



October 1, 2019

The Honorable Rosalyn R. Dance
Chair
Joint Commission on Health Care
600 East Main Street, Suite 301
Richmond, VA 23219

Dear Senator Dance:

The National Association of Chain Drugs Stores (NACDS) would like to express our appreciation for the tremendous work of the Commonwealth of Virginia's Joint Commission on Health Care (JCHC), and for the opportunity to provide comments related to the Commission's ongoing study of dispensing drugs and devices pursuant to prescriptions, pharmacy collaborative practice agreements, standing orders, and statewide protocols pursuant to House Joint Resolution 662 (January 2019).¹ NACDS strongly supports JCHC's efforts to "ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care."²

To achieve this goal and advance the Commonwealth's overarching vision of "becoming the healthiest state in the nation,"³ transformational reform should transcend the entire healthcare continuum. As the Commonwealth achieved scope of practice reform for nurse practitioners⁴ (NPs) and physician assistants (PAs),⁵ we submit that the time is now to assess and modernize the Commonwealth's pharmacy care policies to secure more value, drive innovation and accomplish cost-effectiveness in healthcare delivery to improve the health and well-being of all Virginians.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. In Virginia, NACDS member companies have 1,233 locations that employ 78,014 people. Our members operate 40,000 pharmacies and include regional chains with as few as four stores as well as national companies. Across the nation, chain pharmacies employ more than 3 million individuals, including 157,000 pharmacists.⁶ They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative patient-care services that improve patient health and healthcare affordability. From convenient care clinics to educational programming,

¹ Virginia House Joint Resolution Number 662. Offered January 9, 2019. <https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+HJ662>

² Code of Virginia §§ 30-168 through 170.

³ Virginia Department of Health. Administration. <http://www.vdh.virginia.gov/commissioner/>

⁴ Virginia General Assembly HB 793: Nurse practitioners; practice agreements. 2018 <https://lis.virginia.gov/cgi-bin/legp604.exe?181+sum+HB793>

⁵ PAs in Virginia Attain Collaboration. American Academy of PAs. March 2019. <https://www.aapa.org/news-central/2019/03/pas-virginia-attain-collaboration/>

⁶ Community pharmacists have extensive education and training, which is similar to the amount of education and training required of other non-physician practitioners (e.g., NPs and PAs). Entry-level pharmacists receive a minimum of six (6) years of advanced education as part of the Doctor of Pharmacy degree (PharmD). Pharmacists also must pass a national, comprehensive and standardized board exam (North American Pharmacist Licensure Examination (NAPLEX) and are subject to state licensure requirements. The training of pharmacists emphasizes patient-centered care as a medication expert, which involves interpreting evidence, formulating patient assessments and recommendations, implementing, monitoring and adjusting patient care plans, and documenting activities. <http://www.aacp.org/resources/education/cape/Open%20Access%20Documents/CAPEoutcomes2013.pdf>

many NACDS members employ dietitians, life coaches and pre-diabetes educators, NPs, and PAs to name a few. As of 2014, there are over 2,700 convenient care clinics established throughout the nation; a majority of those clinics located inside NACDS member drug stores.⁷ Pharmacies are now recognized as an indispensable, convenient healthcare destination, meeting a wide variety of patient needs in the health and wellness space.⁸ NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Executive Summary

As the healthcare industry transitions toward the delivery of value-based care, an assessment of the current landscape and identification of areas of opportunity seems warranted. Compelling evidence demonstrates that pharmacy care is a fundamental component to the vitality and sustainability of providing accessible quality care to Americans.^{9,10,11,12} While primary and preventive care services have traditionally been provided by primary care physicians, NPs, and PAs, the role of community pharmacists has blossomed in the last ten years to encompass immunizations, screenings, health and wellness care, treatment for minor illnesses, medication optimization and chronic care management programs among many others. Many of these care services are tethered to a physician first diagnosing a patient and pharmacists providing medication management services, including adjusting therapy, ordering labs, et al. Other pharmacy programs are designed to provide patients convenient access to affordable, quality preventative and acute care, including minor ailment treatment subject to protocols or standing orders, especially to the uninsured, underinsured, and medically underserved.

Noted as the most accessible member of the healthcare team, pharmacists are well-positioned to manage and provide high quality preventive and chronic care through expanded ability to initiate, modify, and monitor therapy.¹³ National and federal agencies, such as the CDC¹⁴ and the U.S. Surgeon General,¹⁵ encourage and recognize the value of pharmacists in an effort to collaboratively improve quality and healthcare outcomes through services such as transitions of care, chronic

⁷ The Evolving Role of Retail Clinics. RAND Corporation. November 10, 2016. <https://doi.org/10.7249/RB9491-2>.
https://www.rand.org/pubs/research_briefs/RB9491-2.html

⁸ O'Dea J. New Role in Providing Healthcare Services. January 2014. <https://www.pm360online.com/the-pharmacys-new-role-in-providing-healthcare-services/>

⁹ Dalton K, Byrne S. Role of the pharmacist in reducing healthcare costs: current insights. *Integr Pharm Res Pract*. 2017;6:37–46. Published 2017 Jan 25. doi:10.2147/IPRP.S108047. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5774321/>

¹⁰ Newman TV, Hernandez I, et al. Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations. *J Manag Care Spec Pharm*. 2019 Sep;25(9):995-1000. doi: 10.18553/jmcp.2019.25.9.995.
<https://www.ncbi.nlm.nih.gov/pubmed/31456493>

¹¹ Armistead LT, Ferreri SP. Improving Value Through Community Pharmacy Partnerships. *Population Health Management*. 2018.
<https://www.liebertpub.com/doi/abs/10.1089/pop.2018.0040?journalCode=pop>

¹² Milosavljevic A, et al. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. *International Journal of Pharmacy Practice*. June 2018.
<https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462>

¹³ Heath S. How Pharmacists Can Drive Patient Engagement, Value-Based Care. March 2019. <https://patientengagementthit.com/news/how-pharmacists-can-drive-patient-engagement-value-based-care>

¹⁴ A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. CDC. August 2012.
https://www.cdc.gov/dhdsdp/programs/spha/docs/pharmacist_guide.pdf

¹⁵ Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011.
https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

Surgeon General supports USPHS report on pharmacists as providers. APhA. January 2012. https://www.pharmacist.com/CEOBlog/surgeon-general-supports-usphs-report-pharmacists-providers?is_sso_called=1

disease management, and more. NACDS commends Virginia's involvement in progressive interprofessional, collaborative clinical programs and educational initiatives along with innovative research conducted at universities that include the deployment of pharmacists to improve patient care. Through these programs, it is observed that allowing pharmacists to be more involved in direct patient care leads to less administrative burden on other healthcare providers, system cost efficacy, more cohesive healthcare teams and, most importantly, improved patient outcomes.¹⁶ With the ability to enhance healthcare quality and influence quality metrics, more can be done to expand the implementation of care delivery and revise statutes accordingly.

Regarding the Commonwealth's pharmacy care laws and policies, some laws have yet to be updated to reflect current practice modifications across the United States. Some antiquated statutes also predate the vast expansion of care transformation, interprofessional care and the execution of value-based delivery models. Moreover, a few other well-intentioned laws seem to include burdensome and unwarranted restrictions, dampening the capacity of pharmacists to practice to the full extent of their education, training and abilities. And, as in most cases, these laws were enacted or revised in a piecemeal fashion to address a specific public health problem, such as vaccinations and naloxone distribution, leading to layers of incremental reform rather than a comprehensive, cohesive approach to achieve the overarching goals of the state with respect to the health of Virginians, population health, and preparedness and resiliency. Rightfully lifting the rigid and unwarranted restrictions on scope of practice for pharmacists will better position community pharmacists to have greater impact on the health of patients and improve the health of the communities they serve.¹⁷

To this end, NACDS applauds the House Joint Resolution and JCHC for taking on a comprehensive assessment and modernization initiative regarding pharmacy care laws and policies as one of the critical means to ensuring the health, safety and welfare of its citizens. We support creating a robust, efficient and effective healthcare environment that advances patient choice and competition to improve accessibility and health quality, and affordability of healthcare. State policies should be modernized to keep pace with innovations and evolving technology (e.g., home diagnostic kits, telemedicine, EKG personal devices, et al). Policies should be reformed to ensure they are broad enough to support new advances in care delivery, care coordination and pharmacy care and treatment. Thus, NACDS proposes the following recommendations for the JCHC and the Commonwealth's consideration:

Recommendation 1: Improve patient access to care in the Commonwealth by enhancing reimbursement coverage for all pharmacy services and pharmacists' authority to initiate, modify, discontinue, dispense, and administer drugs and devices to the broadest extent.

