasing from $110K-$120K in 2013. However, the percent earning above $140,000 increased from 17% in 2016 to 20% in 2020; only 12% were in that income range in 2013. Job satisfaction increased back to the 2018 level of 87% after dropping to 84% in 2019; this was driven by pharmacists who reported being very satisfied with their job who increased from 44% to 47%.

Pharmacists intending to retire in the next decade increased from 22% in the pre-2017 surveys to 23% in 2017 and have stayed at 23% since. The percent planning to retire in the next two years increased from 6% in 2013 to 7% in recent years. Regarding future plans, only 9% intended to pursue additional education in 2020 compared to 13% in 2013.

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	14,588	90%
New Licensees	885	5%
Non-Renewals	732	5%
All Licensees	16,205	100%

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 97% of renewing pharmacists submitted a survey. These represent 91% of pharmacists who held a license at some point in 2020.

Response Rates			
Statistic	Non Respondents	Respondent	Response Rate
By Age			
Under 30	127	870	87%
30 to 34	214	2,309	92%
35 to 39	191	2,440	93%
40 to 44	150	1,957	93%
45 to 49	124	1,772	94%
50 to 54	138	1,677	92%
55 to 59	105	1,331	93%
60 and Over	385	2,415	86%
Total	1,434	14,771	91%
New Licenses			
Issued in 2020	295	590	67%
Metro Status			
Non-Metro	110	1,039	90%
Metro	613	8,039	93%
Not in Virginia	711	5,693	89%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacists

Number:
16,205
New: 5%
Not Renewed: 5%

Survey Response Rates

All Licensees:

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	14,771
Response Rate, all licensees	91%
Response Rate, Renewals	97%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2020.
2. **Target Population:** All pharmacists who held a Virginia license at some point in 2020.
3. **Survey Population:** The survey was available to those who renewed their licenses online. It was not available to those who did not renew, including some pharmacists newly licensed

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	163	28%	426	72%	590	8%
30 to 34	371	31%	821	69%	1,192	16%
35 to 39	333	30%	764	70%	1,096	15%
40 to 44	253	28%	635	72%	888	12%
45 to 49	211	28%	543	72%	754	10%
50 to 54	250	31%	557	69%	807	11%
55 to 59	234	35%	431	65%	665	9%
60 +	654	53%	583	47%	1,237	17%
Total	**2,470**	**34%**	**4,760**	**66%**	**7,230**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	66%
% Under 40 Female:	70%

Age

Median Age:	44
% Under 40:	40%
% 55+:	26%

Diversity

Diversity Index:	53%

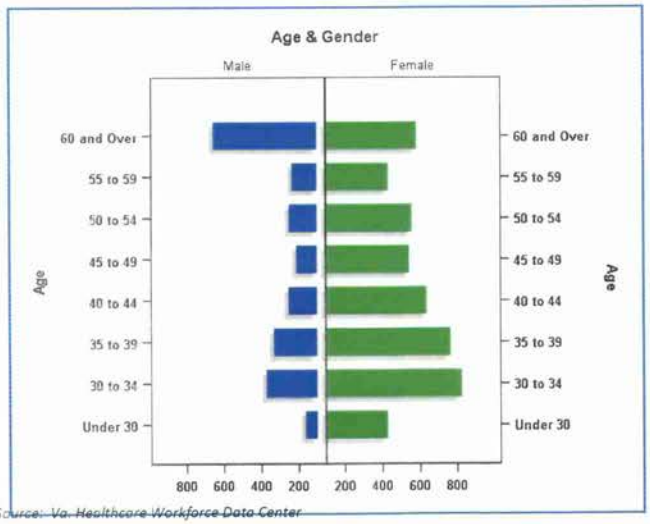
Source: Va. Healthcare Workforce Data Center

Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacists		Pharmacists Under 40	
	%	#	%	#	%
White	61%	4,710	65%	1,704	60%
Black	19%	822	11%	356	12%
Asian	7%	1,328	18%	641	22%
Other Race	0%	118	2%	41	1%
Two or more races	3%	120	2%	66	2%
Hispanic	10%	114	2%	53	2%
Total	**100%**	**7,212**	**100%**	**2,861**	**100%**

** Population data in this chart is from the US Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2018. *Source: Va. Healthcare Workforce Data Center*

In a chance encounter between two pharmacists, there is a 53% chance that they would be of a different race/ethnicity (a measure known as the Diversity Index). For Virginia's population as a whole, the comparable number is 57%.

40% of pharmacists are under the age of 40, and 70% of these professionals are female. In addition, pharmacists who are under the age of 40 are slightly more diverse than Virginia's overall population.



Source: Va. Healthcare Workforce Data Center

At a Glance:

Childhood

Urban Childhood:	17%
Rural Childhood:	32%

Virginia Background

HS in Virginia:	48%
Prof. Education in VA:	49%
HS/Prof. Educ. in VA:	57%

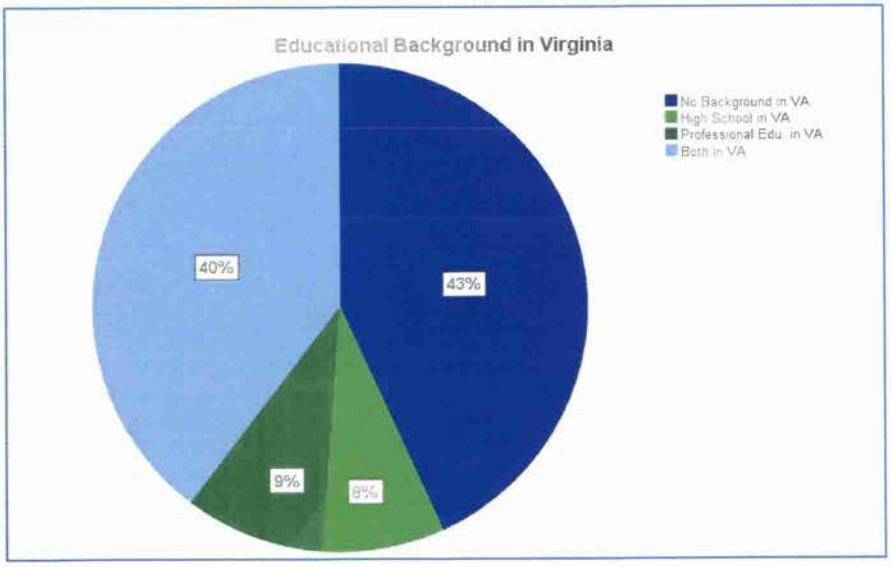
Location Choice

% Rural to Non-Metro:	23%
% Urban/Suburban to Non-Metro:	5%

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 million+	21%	58%	20%
2	Metro, 250,000 to 1 million	51%	42%	7%
3	Metro, 250,000 or less	40%	47%	13%
	Non-Metro Counties			
4	Urban pop 20,000+, metro adjacent	56%	35%	9%
6	Urban pop, 2,500-19,999, metro adjacent	60%	30%	11%
7	Urban pop, 2,500-19,999, non adjacent	89%	6%	5%
8	Rural, metro adjacent	54%	37%	9%
9	Rural, non adjacent	60%	27%	13%
	Overall	**32%**	**51%**	**17%**

Source: Va. Healthcare Workforce Data Center



32% of pharmacists grew up in self-described rural areas, and 23% of these professionals currently work in non-metro counties. Overall, 11% of Virginia's pharmacist workforce currently work in non-metro counties.