To accomplish this goal, NACDS recommends Priority Action 1.1: Develop unrestricted, autonomous, category-specific authority and coverage for pharmacist prescribing in the Commonwealth, including the ability to initiate, modify, discontinue, and administer therapy. Specific areas of interest include:

- *Test and treat patients (seasonal influenza treatment/prophylaxis and Group A streptococcal pharyngitis (strep throat);*
- *Treat uncomplicated minor ailments;*
- *Chronic care management programs;*

¹⁶ UVA Center for Interprofessional Collaborations. About. 2019. <https://ipe.virginia.edu/about/>

¹⁷ CDC. How Pharmacists Can Improve Our Nation's Health. 2014. <https://www.cdc.gov/grand-rounds/pp/2014/20141021-pharmacist-role.html>

- *Statins in patients with diabetes;*
- *Hormonal contraceptives;*
- *Tobacco cessation products;*
- *Pre-Exposure HIV Prophylaxis (PrEP)/Post-Exposure HIV Prophylaxis (PEP);*
- *Tobacco cessation products; and*
- *Medical devices.*

Recommendation 2: Drive coverage and breadth of pharmacy care to advance preventive health and population health, including improving access to immunizations and screenings within the Commonwealth, by authorizing and covering pharmacists to initiate and manage these services without requiring a diagnosis, prescription, or individualized plan of care from a prescriber.

To accomplish this goal, NACDS recommends Priority Action 2.1: Remove constraining and unnecessary requirements for protocols and prescriptions for pharmacists to immunize patients of any age in the Commonwealth.

II. Background: In The National Landscape There is Already Significant Deployment of Broad Pharmacy Care

Significant evidence indicates that the inclusion of pharmacists in patient care teams – as healthcare professionals utilizing their clinical judgment – can lead to significant improvements in patient care and reductions in total healthcare expenditures.¹⁸ Not only does care improve and avoidable total costs decrease, but patients experience greater choice in healthcare options that are accessible and more affordable for them.

Pharmacy care has been a component of the vast expansion of care transformation, and community pharmacies have acquired knowledge of value-based delivery models, including how social determinants of health play a major role in complex health and poor health outcomes. Deemed the most accessible and most frequently visited member of the healthcare team,¹⁹ community pharmacists are engaged in chronic medication management programs, specialty medication care and counseling, preventive health screenings (A1C, HIV et al) and immunizations, pharmacogenomics counseling, transitions of care services to reduce hospital readmissions and improve health outcomes, and with high risk patient programs in conjunction with Accountable Care Organizations (ACOs) to name a few. As will be explained below, several states across the country have recently accelerated the pace of change to adopt broader authority for pharmacists to advance clinical patient care.²⁰ Nearly all states now allow pharmacists to select, initiate, monitor, continue, discontinue, modify and/or administer drug therapy.²¹ The form of this authority runs from autonomous prescriptive authority where a specific diagnosis is not needed (Idaho) to autonomous prescribing authority under predetermined, medical protocols (such as Kentucky and

¹⁸ Dalton K, Byrne S. Role of the pharmacist in reducing healthcare costs: current insights. *Integr Pharm Res Pract.* 2017;6:37–46. Published 2017 Jan 25. doi:10.2147/IPRP.S108047. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5774321/>

¹⁹ Manolakis PG, Skelton JB. Pharmacists' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Provider. *Am J Pharm Educ.* Dec 2010. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/>

²⁰ Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy.* June 2016. Volume: 50 issue: 9, page(s): 778-784. <https://journals.sagepub.com/doi/abs/10.1177/1060028016653608>

²¹ CDC "State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws" updated Dec. 2012. http://www.cdc.gov/dhdp/pubs/docs/Pharmacist_State_law.PDF

New Mexico); to circumscribed, statewide protocols (e.g. Colorado and California) to more burdensome and constrained collaborative practice agreements (See Appendix 1 for the Continuum of Pharmacist Prescriptive Authority).²² For a more detailed discussion of this topic see section IV.

Reviews by the U.S. Public Health Service (PHS) and other federal organizations have highlighted the improved clinical outcomes and healthcare savings that result when pharmacists provide clinical care, services and tests. The federal infrastructure has provided pharmacy practice a progressive environment, producing some of the oldest documented examples of successful practice advancement through expanded roles in direct patient care, disease management, and public health.²³ Specifically, a Centers for Disease Control and Prevention (CDC) review found that “pharmacist engagement in interdisciplinary health management with physicians and other providers significantly improved patients’ blood pressure, hemoglobin A1c” among other things, and those pharmacists’ “care services also reduced fragmentation of care, decreased health expenditures, and optimized health outcomes.”²⁴ Leading healthcare policymakers echoed this sentiment in highlighting the critical need to integrate pharmacists into collaborative and emerging care models, noting that the inclusion of all skilled clinicians in the team improves patient care experience and outcomes.²⁵

Moreover, many federal health agencies and programs, like the Department of Veterans Affairs (VA) and PHS designate pharmacists to run patient care clinics and perform other significant clinical services, such as ordering, changing or discontinuing medications and ordering necessary lab tests. According to a study conducted by the Johns Hopkins Center for Health Security, “for more than 40 years, pharmacists in the US federal government system such as the Department of Veterans and the Indian Health Service (IHS), have collaboratively managed disease through medication and other clinical pharmacy services.”^{26,27} By 1974, more than 90 percent of IHS sites had one or more pharmacist-run disease management programs in place. In doing so, these federal programs along with the federal prison system and other military programs embraced reform efforts to eliminate unnecessary, confining, and unwarranted restrictions on scope of practice for pharmacists, and to utilize pharmacists in a manner that is consistent with the full extent of their education, training and abilities to drive better health outcomes.²⁸ These reform initiatives have fostered development and execution of innovative patient care models, reducing the costs of care services and expanding access to more affordable care in medically underserved areas to name a few. Unfortunately, these

²² Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy*. June 2016. Volume: 50 issue: 9, page(s): 778-784. <https://journals.sagepub.com/doi/abs/10.1177/1060028016653608>

²³ Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

²⁴ Centers for Disease Control and Prevention. Collaborative Practice Agreements and Pharmacists’ Patient Care Services: A Resource for Doctors, Nurses, Physician Assistants, and Other Providers. Atlanta, GA: US Dept. of Health and Human Services, Centers for Disease Control and Prevention; 2013. https://www.cdc.gov/dhds/pubs/docs/Translational_Tools_Providers.pdf

²⁵ Manolakis PG, Skelton JB. Pharmacists' contributions to primary care in the United States collaborating to address unmet patient care needs: the emerging role for pharmacists to address the shortage of primary care providers. *Am J Pharm Educ*. 2010;74(10):S7. doi:10.5688/aj7410s7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/>

²⁶ Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017.

²⁷ Morrison CM, Glover D, et al. Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. A Program Guide for Public Health. Centers for Disease Control. 2012. https://www.cdc.gov/dhds/pubs/docs/spha/docs/pharmacist_guide.pdf

²⁸ Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

practice models have yet to be broadly implemented across the U.S. due to various restrictive, unwarranted and unnecessary state legislative and regulatory barriers.²⁹

Lastly, beyond the United States, Canada offers another compelling model for pharmacy practice change and advancement, steeped in evidence-based outcomes that improve patient health. A few years back, Canada was wrestling with healthcare challenges similar to those of the U.S., including physician shortages and increased healthcare spending largely driven by an increase in prevalence of chronic disease.³⁰ The Canadian government set out to improve access to patient care while reducing use of higher cost healthcare resources. Canada determined that one promising solution involved the expansion of the community pharmacy scope of practice so Canadians can gain greater access to efficient and efficacious care in their neighborhoods.³¹

Canadian provincial governments are in the process of aggressively implementing the expanded scope of pharmacy practice to provide enhanced, coordinated, innovative patient care and collaborative medication management.³² Pharmacists in Alberta, Canada, have been prescribing a variety of medications since 2007, and administering drugs and blood products via injection since 2008.^{33,34} Further, four additional Canadian provinces (Alberta, Saskatchewan, Manitoba, and New Brunswick) also authorize autonomous pharmacist initiation of therapy for a chronic disease once diagnosed. Almost all provinces allow pharmacists to adapt, renew, and extend prescriptions, promoting continuity of care and preventing gaps in therapy, especially during transitions of care. Quebec, Prince Edward Island, Newfoundland and Labrador, Nova Scotia and New Brunswick authorize pharmacists to assess and treat certain minor ailments³⁵ -- with Ontario on the cusp of providing this authority.³⁶ Canadian research conducted to date illustrates the benefits of pharmacist-prescribing. Research in this area includes clinically important, and statistically significant reductions in blood pressure³⁷ and cholesterol.³⁸ Research further points to the impact of pharmacist de-prescribing initiatives to reduce inappropriate medication use (63% of the intervention group discontinued inappropriate therapy versus only 12% of the control group at 6

²⁹ Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017.

³⁰ Canadian Institute for Health Information "Seniors and the Health Care System: What is the Impact of Multiple Chronic Conditions?" Updated January 2011. https://secure.cihi.ca/free_products/air-chronic_disease_aib_en.pdf

³¹ Pharmacists in Canada have the exact education and training requirements as pharmacists in the U.S. Under the expanded scope of practice, pharmacists across Canada "deliver a range of innovative services, including medication reviews, chronic disease management, immunization services and wellness programs," supported by the authority to prescribe for minor ailments and conditions, order and interpret lab tests, renew and extend prescriptions, among other actions. Canadian Pharmacists Association. "Pharmacists in Canada."

<https://www.pharmacists.ca/pharmacy-in-canada/pharmacists-in-canada/>

³² Canadian Pharmacists Association. "Pharmacists in Canada." <https://www.pharmacists.ca/pharmacy-in-canada/pharmacists-in-canada/>

³³ Bhatia S, Simpson SH, Bungard T. Provincial Comparison of Pharmacist Prescribing in Canada Using Alberta's Model as the Reference Point. *Can J Hosp Pharm*. 2017;70(5):349–357. doi:10.4212/cjhp.v70i5.1696. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5659246/>

³⁴ Guirguis LM, Hughes CA, Makowsky MJ, Sadowski CA, Schindel TJ, Yuksel N. Survey of pharmacist prescribing practices in Alberta. *American Journal of Health-System Pharmacy*. 2017;74(2):62-69. doi:10.2146/ajhp150349. <https://academic.oup.com/ajhp/article-abstract/74/2/62/5102634?redirectedFrom=fulltext>

³⁵ Bhatia S, Simpson SH, Bungard T. Provincial Comparison of Pharmacist Prescribing in Canada Using Alberta's Model as the Reference Point. *Can J Hosp Pharm*. 2017;70(5):349–357. doi:10.4212/cjhp.v70i5.1696. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5659246/>

³⁶ Ferguson R. Ontario to allow pharmacists to diagnose and treat minor ailments such as skin rashes. *The Star*. April 2019. <https://www.thestar.com/news/canada/2019/04/18/ontario-may-let-pharmacists-prescribe-treatments-for-minor-issues-like-pink-eye.html>

³⁷ Tsuyuki RT, Houle SK, Charrois TL, et al. Randomized Trial of the Effect of Pharmacist Prescribing on Improving Blood Pressure in the Community. *Circulation*. 2015;132(2):93-100. doi:10.1161/circulationaha.115.015464. <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.115.015464>

³⁸ Pharmacist prescribing of cholesterol-lowering drugs leads more patients to reach cholesterol goals: study. Canadian Pharmacists Association. <https://www.pharmacists.ca/news-events/news/pharmacist-prescribing-of-cholesterol-lowering-drugs-leads-more-patients-to-reach-cholesterol-goals-study/>

months).³⁹ The success of expanded pharmacist authority in Canada exemplifies the benefit of pharmacy practice innovation and suggests the tremendous opportunity of pharmacy care to also advance healthcare in the US.

Accordingly, the modernization of pharmacy care policies will lead to more affordable, efficacious and accessible care and allow for increased competition and consumer choice. Virginia has been a national leader on interdisciplinary education, and its research universities have led several meaningful studies using team-based care to improve health outcomes. Yet, more must be done to remove impeding, unnecessary, and outdated restrictions in laws and regulations to align scope of practice with advancements in federal programs and other states. Removal of these restrictions will not only drive innovation, but also will significantly improve access to care across the state driving population and public health initiatives.

III. Modernization Discussion:

Improve Health Outcomes for Virginians. Despite increasing demand, experts estimate a shortage of providers within the United States—rising up to a shortage of 122,000 physicians by 2032.⁴⁰ According to the Health Resources and Services Administration’s (HRSA’s) Health Workforce Simulation Model, primary care physician shortages are projected throughout the United States by 2025, including Virginia.⁴¹ Specifically, the Commonwealth’s Department of Health conducted a primary care needs assessment that found that approximately 1.4 million Virginians (about 17% of the population) live in designated primary care physician shortage areas.⁴² Moreover, 15.4% of the state’s population is over the age of 65,⁴³ and many of the general populace have one or more chronic diseases. According to the aforementioned Hopkins study, approximately 50% of patients with chronic illness do not take their medications as prescribed leading to morbidity, mortality, and costs of approximately \$100 billion per year.⁴⁴ Specifically, at least 10.5% of Virginians have been diagnosed with diabetes, 32.4% suffer from hypertension, and 34.7% of them have high cholesterol. Many others could be at risk of developing these diseases as nearly a third of the population is obese, a 9% increase over the past 5 years.⁴⁵ Community pharmacists are among the healthcare professionals well-positioned to provide high quality, convenient care, which is increasingly important as chronic disease prevalence and medication use increase and the projected physician shortage continues to loom. Pharmacists can offset gaps in access to healthcare if the Commonwealth takes the opportunity to modernize its policies to provide more affordable

Commonwealth of Virginia Demographics	
Population over age 65	15.4%
Diabetes	10.5%
Hypertension	32.4%
High Cholesterol	34.7%

³⁹ Martin P, Tamblyn R, Benedetti A, Ahmed S, Tannenbaum C. Effect of a Pharmacist-Led Educational Intervention on Inappropriate Medication Prescriptions in Older Adults. *Jama*. 2018;320(18):1889-1898. doi:10.1001/jama.2018.16131.

<https://jamanetwork.com/journals/jama/fullarticle/2714531>

⁴⁰ Association of American Medical Colleges. New Findings Confirm Predictions on Physician Shortage. April 2019. <https://www.aamc.org/news-insights/press-releases/new-findings-confirm-predictions-physician-shortage>

⁴¹ Streeter RA, Zangaro GA, et al. Perspectives: Using Results from HRSA's Health Workforce Simulation Model to Examine the Geography of Primary Care. *Health Serv Res*. January 2017. doi:10.1111/1475-6773.12663. <https://www.ncbi.nlm.nih.gov/pubmed/28127767>

⁴² Primary Care Needs Assessment. Virginia Department of Health. <http://www.vdh.virginia.gov/content/uploads/sites/76/2016/05/Primary-Care-Needs-Assessment-OHE.pdf>

⁴³ US Census Bureau. QuickFacts: Virginia. 2018. <https://www.census.gov/quickfacts/VA>

⁴⁴ Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017.

⁴⁵ America’s Health Rankings. <https://www.americahealthrankings.org/learn/reports/2018-annual-report/state-summaries-virginia>

and effective care to Virginians, advance better population health within the state, and harmonize policies for the good of the U.S. healthcare system.^{46,47}

With respect to preventive care, Virginia's immunization rates are somewhat similar to national averages, with significant room for improvement to reach national goals and improve overall health. Specifically, only 58.9% of adults aged 65+ reported a flu shot in 2018; 73.9% of them reported receiving at least one pneumonia vaccine; only 30.4% of older Virginians reported receiving a tetanus shot between 2005 and 2013, and similarly only 30.4% of this targeted population report receiving the shingles vaccine.⁴⁸ As the literature demonstrates, extending full pharmacist authority to provide immunizations has improved vaccination coverage.⁴⁹ As such, NACDS encourages further innovation in Virginia to remove outdated restrictions on pharmacists' vaccination authority to advance public health by providing another convenient healthcare destination for vaccination delivery.