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): 11%
Community Pharmacy: 5%
Pharmacy Practice (Pre 1993): 3%

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	938	11%
Community Pharmacy	412	5%
Pharmacy Practice (Pre 1993)	288	3%
Managed Care Pharmacy	38	0%
Other	0	0%
Total	**1,676**	**19%**
PGY2		
Ambulatory Care	109	1%
Critical Care	66	1%
Internal Medicine/Cardiology	40	<1%
Drug Information	37	<1%
Health-system Pharmacy Administration	33	<1%
Infectious Disease	32	<1%
Pediatrics	29	<1%
Psychiatry	28	<1%
Oncology	25	<1%
Pharmacotherapy	21	<1%
Geriatrics	21	<1%
Informatics	14	<1%
Solid Organ Transfer	13	<1%
Other	148	2%
At Least One	**616**	**7%**

Board Certifications		
Certification	#	%
BPS-Pharmacotherapy	503	6%
BPS-Ambulatory Care	99	1%
BCGP-Geriatrics	84	1%
BPS-Oncology	43	<1%
BPS- Psychiatric	23	<1%
BPS- Nutrition	13	<1%
BPS-Nuclear Pharmacy	7	<1%
ABAT-Applied Toxicology	2	0%
Other Board Certification	229	2%
At Least One Certification	**912**	**10%**

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: 24%

Disease Management
Anticoagulation: 20%
Diabetes: 3%

A Closer Look:

Services Provided	Primary		Secondary	
Services	#	%	#	%
Primary Service, Immunization	2,862	32%	2,862	32%
Primary Service, Medication Therapy Management	2,533	29%	310	4%
Primary Service, Compounding	2,102	24%	214	2%
Primary Service, Central Filling	1,140	13%	143	2%
Primary Service, Remote Order Processing	1,004	11%	95	1%
Primary Service, Collaborative Practice Agreement	587	7%	68	1%
At Least One	4,625	52%	3,086	35%

Source: Va. Healthcare Workforce Data Center

Disease Management in Collaborative Practice	#	%
Anticoagulation	69	20%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Anticoagulation, Diabetes	34	10%
Hypertension, Hypercholesterolemia, Diabetes	24	7%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Travel medications, Anticoagulation, Diabetes	23	7%
Travel medications	21	6%
Anticoagulation, Diabetes	19	5%
Hypertension, Hypercholesterolemia, Tobacco cessation, Diabetes	19	5%
Hypertension, Hypercholesterolemia, Asthma, Anticoagulation, Diabetes	17	5%
Hypertension, Hypercholesterolemia, Tobacco cessation, Anticoagulation, Diabetes	13	4%
Hypertension, Hypercholesterolemia, Anticoagulation, Diabetes	12	3%
Tobacco cessation	12	3%
Hypertension, Diabetes	11	3%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Diabetes	11	3%
Diabetes	10	3%
Hypertension, Anticoagulation, Diabetes	8	2%
Hypertension, Hypercholesterolemia, Asthma, Diabetes	4	1%
Hypertension	3	1%
Hypertension, Asthma, Anticoagulation, Diabetes	3	1%
Hypertension, Asthma, Diabetes	3	1%
Hypertension, Tobacco cessation, Anticoagulation, Diabetes	3	1%
Other	30	9%
Total	**349**	**100%**

Agenda Topic:

Drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy

Included in Agenda Packet:

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

- *Pharmacy Today* article, June2020

Resources from the National Alliance of State Pharmacy Associations (NASPA)

Oregon Tobacco Cessation Protocol – NRT and Non-NRT

Action Needed:

Discuss and provide recommendations regarding the development of protocols for the initiation of treatment by pharmacists to persons 18 years of age or older, including controlled substances for the treatment of diseases or conditions for which clinical decision-making can be guided by a CLIA-waived test, including influenza virus, urinary tract infection, and group A Streptococcus bacteria.

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."

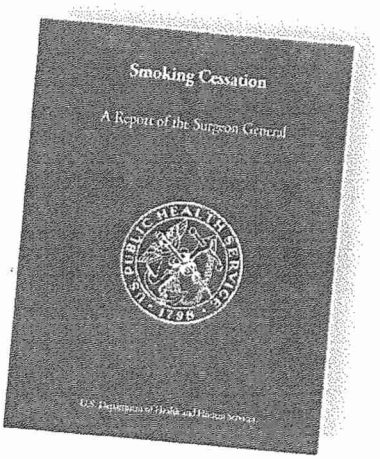
Patients may also not know all of their options. While cessation advice from providers has increased over the years, the report notes that more than 40% of adult smokers still don't receive advice to quit from a health professional.