A 2019 poll commissioned by NACDS and conducted by Morning Consult indicated that 80% of Virginia voters say pharmacies are easy to access, the highest accessibility rating of healthcare delivery entities tested. In that same poll, 63% of voters in Virginia support allowing Medicare enrollees to receive basic healthcare services from their pharmacists, indicating an interest for greater access to pharmacist-delivered care.⁵⁰ Evidence indicates that pharmacist-provided direct patient care favorably impacts various patient outcomes, healthcare settings, and disease states.^{51,52,53}

As concluded in a 2010 systematic review, pharmacist interventions improve therapeutic and safety outcomes and the results of various meta-analyses conducted for hemoglobin A1c, cholesterol levels, and blood pressure demonstrated the significant benefits of pharmacist care—favoring pharmacists' direct patient care impact over comparative services.⁵⁴ Specifically, evidence suggests pharmacists can prescribe to the same standards as other providers of care, including the ability to better adhere to dosing guidelines when prescribing by protocol.⁵⁵ Pharmacists are uniquely qualified to provide patient care services through synergistic efforts that complement

⁴⁶ Exploring Pharmacist' Role in a Changing Healthcare Environment. NACDS/Avalere. May 2014.

<https://www.nacds.org/pdfs/comm/2014/pharmacist-role.pdf>

⁴⁷ Association of American Medical Colleges. 2019 Update: The Complexities of Physician Supply and Demand: Projections from 2017 to 2032. April 2019. https://aamc-black.global.ssl.fastly.net/production/media/filer_public/31/13/3113ee5c-a038-4c16-89af-294a69826650/2019_update_-_the_complexities_of_physician_supply_and_demand_-_projections_from_2017-2032.pdf

⁴⁸ Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health. BRFSS Prevalence & Trends Data. 2015. <https://www.cdc.gov/brfss/brfssprevalence/>

⁴⁹ Drozd EM, Miller L, et al. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States. Aug 2017. Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004. <https://www.ncbi.nlm.nih.gov/pubmed/28781217>

⁵⁰ Morning Consult 2019 Poll. NACDS. <https://nacds.morningconsultintelligence.com/virginia/>

⁵¹ Newman TV, Hernandez I, et al. Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations. J Manag Care Spec Pharm. 2019 Sep;25(9):995-1000. doi: 10.18553/jmcp.2019.25.9.995. <https://www.ncbi.nlm.nih.gov/pubmed/31456493>

⁵² Armistead LT, Ferreri SP. Improving Value Through Community Pharmacy Partnerships. Population Health Management. 2018. <https://www.liebertpub.com/doi/abs/10.1089/pop.2018.0040?journalCode=pop>

⁵³ Milosavljevic A, et al. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. June 2018. <https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462>

⁵⁴ Chisholm-Burns AM, et al. US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses. Medical Care: October 2010 - Volume 48 - Issue 10 - p 923-933

https://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists_Effect_as_Team_Members_on_Patient.10.aspx

⁵⁵ Poh EW, McArthur A, et al. Effects of pharmacist prescribing on patient outcomes in the hospital setting. JBI Database of Systematic Reviews and Implementation Reports. September 2018.

https://journals.lww.com/jbisrir/Abstract/2018/09000/Effects_of_pharmacist_prescribing_on_patient.9.aspx

other provider services in a variety of ways, for example, through medication therapy optimization and promotion of medication adherence.^{56,57} Thus, care collaboration across the healthcare team provides patients with higher quality, safer, and more comprehensive care.⁵⁸ Further, pharmacists have been shown to improve healthcare quality, including the ability to influence a variety of endorsed quality metrics as part of value-based and alternative payment models, specifically related to transitions of care, medication optimization, chronic care, preventive care, and more.⁵⁹ Specific to community pharmacy collaborations with hospitals, a multitude of examples effectively support increased pharmacist involvement in transitions of care to improve outcomes and reduce readmissions.⁶⁰ (See Appendix 2 for examples of value-based community pharmacy programs).

Commonwealth of Virginia - Ongoing Efforts. The CDC continues to encourage pharmacists to be folded into care models, pointing to the value of including pharmacists in patient care. Specifically, CDC released several guidance documents to support the integration of pharmacists into chronic care, including in the area of hypertension prevention. In fact, the Virginia Pharmacists Association has partnered with the CDC and the National Association of Chronic Disease Directors in a project that is advancing pharmacists' role in managing high blood pressure. The National Community Preventive Services Task Force,⁶¹ governed by CDC, recently recommended pharmacy-based adherence interventions for cardiovascular disease prevention based on a comprehensive literature review of 48 studies.^{62,63}

Likewise, the state Addiction and Recovery Treatment Services (ARTS) program was implemented in Virginia Medicaid in 2017, authorizing Early Intervention/ SBIRT compensated services to be provided by pharmacists in the community pharmacy setting among other places. The ARTS program includes identifying individuals who may have alcohol or other substance use problems using an evidence-based screening tool. Following administration of the evidence-based screening tool, a brief intervention by the pharmacist is provided to educate individuals about substance use, alert these individuals to possible consequences and, if needed, begin to motivate individuals to take steps to change their behaviors or provide linkage to care.⁶⁴

⁵⁶ Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. December 2011.

https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

⁵⁷ Manolakis PG, Skelton JB. Pharmacists' contributions to primary care in the United States collaborating to address unmet patient care needs: the emerging role for pharmacists to address the shortage of primary care providers. *Am J Pharm Educ.* 2010;74(10):S7.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/>

⁵⁸ Isasi F. The Expanding Role of Pharmacists in Transformed Health Care System. National Governors Association. 2015. <https://icpp.net/wp-content/uploads/2015/09/NGA-TheExpandingRoleOfPharmacists.pdf>

⁵⁹ Bonner L. A Whirlwind Tour of Value-Based Payment Models- with Pharmacists as your guide. *Pharmacy Today.* June 2018.

[https://www.pharmacytoday.org/article/S1042-0991\(18\)30783-7/fulltext](https://www.pharmacytoday.org/article/S1042-0991(18)30783-7/fulltext)

Payment Methods in Outpatient Team-based Clinical Pharmacy Practice, Part 2: MACRA for Pharmacists. American College of Clinical Pharmacy. August 2018. https://www.accp.com/docs/positions/misc/Practice_Advancement_Issue_Brief.pdf

⁶⁰ Shaver A. Impact of a community pharmacy transitions-of-care program on 30-day readmission. *Journal of the American Pharmacists Association* Volume 59, Issue 2, March–April 2019, Pages 202–209.

<https://www.sciencedirect.com/science/article/pii/S1544319118304412?via%3Dihub>

Shull MT, Braitman LE, Stites SD, DeLuca A, Hauser D. Effects of a pharmacist-driven intervention program on hospital readmissions. *Am J Health Syst Pharm.* 2018 May 1;75(9):e221-e230. doi: 10.2146/ajhp170287. <https://www.ncbi.nlm.nih.gov/pubmed/29691265>

⁶¹ The Community Guide. About The Community Preventive Services Task Force. <https://www.thecommunityguide.org/task-force/about-community-preventive-services-task-force>

⁶² CDC. Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2016.

<https://www.cdc.gov/dhds/pubs/docs/pharmacist-resource-guide.pdf><https://www.cdc.gov/dhds/pubs/docs/CPA-Team-Based-Care.pdf>

⁶³ Guide to Community Preventive Services. Cardiovascular Disease: Tailored Pharmacy-based Interventions to Improve Medication Adherence. <https://www.thecommunityguide.org/findings/cardiovascular-disease-tailored-pharmacy-based-interventions-improve-medication-adherence>

⁶⁴ Virginia Administrative Code. [12VAC30-130-5070](https://www.sos.virginia.gov/divisions/health/12VAC30-130-5070): Covered Services: Practitioner Services - Early Intervention/Screening Brief Intervention and Referral to Treatment

The Virginia Department of Health also has been actively spearheading population health initiatives including partnering with community pharmacies to provide HIV screenings and linkage to care to at-risk individuals, thereby extending the reach of public health. Through this program, more than 3,600 individuals were tested for HIV over two years. Approximately half of these patients had never been tested for HIV before, and those who tested positive were linked to appropriate care with the assistance of a pharmacist.⁶⁵ Other population health initiatives include Virginia's Congregations for Million Hearts, which raises awareness for heart disease by offering blood pressure screenings at pharmacies and other participating partners like universities,⁶⁶ as well as an educational program that distributes flyers to physicians and pharmacists regarding women's health, depression, and diabetes.⁶⁷

Moreover, the Carilion Clinic Health System received a 2012 Center for Medicare and Medicaid Innovation (CMMI) grant to test a pharmacist-physician collaborative care model where pharmacists provide comprehensive medication management (CMM) and chronic disease state management (CDSM) services after the physician makes the diagnosis. The research assessed the impact of pharmacy interventions in both hospital and clinic settings.

Preliminary results showed that pharmacists performed around 5,500 pharmacy interventions that reduced drug use and ED and hospital visits.⁶⁸ Further analysis also demonstrated improved chronic disease markers, improved patient and provider satisfaction, and cost savings.⁶⁹ Specifically, the study showed significant improvements in patients' A1c, blood pressure, LDL cholesterol, and total cholesterol. Pharmacist involvement in these services also contributed to a reduction in overall healthcare costs, with cost savings of \$2,378 per patient and net savings around \$4.7 million.⁷⁰

Carilion Clinic CMMI Project	
Total Cost Savings	\$4.7 million
Pharmacy Interventions	5,500
Improved A1c, BP, LDL, Cholesterol Reduced ED/Hospital Visits	

⁶⁵ Collin B, et al. The "No Wrong Door" Approach to HIV Testing: Results From a Statewide Retail Pharmacy-Based HIV Testing Program in Virginia, 2014-2016. 2018. Public Health Rep. 2018;133(2):34S-42S. <https://journals.sagepub.com/doi/full/10.1177/0033354918801026>

⁶⁶ Virginia Congregations Come Together to Act on Heart Disease and Stroke. WWCDPC Database. 2017. <https://chronicdisease.host/WWCDPC/display-success.php?id=649>

⁶⁷ Resources for Health Professionals on Women, Diabetes and Depression. WWCDPC Database. 2009. <https://chronicdisease.host/WWCDPC/display-success.php?id=229>

⁶⁸ Tyrrell R. How Carilion Clinic saved \$1.7M by expanding the role of pharmacists. Advisory Board. September 15, 2017. <https://www.advisory.com/research/care-transformation-center/care-transformation-center-blog/2017/09/carilion-clinic>

⁶⁹ Bringing Pharmacies to the Table: Carilion Program Engages Pharmacists in Care Transitions Initiative. Carilion Clinic Awarded CMMI Funding. http://qin.hqi.solutions/wp-content/uploads/2014/12/Carilion_Clinic_Awarded_CMMI_Funding.pdf

⁷⁰ Matzke GR et al. Impact of a pharmacist-physician collaborative care model on patient outcomes and health services utilization. Am J Health-Syst Pharm. 2018; 75:1039-47. doi: 10.2146/ajhp170789. <https://www.ncbi.nlm.nih.gov/pubmed/29789318>

Another Virginia team-based care program that reached rural, underserved patients included a collaboration between A&B Pharmacy and Emporia Medical Associates that yielded significant patient outcomes. Through this program, pharmacists provided chronic care management (CCM) services for Emporia Medical Associates' Medicare patients. Pharmacists were able to help patients by providing medication reconciliation/synchronization services, educating on how to self-monitor blood glucose and blood pressure, and answering questions about chronic disease management during monthly CCM appointments. Pharmacists also worked collaboratively with the physician to develop an appropriate care plan with the physician. The program resulted in an 8% increase in medication reconciliation, an 11% increase in use of tobacco cessation services, and a 6% increase in the number of patients receiving chronic care management through the provision of pharmacist-led services. All participating patients also reported improvements in health outcomes related to healthy eating and exercise.^{71,72} These state programs are evidence that pharmacist care services can benefit broader populations in Virginia.

A&B Pharmacy and Emporia Medical Associates Team-Based Care Program	
Medication Reconciliation	8% increase
Tobacco Cessation Services Utilization	11% increase
Patients Receiving Chronic Care Management	6% increase

Modernization of Pharmacy Care Policies Should Advance Patient Care in the Commonwealth.

Pharmacy care services, including the ones described above, are not being provided to most of the state's population due to overly restrictive laws surrounding pharmacists' authority and ability to provide comprehensive care across the healthcare continuum. To optimize pharmacy care and to align the Commonwealth with transformational, national healthcare efforts, we urge JCHC to recommend that the state pharmacy scope of practice laws and policies be modernized to build a more expansive public health-centric state framework and provide for greater care capacity to meet the needs of the Commonwealth. For the specific reasons described below, an assessment of pharmacy care policies and the development of patient-centered care delivery reforms are warranted – reforms aimed at maximizing the health and economic benefits to the state's population, yielding strong patient health outcomes, delivering more cost efficiencies, and eliminating needless administrative pharmacy and physician burdens.

First, the statutory constraints on pharmacy care limit the ability of community pharmacists to expand access to basic care services across the Commonwealth, especially to those in medically underserved need and professional shortage areas; particularly the inner cities and rural areas. In assessing care delivery, the Virginia Coordinated Care (VCC) - a 13-year research project on Medicaid workforce expansion - revealed that one size does not fit all for 30,000 previously uninsured Virginians. Instead, despite access to program-provided primary care,

more than half of the VCC individuals use only episodic care, and never visited a primary care physician.... they continued to seek care for non-urgent, episodic problems in emergency departments ... an abysmal setting for vaccinations, screenings, and health counseling. Therefore, ***policy makers may need other approaches to promote the health of the newly covered beneficiaries.*** ...whether it involves steering newly covered

⁷¹ A Team-based Care Approach to Reach Rural, Underserved Virginia Patients. WWCDPC. 2018.

<https://chronicdisease.host/WWCDPC/admin/dompdf/SuccessStories.php?id=712>

⁷² Health Quality Innovators. A Partnership in Chronic Care Management. <http://qin.hqi.solutions/wp-content/uploads/2018/05/CCM-poster-with-3-video-QR-link.pdf>

individuals to primary care for health promotion and disease prevention, or managing chronic illnesses with a multidisciplinary team, ***the workforce model needs a makeover.***⁷³

(Emphasis added). The delivery of care for certain populations clearly present challenges to all states, including Virginia as referenced above. Authorizing the full extent of pharmacy care practice is an essential strategy to drive better patient and population health. In fact, based on data from a high-risk Medicaid population, ***patients visit pharmacies ten times*** more frequently than they see other healthcare providers,⁷⁴ meaning that pharmacists can fill gaps in patient care and support the healthcare team. Full practice of pharmacy care authority includes providing certain autonomous direct care to their patients – a step that several states have executed successfully.

With respect to Virginia, VCU School of Pharmacy hosted a 2011 consensus-seeking conference as part of its Pharmacy Practice Transformation Project. During this conference, a consensus was reached on critical elements needed to transform the pharmacy profession, including basic legislative and regulatory changes to expand pharmacist scope of practice.⁷⁵ These pharmacy practice advancement and innovation consensus recommendations have yet to be implemented eight years later; and the state has not yet aligned itself with the current trajectory towards full practice of pharmacy across the nation.

Second, in recent years, there has been an increased focus on interprofessional collaboration due to its proven positive effects on patient care, including improving the quality and safety of care, providing more comprehensive care, and reducing medical errors which ultimately leads to fewer hospital readmissions and decreased healthcare costs.^{76,77} Also, some academic institutions in Virginia have already implemented interprofessional collaboration initiatives within their curriculum to create awareness for future generations of healthcare professionals. This includes programs and interventions that allow students from disciplines such as medicine, occupational therapy, social work, pharmacy and/or nursing to collaborate and provide quality patient care to their surrounding communities (see Appendix 3 for details on current interprofessional collaboration efforts in Virginia). Despite innovative groundwork in Virginia, extensive opportunities exist to modernize the Commonwealth's laws and regulations to advance and maximize pharmacy care for the ultimate benefit of patients. Such reform efforts are critically important to the future of healthcare and innovative care delivery models within the state and beyond.⁷⁸

⁷³ Retchin S, Dow A. Right-Sizing the Nation's Workforce for the Affordable Care Act. November 5, 2014. Academic Medicine. <http://academicmedicineblog.org/right-sizing-the-nations-workforce-for-the-affordable-care-act/>

⁷⁴ Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. <http://www.ncmedicaljournal.com/content/78/3/198.full>

⁷⁵ Matzke GR, Moczygemba LR, Goode JV, Silvester JA. Executive summary: The Virginia Commonwealth University pharmacy practice transformation conference. Annals of Pharmacotherapy. 2012 Apr;46(4):S1-11. doi: 10.1345/aph.1Q801. <https://journals.sagepub.com/doi/abs/10.1345/aph.1Q801>

⁷⁶ Some academic institutions within Virginia have already implemented interprofessional collaboration initiatives within their curriculum to create awareness for future generations of healthcare professionals. This includes programs and interventions that allow students from disciplines such as medicine, occupational therapy, social work, pharmacy and/or nursing to collaborate and provide quality patient care to their surrounding communities (see Appendix 3 for details on current interprofessional collaboration efforts in Virginia). Such an education prepares students with a comprehensive understanding of the strengths of building multi-disciplinary teams, and allows them to practice such teamwork, which is invaluable experience for when they enter into practice.