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

Home / Resources / State Policy

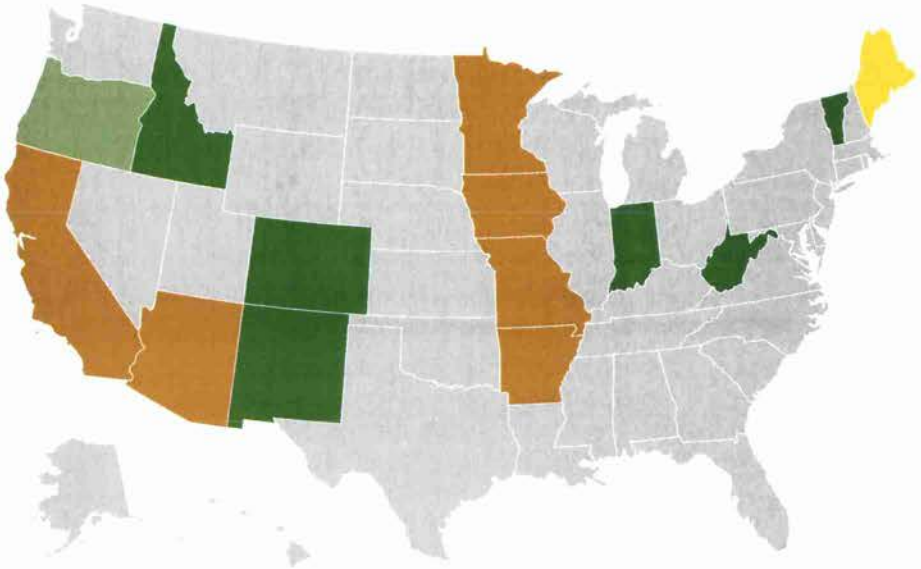
Pharmacist Prescribing: Tobacco Cessation Aids

FEBRUARY 10, 2021

Currently, there are 14 states with statutes or regulations addressing pharmacist prescribing of tobacco cessation aids (without a CPA).

In the map below, green states allow pharmacists to prescribe all FDA-approved tobacco cessation aids (including varenicline and bupropion), orange states allow pharmacists to prescribe all FDA-approved nicotine replacement products, and yellow states allow pharmacists to prescribe nicotine replacement products that are available over-the-counter.

Tobacco Cessation Prescribing Map



Updated
2.10.21 – hover over state to view details

Advocacy Resources

- Pharmacist-provided tobacco cessation services fact sheet
- Pharmacist prescribing tobacco cessation infographic
- Pharmacist prescriptive authority for smoking cessation medications in the United States
  - Includes FAQs helpful for advocacy!

NASPA Members log-in for more!

· Outside Support

- CMCS Bulletin on the Value of Pharmacist Prescribing
- ASTHO: Access to Tobacco Cessation Medication through Pharmacists

News

- Pharmacists Authorized to Prescribe Tobacco Cessation Therapy in More States
- **Video:** 'We're Passionate About It': Pharmacists Help Coloradans Quit Smoking (CBS Denver; October 10, 2018)

CPE Opportunities from State Pharmacy Associations:

- Furnishing Nicotine Replacement Therapy: Smoking Cessation Training Program for Pharmacists (California)
- Tobacco Cessation Training Course (Pennsylvania)
- Tobacco Cessation Certificate: Pharmacists as Tobacco Cessation Counselors (Washington)

Other State Pharmacy Association Resources:

- Smoking Cessation Toolkit: Clinical Training Resources/ Continuing Education (Pennsylvania)
- Nicotine Cessation Counseling: Home Study Continuing Education (Nebraska)
- Nicotine Cessation Counseling Toolkit (Nebraska)

Other Resources

- Tobacco Cessation Change Package – 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 – The CDC has compiled a plethora of resources to help pharmacists help patients to quit smoking.
- 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 – 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

Topics: Scope of Practice Tagged: pharmacist prescribing, smoking cessation, tobacco cessation, statewide protocols, statewide protocol, SWP

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
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
  - Nicotine replacement (like patches, gum, inhalers, lozenges, etc.)
  - Prescription medications (ex. bupropion [Zyban®, Wellbutrin®], varenicline [Chantix®])
- ☐ Other_____

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.