⁷⁷ UVA Center for Interprofessional Collaborations. <https://ipe.vcu.edu/>

⁷⁸ State practice policies on pharmacy care among the fifty states have evolved independently, leading to profound variations in access to patient care. Ordinarily different approaches are generally not a problem, but variations could prevent an efficient and effective implementation of innovative, value-based care delivery models by federal government and private insurers, which may transcend more than one state or region. Coordination of patient care also is critical but is undermined by disparate state policies.

Third, improved collaborative care opportunities and prescriptive authority for pharmacists will alleviate strain on the rest of the healthcare team so that all skills and expertise can be leveraged to their fullest. Specifically, when pharmacists provide uncomplicated, routine care for patients with improved access, this translates to physicians, NPs and PAs expanding their capacity to provide care where it's needed most - on extremely complex and challenging patients.

This care approach has been studied extensively.

Research demonstrates that primary care physicians are more efficient when they delegate preventive care and chronic care management to other care-team members, like pharmacists.⁷⁹ This is especially important when you consider workload and time constraints of primary care physicians. Notably, it has been observed that general practitioners have about 2 minutes per clinic visit to properly implement preventive care, leading to a care deficit of over 5 hours per day for preventive care.⁸⁰

To buttress this point, it's been estimated that 1,773 hours of a physician's annual time, or 7.4 hours per working day would be needed to fully satisfy the United States Preventive Services Task Force (USPSTF) recommendations for these preventive services.⁸¹ These unmet national and state preventative care needs can be lessened by expanding the scope of pharmacists to provide evidence-based, low-risk, high-value interventions, such as preventive care screenings and immunizations to name a few.

Physician Time Restraints	
Time Per Clinic Visit	2 minutes
Daily Deficit for Shared Decision Making for Preventive Care Services	5 hours
Annual Time Needed to Provide Preventive Services	1,773 hours
Daily Time Requirements for Preventive Services	7.4 hours

Fourth, removal of existing scope barriers for pharmacists also may reduce the costs of care services and foster innovation. Like NPs, pharmacists tend to provide preventive care, acute care for minor ailments, and chronic care management at lower costs than physicians. Furthermore, restrictions and rigid supervision collaborative practice requirements also needlessly dampen access to care and stifle innovation in the delivery of care throughout the Commonwealth. As mentioned previously, federal programs (the VA, PHS, DoD), certain states, and Canada leverage the full practice authority of pharmacists to successfully achieve health and budgetary goals and objectives. Likewise, collaboration between physicians and pharmacists within the Commonwealth has taken hold, fostered by local interdisciplinary and interprofessional education and care programs within the state, including allowing pharmacists to have direct supervision of chronic care management programs under CPAs. Yet, many pharmacists in federal and other state programs who practice "autonomously," typically consult primary care physicians and other healthcare professionals and refer patients appropriately and diligently. In these models, patient care and care coordination are the primary focus,⁸² not compliance with excessive statutory or regulatory collaborative practice requirements. In addition, collaborative practice requirements can impose burdensome limits and excessive administrative requirements, and these costs most likely increase costs of care for these services to patients, the Commonwealth and taxpayers.

⁷⁹ Altschuler J, Margolius D, Bodenheimer T, Grumbach K. Estimating a reasonable patient panel size for primary care physicians with team-based task delegation. *Ann Fam Med*. 2012 Sep-Oct;10(5):396-400. doi:10.1370/afm.1400. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3438206/>

⁸⁰ Caverly TJ et al. Much to do with nothing: microsimulation study on time management in primary care. 2018. *BMJ*. 2018;363 <https://www.bmj.com/content/363/bmj.k4983>

⁸¹ Yarnall, Kimberly S H et al. "Primary care: is there enough time for prevention?" *American journal of public health* vol. 93,4 (2003): 635-41. doi:10.2105/ajph.93.4.635 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447803/>

⁸² Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017. ⁸³ Dow A, Bohannon A, et al., The effects of expanding primary care access for the uninsured: implications for the health care workforce under health reform. *Acad Med*. 2013;88(12):1855-61. <https://www.ncbi.nlm.nih.gov/pubmed/24128619>

Importantly, as the VCC aptly noted, innovation in workforce models and care delivery models are necessary – with one size not fitting all.⁸³ As value-based care delivery models within the shifting healthcare environment take hold, the Commonwealth should remove barriers that constrain innovation through needless and burdensome scope restrictions. This care delivery approach aligns with the compelling literature cited throughout this document, demonstrating the tremendous value of pharmacy care and noting how it is underutilized.⁸⁴ Community pharmacy has a strong presence with nearly 1,350 stores throughout the Commonwealth, including in the urban medically underserved and rural professional shortage areas. Yet, because of limiting and needless restrictions on the practice of pharmacy in Virginia, many barriers to the access of affordable and quality care, preventive care, acute care, and chronic care unfortunately exist. By permitting pharmacists to deliver additional care at the fullest practice level, these groundless barriers to inner city and rural healthcare access can be eliminated and population health can flourish.

Recommendations. NACDS strongly recommends the following practice innovations – derived from enacted law and rules successfully implemented in other states – to provide pharmacists the broadest authority to administer, initiate, modify, and discontinue drugs and devices for the benefit of improved access to care for Virginians:

Recommendation 1: Improve patient access to care in the Commonwealth by enhancing reimbursement coverage for all pharmacy services and pharmacists' authority to initiate, modify, discontinue, dispense, and administer drugs and devices to the broadest extent.

Priority Action 1.1: Develop unrestricted, autonomous, category-specific authority and coverage for pharmacist prescribing in the Commonwealth, including the ability to initiate, modify, discontinue, and administer therapy. Specific areas of interest include:

- *Test and treat patients (seasonal influenza treatment/prophylaxis and Group A streptococcal pharyngitis (strep throat);*
- *Treat uncomplicated minor ailments;*
- *Chronic care management programs;*
- *Statins in patients with diabetes;*
- *Hormonal contraceptives;*
- *Tobacco cessation products;*
- *Pre-Exposure HIV Prophylaxis (PrEP)/Post-Exposure HIV Prophylaxis (PEP);*
- *Tobacco cessation products; and*
- *Medical devices.*

Recommendation 2: Drive coverage and breadth of pharmacy care to advance preventive health and population health, including improving access to immunizations and screenings within the Commonwealth, by authorizing and covering pharmacists to initiate and manage these services without requiring a diagnosis, prescription, or individualized plan of care from a prescriber.

Priority Action 2.1: Remove constraining and unnecessary requirements for protocols and prescriptions for pharmacists to immunize patients of any age in the Commonwealth.

⁸³ Dow A, Bohannon A, et al., The effects of expanding primary care access for the uninsured: implications for the health care workforce under health reform. Acad Med. 2013;88(12):1855-61. <https://www.ncbi.nlm.nih.gov/pubmed/24128619>

⁸⁴ Armistead LT, Ferreri SP. Improving Value Through Community Pharmacy Partnerships. Population Health Management. 2018. <https://www.ncbi.nlm.nih.gov/pubmed/29757078>

IV. Explanation of Recommendations and Proposed Changes

To maximize value, drive innovation, and improve patient access to care, NACDS has responded to the five areas of inquiry designated for the JCHC's study through House Joint Resolution No. 662, as follows, beginning with section (i) focused on opportunities for innovation through review of current law:

Section (i): Review and evaluate laws and regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth, including the prescribing, dispensing, and administration of drugs and devices pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols.