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 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

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.2): • 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.	**Refer** Score ≥ 1 on suicide screening. **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: ○ 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 ○ Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day) ○ 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: ○ 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 ○ Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) ○ 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

Agenda Topic:

Controlled substances, devices, controlled paraphernalia, and supplies and equipment 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, urinary tract infection, and group A Streptococcus bacteria

Included in Agenda Packet:

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 (GAS) Pharyngitis Infection Protocol for Use During the COVID-19 Pandemic

Kentucky Acute, Uncomplicated Urinary Tract Infection Treatment Protocol

Action Needed:

Discuss and provide recommendations regarding the development of protocols for the initiation of treatment by pharmacists to persons 18 years of age or older, including controlled substances for the treatment of diseases or conditions for which clinical decision-making can be guided by a CLIA-waived test, including influenza virus, 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?		

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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 FOR USE DURING THE COVID-19 (SARS-CoV-2) PANDEMIC v5
Approved 07/27/2021

***UPDATE* to Protocol Requirements During the COVID-19 (SARS-CoV-2) Pandemic**

Due to the similarities in clinical presentation of influenza and COVID-19 viruses, persons with influenza symptoms must also be tested for SARS-Cov-2. Accordingly, pharmacists using this protocol to test for influenza and initiate the dispensing of antiviral therapy must be able to test for SARS-CoV-2. Pharmacists unable to conduct a rapid SARS-CoV-2 test, or collect a sample for send-off testing, are not authorized to use this or any previously approved versions of the acute influenza infection protocols unless US Department of Health and Human Services or US Centers for Disease Control and Prevention release guidelines that allow for acute influenza testing in the absence of SARS-CoV-2 testing during the COVID-19 Pandemic.

To provide point-of-care COVID-19 testing pharmacists must:

1) Meet the requirements established by the Kentucky Board of Pharmacy and in accordance with the Governor's Executive Order to prevent the spread of COVID-19 in the Commonwealth.
2) Follow all criteria and procedures for point-of-care COVID-19 testing as outlined in the current Kentucky Statewide Physician Protocol for Point of Care COVID-19 Testing (except for reimbursement, unless applicable).
3) Comply with all current reporting requirements per the Kentucky Department of Public Health.

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 testing[1].

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 CLIA-waived testing techniques appropriate to the test employed by the pharmacy 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.[2]

Provider of Training: _____

Date of Training: _____

[1] https://www.cdc.gov/flu/professionals/diagnosis/table-nucleic-acid-detection.html and https://www.cdc.gov/flu/professionals/diagnosis/table-nucleic-acid-detection.html

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

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)
- 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 CLIA-waived test for influenza

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)
- Patients allergic to milk protein (zanamivir)
- Weight under 40kg (baloxavir)
- Under 7 years of age (zanamavir)
- Under 12 years of age(baloxavir)

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 CLIA-waived point- of-care test 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.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

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

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

<u>Billing—Prescription:</u>
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.

<u>Billing—Service:</u>
- 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?		

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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 (GAS) PHARYNGITIS INFECTION PROTOCOL FOR USE DURING THE COVID-19 (SARS-CoV-2) PANDEMIC v4
Approved 07/27/2021

***UPDATE* to Protocol Requirements During the COVID-19 (SARS-CoV-2) Pandemic**

Due to the similarities in clinical presentation of GAS and COVID-19, persons with GAS symptoms must also be tested for SARS-Cov-2. Accordingly, pharmacists using this protocol to test for GAS and initiate the dispensing of antibiotic therapy must be able to test for SARS-CoV-2. Pharmacists unable to conduct a rapid SARS-CoV-2 test, or collect a sample for send-off testing, are not authorized to use this or any previously approved versions of the acute GAS protocols unless US Department of Health and Human Services or US Centers for Disease Control and Prevention release guidelines that allow for acute GAS testing in the absence of SARS-CoV-2 testing during the COVID-19 Pandemic.