Collaborative Practice Agreements. Unlike other states and federal programs (like the VA and PHS), the Commonwealth does not allow for autonomous prescribing by pharmacists in any form. Instead, the state has maintained restrictive and rigid collaborative practice requirements, which impede pharmacists' ability to efficiently and effectively provide collaborative care on a broad scale. Specifically, the Commonwealth's collaborative agreement language^{85,86} contains the following constraints:

- *Site restrictions* – Pharmacists at a “single physical location where patients receive services.” Such restrictions make it difficult to leverage the scalable and convenient benefit of pharmacy services across multiple pharmacies to reach broader populations and this restriction may also increase costs and reduce efficiency.
- *Prescriber restrictions* – Restrictive requirements about what type of prescribers may participate and in certain instances, what constitutes a physicians' office, undermines the ability of collaboration to reach public health and population health goals.
- *Patient restrictions* – “A prescriber may elect to have a patient not participate...by contacting the pharmacist...or by documenting the same on the patient's prescription.” Allowing the prescriber to have the authority to circumvent the choice of patients and/or dampen the willingness of patients to participate in collaborative practice models can severely impede accessibility to affordable and quality care.
- *Clinical implementation* – The agreements “may only be used for conditions which have protocols that are clinically accepted as standard of care or are approved by the Boards of Medicine and Pharmacy.” Requiring the Board of Medicine and Board of Pharmacy to “jointly develop and promulgate regulations,” is antiquated and results in overly burdensome, lengthy, and constraining requirements.

These restrictions stifle innovation with burdensome and futile restrictions, constraining the practice of pharmacy, increasing healthcare costs and hampering the ability of pharmacy to broadly provide affordable, convenient patient care. These restrictions also impede comprehensive care for vulnerable populations in medically underserved areas with the greatest gaps in healthcare. Collaborative practice agreements in other states offer broader ability of pharmacists than what is currently permissible in Virginia allowing services to be provided to a more comprehensive patient population without restrictions on pharmacists, prescribers, patients, or sites. The benefit and

⁸⁵ Virginia Code. 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy. <https://law.lis.virginia.gov/vacode/title54.1/chapter33/section54.1-3300.1/>

⁸⁶ Virginia Board of Pharmacy and Board of Medicine. Regulations for Collaborative Practice Agreements. https://www.dhp.virginia.gov/pharmacy/leg/Collaborative_Practice_042314.doc

utility of full authority of pharmacists for Virginians is largely unrealized given the various enacted restrictions. Thus, to make even greater strides in advancing the state’s health and to foster innovation in care delivery, the Commonwealth should eliminate the current, restrictive collaborative practice agreement requirements and replace them with full, autonomous prescriptive authority for pharmacists to advance efficient and effective care to Virginians.

Naloxone Standing Order. Virginia has issued a statewide standing order for pharmacists with respect to naloxone.⁸⁸ This 2018 order provides that pharmacists with a current, active Virginia license may dispense naloxone in accordance with the current Board of Pharmacy-approved protocol. While Virginia’s naloxone standing order is somewhat in line with eleven (11) other states, sixteen (16) states went beyond a standing order, expanding access by issuing statewide protocols/pharmacist prescribing for naloxone.⁸⁹

Pharmacist Authority	States Permissible
Prescriptive Authority for Naloxone ⁸⁷ (28 states)	<p>Statewide Protocol/Pharmacist Prescribing: California, Connecticut, Idaho, Iowa, Kansas, Maine, Massachusetts, New Jersey, New Mexico, North Dakota, Oklahoma, Oregon, Tennessee, Vermont, West Virginia, Wyoming (16)</p> <p>Statewide Standing Order: Alabama, Georgia, Illinois, Indiana, Maryland, Michigan, Missouri, North Carolina, Pennsylvania, Texas, <i>Virginia</i>, Wisconsin (12)</p>

(ii) Review the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices in accordance with laws and regulations, including the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols; such review shall include evaluation of the roles and responsibilities of pharmacists authorized to practice pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols conducting patient assessments and identifying appropriate drugs or devices for dispensing or administration.

To respond to Section (ii) above, NACDS provides the following critical recommendations. As noted above, NACDS’ strong preference is for implementation of priority action 1.1.; however, we also set forth alternative paths to advance health in the Commonwealth.

Recommendation 1: Improve patient access to care in the Commonwealth by enhancing reimbursement coverage for all pharmacy services and pharmacists’ authority to initiate, modify, discontinue, dispense, and administer drugs and devices to the broadest extent.

To accomplish this goal, NACDS recommends Priority Action 1.1: Develop unrestricted, autonomous, category-specific authority and coverage for pharmacist prescribing in the Commonwealth, including the ability to initiate, modify, discontinue, and administer therapy. Specific areas of interest include:

⁸⁷ NASPA 2019. <https://naspa.us/resource/naloxone-access-community-pharmacies/>

⁸⁸ Virginia Department of Health. Virginia Statewide Standing Order for Naloxone. <http://www.vdh.virginia.gov/content/uploads/sites/4/2016/11/Standing-Order-w-o-DEA-FINAL.pdf>

⁸⁹ NASPA. Pharmacist Prescribing: Naloxone. January 2019. <https://naspa.us/resource/naloxone-access-community-pharmacies/>

- *Test and treat patients (seasonal influenza treatment/prophylaxis and Group A streptococcal pharyngitis (strep throat);*
- *Treat uncomplicated minor ailments;*
- *Chronic care management programs;*
- *Statins in patients with diabetes;*
- *Hormonal contraceptives;*
- *Tobacco cessation products;*
- *Pre-Exposure HIV Prophylaxis (PrEP)/Post-Exposure HIV Prophylaxis (PEP);*
- *Tobacco cessation products; and*
- *Medical devices.*

Priority Action 1.1: Develop unrestricted category-specific authority for pharmacists to prescribe, including ability to administer, initiate, modify, and discontinue therapy.

The above recommendation offers the greatest opportunity for innovation, cost reduction, and impact on improving patient care and choice. Unrestricted authority for pharmacists to prescribe means that a pharmacist can autonomously provide a patient with prescription medications without physician diagnosis and free from the undue burden of a collaborative practice agreement. Prescriptive authority allows for not only initiation of medication, but also modification and discontinuation of therapy for the purpose of optimizing therapy and care in accordance with national clinical guidelines. Given that care coordination is paramount to advance healthcare, even when autonomous pharmacist prescribing is permitted, pharmacists will enhance their work by collaborating with patients' primary care providers and other professionals to ensure care coordination and linkage to care.⁹⁰ Implementing such broad reform provides the headroom for future innovation and allows for system refinements based on evolving evidence-based practice guidelines.

As mentioned earlier, pharmacists are authorized to prescribe an array of medications for certain disease states and conditions within federal programs, provinces of Canada, and the state of Idaho without the administrative burden of a statewide protocol, standing order, or CPA. Another dozen states provide prescriptive authority for hormonal contraception and/or tobacco cessation products.^{91,92} And with more broad authority, a pharmacist is authorized to prescribe opioid antagonists (such as naloxone), epinephrine auto-injectors (Epi-Pens®), tobacco cessation products, tuberculosis skin tests, and drugs or devices that:

- (i) Do not require a new diagnosis;
- (ii) Are minor and generally self-limiting;
- (iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or
- (iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such

⁹⁰ Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy*. June 2016. Volume: 50 issue: 9, page(s): 778-784. <https://journals.sagepub.com/doi/abs/10.1177/1060028016653608>

⁹¹ NASPA. Pharmacist Prescribing: Hormonal Contraceptives. May 2019. <https://naspa.us/resource/contraceptives/>

⁹² NASPA. Pharmacist Prescribing: Tobacco Cessation Aids. August 2019. <https://naspa.us/resource/tobacco-cessation/>

cases, only a sufficient quantity may be provided until the patient is able to be seen by another provider.⁹³

Set forth below is evidence and information to support reform measures in Virginia.

- ***Test and Treat Patients (Seasonal influenza treatment/prophylaxis and Group A streptococcal pharyngitis (strep throat).*** Several studies reveal that when pharmacists have the authority to test and treat for conditions such as group A streptococcus and influenza, access to care increases significantly for those who do not have a primary care physician. Also, access to care within a community broadly increases due to the convenience of accessible locations and extended hours served by pharmacies.^{94,95,96,97} (See Appendix 4 for study protocols).

Test and treat by pharmacists supports community antibiotic stewardship efforts, which is especially important given estimates that over 20% of outpatient antibiotic use is inappropriate.⁹⁹ When pharmacists “test and treat” autonomously, evidence-based protocols are used to

Pharmacist Authority	States Permissible
<p>Test and Treat for Strep and Flu⁹⁸</p> <p>(15 states)</p>	<u>Prescriptive Authority:</u> Idaho (1)
	<u>Statewide Protocol:</u> Kentucky (1)
	<u>CPA:</u> Illinois, Michigan, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Tennessee, Utah, Vermont, Washington, Wisconsin (13)

ensure that only patients testing positive receive antibiotic therapy, and those who test negative receive over the counter treatment and referral for follow up care and further evaluation. In contrast, a myriad of research points to the overprescribing of antibiotics, which is rampant in settings outside of pharmacies. For example, a study conducted in 2018 determined that in a sample of over a half a million prescriptions for antibiotics, that 46% were prescribed without an infection-related diagnosis.¹⁰⁰ Pharmacists can significantly help reduce such unnecessary use as they have been shown to better adhere to evidence-based assessment and prescribing protocols and standards/guidelines of care compared to other prescribers.¹⁰¹

Virginia pharmacists currently have the ability to implement, modify, continue, or discontinue drug therapy, as well as order lab tests, but only through a collaborative practice

⁹³ Idaho State Legislature. [Section 54-1704](#): Practice of Pharmacy.