To provide point-of-care COVID-19 testing pharmacists must:

1) Meet the requirements established by the Kentucky Board of Pharmacy and in accordance with the Governor's Executive Order to Prevent the spread of COVID19 in the Commonwealth.
2) Follow all criteria and procedures for point-of-care COVID-19 testing as outlined in the current Kentucky Statewide Physician Protocol for Point of Care COVID-19 Testing (except for reimbursement, unless applicable).
3) Comply with all current reporting requirements per the Kentucky Department of Public Health.

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 testing.

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 CLIA-waived testing techniques appropriate to the test employed by the pharmacy 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 test

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)
- 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 o Pulse >125 beats/min o Respiratory rate >30 breaths/min o 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 CLIA-waived testing 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 testing 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.

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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/

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 CLIA-waived point-of-care test 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

Antibiotic 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 CLIA-waived point- of-care test 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 care provider, 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.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

ACUTE, UNCOMPLICATED URINARY TRACT INFECTION TREATMENT PROTOCOL
V2 Approved 12/11/2019

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotic and urinary analgesic therapies to treat acute, uncomplicated urinary tract infection (UTI) in adult females. The purpose of this protocol is to provide timely and accessible treatment for adult females with acute, uncomplicated UTI (also known as acute, uncomplicated cystitis) following diagnostic confirmation via CLIA-waived point-of-care urine dipstick rapid screening test.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing of antibiotics under this protocol, pharmacist(s) must have received education and training in UTI and the supplies necessary to perform point-of-care urine dipstick testing 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 current Infectious Disease Society of America (IDSA)'s Guidelines for the treatment of Uncomplicated Cystitis and Pyelonephritis (UTI)[1] and the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin for the Treatment of Urinary Tract Infections in Nonpregnant Women.[2]

Provider of Training: _____

Date Training Complete: _____

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute uncomplicated UTI infection will treat individuals according to current IDSA/ACOG guidelines.[1,2]

Inclusion criteria:

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

- Female patient ≥18 years of age but <65 years
- Prior history of UTI(s)
- 1 or more of the following symptoms: dysuria, increased frequency, and/or urgency
- Positive urine dipstick for nitrites and leukocytes via a CLIA-waived point-of-care detection test kit

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[1]Gupta K, Hooton TM, Naber KG, et al. International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. *Clinical Infectious Diseases.* 2011; 52(5):e103–e120. https://www.idsociety.org/practice-guideline/uncomplicated-cystitis-and-pyelonephritis-uti/. Accessed March 2019. *(This guideline is currently being updated. Projected publication update: Summer 2022)*

[2]Treatment of urinary tract infections in nonpregnant women. ACOG Practice Bulletin No. 91 2008. American College of Obstetricians and Gynecologists. *Obstetrics & Gynecology.* 2008; 111:785-794. https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Treatment-of-Urinary-Tract-Infections-in-Nonpregnant-Women?IsMobileSet=false ***(Reaffirmed 2016)***

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

- Male
- Pregnant
- Post-menopausal
- Vaginitis symptoms (e.g., vaginal discharge or itching)
- Symptom onset >7 days prior
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Renal transplantation
- Abnormal urinary tract function or structure (e.g., indwelling catheter, neurogenic bladder, renal stones, renal stents)
- Has or reports symptoms suggestive of pyelonephritis including:
  - Presence of fever (≥100.4 F; taken orally)
  - Nausea and vomiting
  - Flank pain
- Diabetes mellitus
- Renal dysfunction (based on individual's report or pharmacy records)
- Antibiotic therapy prescribed for UTI within the previous 30 days
- Inpatient stay at a healthcare facility within the previous 30 days
- History of recurrent UTIs (>3 per year)

All individuals who request UTI testing but do not qualify for antibiotic/urinary analgesic therapy dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate. Individuals who do not qualify for antibiotic dispensing following point-of-care urine dipstick test 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 antibiotic medication regimens recommended by current IDSA guidelines for the treatment of acute, uncomplicated cystitis to an individual meeting the criteria:

Nitrofurantoin monohydrate/macrocrystals 100 mg PO BID for 5 days
OR
Trimethoprim-sulfamethoxazole 160/800 mg PO BID for 3 days
OR
Fosfomycin trometamol 3 gm PO single dose

The choice between the above antibiotic medication regimens should be individualized and based on patient allergy, contraindications/precautions, adherence history, local community resistance patterns, cost, and availability.

This protocol also authorizes pharmacists to initiate the dispensing of the following medication for the treatment of UTI related dysuria: Phenazopyridine 100-200 mg PO TID after meals for up to 2 days when used concomitantly with an antibiotic agent.

PROCEDURES FOR INITIATION OF THERAPY

Perform point-of-care urine dipstick test to determine if acute, uncomplicated UTI is present

- If positive, continue to evaluate with protocol
- If negative, refer to a primary care provider or urgent/emergent treatment facility if clinically appropriate

Antibiotic 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
- Medical history
- Relevant social history
- Current medications
- Medication allergies and hypersensitivities

Evaluate for Contraindications and Precautions:

- Allergic reaction to sulfa drugs (trimethoprim-sulfamethoxazole)
- Allergic reaction/hypersensitivity to nitrofurantoin monohydrate/macrocrystals, trimethoprim-sulfamethoxazole, or fosfomycin trometamol
- Renal insufficiency (nitrofurantoin monohydrate/macrocrystals and phenazopyridine)
- Previous UTI treatment failure

Selection of antibiotic regimen will be individualized and based on patient specific factors including drug allergies and contraindications to therapy. The pharmacist will assess reported drug allergies for validity by reviewing the individual's pharmacy record and documenting the reported reaction. The pharmacist will document the clinical reasoning for the antibiotic 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
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

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

- Medication counseling consistent with state and federal requirements for prescription drug products
- Counseling on importance of adherence to antibiotic regimen and completion of entire course
- Instructions on when to seek medical attention:
    - Symptoms that do not resolve or worsen within 3 days
    - Development of fever (temperature ≥100.4 F; taken orally)
    - Presence of flank pain
- Counseling regarding prevention of UTIs
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document via prescription record each individual who receives testing and medications to treat UTI 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 urine dipstick test used to determine UTI status
- Documentation that the individual received the education required by this protocol
- Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and evaluation if warranted

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 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, urine dipstick test results, medication dispensed, and follow-up plan, within 2 business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive UTI treatment under this protocol provided all other applicable requirements of the protocol are met.

[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 UTI treatment 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	

References used to develop this protocol:

1. Gupta K, Hooton TM, Naber KG, et al. International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. *Clinical Infectious Diseases.* 2011; 52(5):e103–e120. https://www.idsociety.org/practice-guideline/uncomplicated-cystitis-and-pyelonephritis-uti/ . Accessed March 2019. *(This guideline is currently being updated. Projected publication update: Summer 2022)*
2. Treatment of urinary tract infections in nonpregnant women. ACOG Practice Bulletin No. 91 2008. American College of Obstetricians and Gynecologists. *Obstetrics & Gynecology*. 2008; 111:785-794. https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Treatment-of-Urinary-Tract-Infections-in-Nonpregnant-Women?IsMobileSet=false . (Reaffirmed 2016)
3. Mazzulli T. Diagnosis and management of simple and complicated urinary tract infections (UTIs). *Canadian Journal of Urology*. 2012:19(supp1):42-48.
4. University of Michigan Clinical Care Guidelines: Urinary Tract Infection. http://www.med.umich.edu/1info/FHP/practiceguides/uti/uti.pdf. Published September 2016. Accessed March 2019.