⁹⁴ Klepser ME, Adams AJ, Klepser DG. Antimicrobial Stewardship in Outpatient Settings: Leveraging Innovative Physician-Pharmacist Collaborations to Reduce Antibiotic Resistance. *Health Security*. 2015;13(3):166-173. doi:10.1089/hs.2014.0083

⁹⁵ Klepser DG, Klepser ME, Smith JK, Dering-Anderson AM, Nelson M, Pohren LE. Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting. *Research in Social and Administrative Pharmacy*. 2018;14(4):356-359. doi:10.1016/j.sapharm.2017.04.012

⁹⁶ Klepser DG, Klepser ME, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Community pharmacist-physician collaborative streptococcal pharyngitis management program. *Journal of the American Pharmacists Association*. 2016;56(3):323-329.e1. doi:10.1016/j.japh.2015.11.013

⁹⁷ Klepser ME, Klepser DG, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. *Journal of the American Pharmacists Association*. 2016;56(1):14-21. doi:10.1016/j.japh.2015.11.008

⁹⁸ [NASPA 2019](#); APhA Policy (2016), Research in Social and Administrative Pharmacy (2016), CDC (2017)

⁹⁹ Chua K, Fischer MA, Linder JA. Appropriateness of outpatient antibiotic prescribing among privately insured US patients: ICD-10-CM based cross sectional Study. January 2019. <https://www.bmj.com/content/364/bmj.k5092>

¹⁰⁰ Linder JA, Brown T, Lee Jy, et al. Non-Visit-Based and Non-Infection-Related Ambulatory Antibiotic Prescribing. Oral Abstract Session: ID Week. October 2018. <https://idsa.confex.com/idsa/2018/webprogram/Paper71530.html>

¹⁰¹ Poh EW, McArthur A, et al. Effects of pharmacist prescribing on patient outcomes in the hospital setting. JBI Database of Systematic Reviews and Implementation Reports. September 2018.

https://journals.lww.com/jbisrir/Abstract/2018/09000/Effects_of_pharmacist_prescribing_on_patient.9.aspx

agreement which includes undue administrative burden. Expanding the authority for pharmacists to be able to conduct these functions without CPAs or protocol, would significantly impact the quality of care patients receive, expand access, and drive innovation and care coordination. As referenced above in some models of care, pharmacists can appropriately use a test “to guide diagnosis or clinical decision-making and are waived under the federal Clinical Laboratory Improvements Amendments (CLIA) of 1988” as a basis to prescribe/treat patients.

Fifteen states allow pharmacists to test and treat patients as a result of a CLIA-waived test (See Appendix 5 for CLIA-waived and Test and Treat Map). However, Idaho offers the broadest authority where pharmacists can prescribe products for strep throat and influenza pursuant to the results of a CLIA-waived test, without a statewide protocol, and other states like Colorado, Florida and Texas are considering revising their “test and treat” policies.¹⁰²

- ***Treat uncomplicated minor ailments:*** When a patient is suffering from acute, minor conditions such as allergies, insect bites/stings, urinary tract infections, among others – conditions that are generally self-diagnoseable - convenient and accessible care is desired by most. However, given the constraints of most practice settings, such as traditional office hours and long waits for an appointment, along with cost barriers, patients can encounter delays when seeking care. Rather than utilizing more expensive care options like emergency departments, patients should have the option to see their local pharmacist who is qualified and well-positioned to provide such care and appropriate treatment.^{103,104} Therefore, expansion of pharmacist authority can ensure patients receive prompt, convenient and quality care. Pharmacists are not only accessible, but they are highly qualified to manage these conditions. Idaho is a prime example of such a model, as the state authorizes pharmacists to prescribe for certain minor conditions. Further, patient and physician support for pharmacists treating minor ailments has been demonstrated in the literature¹⁰⁵ and additional research on pharmacists treating minor ailments is underway with success. (See Appendix 6 for List of ID Minor Ailments).¹⁰⁵

- ***Chronic care management programs:*** Nationally, utilization of prescription medications continues to increase in parallel to the rising prevalence of chronic conditions. At the point of dispensing, pharmacists are well positioned to deliver chronic care management services. With expanded authority to initiate, discontinue, and modify therapy, pharmacists would be able to not only identify drug therapy problems that threaten medication safety and efficacy, but

Chronic Care Management (One Year Review)	
Drug Therapy Problems	3,100
Patient Encounters	3,309
Estimated Cost Savings	\$270,591

¹⁰² NASPA. Pharmacist Prescribing: “Test and Treat.” February 2019. <https://naspa.us/resource/pharmacist-prescribing-for-strep-and-flu-test-and-treat/>

¹⁰³ Mehrotra A, Liu H, Adams JL, et al. Comparing Costs and Quality of Care at Retail Clinics With That of Other Medical Settings for 3 Common Illnesses. Ann Intern Med. 2009. <https://annals.org/aim/article-abstract/744702/comparing-costs-quality-care-retail-clinics-other-medical-settings-3?doi=10.7326%2f0003-4819-151-5-200909010-00006>

¹⁰⁴ Weinick RM, Burns RM, et al. Many Emergency Department Visits Could be Managed at Urgent Care Centers and Retail Clinics. Health Affairs. September 2010. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0748>

¹⁰⁵ McKeirnan KC, Garrelts MacLean L. Pharmacist, physician, and patient opinions of pharmacist-treated minor ailments and conditions. J Am Pharm Assoc (2003). 2018 Nov - Dec;58(6):599-607. doi: 10.1016/j.japh.2018.08.008. <https://www.sciencedirect.com/science/article/pii/S1544319118303911?via%3Dihub>

also make necessary modifications to resolve such problems appropriately using their clinical judgment, without incurring delays when physician approval or uptake of the recommendation is needed. Evidence supports pharmacists' ability to identify and resolve drug therapy problems, improving patient health outcomes and reducing downstream harms and costs.^{106,107,108} Specifically, a retrospective chart review conducted in a geriatric practice evaluated the impact of pharmacist identification of drug therapy problems and the corresponding action to resolve such issues. In the one-year review, 3,100 drug therapy problems were identified during 3,309 patient encounters. The most common issue was dose too low, followed by dose too high. The most common interventions were laboratory monitoring and dose changes, with an estimated financial savings of up to \$270,591.¹⁰⁹

USC/AltaMed Project Results			
Pharmacist Interventions		Patient Impact	
Dose/Drug Interval Change	14,981	Medication-Related Problems Identified	67,169
Medications Added	5,554	Increase in Controlled LDL	14%
Tests Ordered	4,230	Increase in Controlled BP	9%
Medications Discontinued	3,847	Reduction in Uncontrolled Blood Sugar	23%
Medications Substituted	2,665	Reduction in Readmissions	33%

Other examples of pharmacy-led chronic care management programs include a \$12 million CMMI grant to the University of Southern California and AltaMed, aimed to optimize patient health, reduce avoidable hospitalizations and emergency visits by integrating pharmacists into safety-net clinics in Southern California. This collaborative program resulted in reduced

rates of uncontrolled blood sugar by nearly a quarter (23%), improvements in elevated LDL with 14% more patients controlled, and improvements in blood pressure with 9% more patients controlled at 6 months in the intervention group (collaborative care model with pharmacists as leads) versus the control group (primary care physicians only). The program resulted in a 33% reduction in readmissions per patient per year primarily attributed to medications estimated at 6 months. Through this project, pharmacists identified 67,169 medication-related problem in 5,775 patients. The top actions made by pharmacists to resolve these problems included: 14,981 dose change/drug interval, 5,554 medications added, 4,230 tests ordered, 3,847 medications discontinued, and 2,665 medication substituted.

Further, 100% of program physicians either “strongly agreed” or “agreed” that having pharmacists in their clinics improves their patients’ care, and that pharmacists are knowledgeable. And, 92% of patients rated the program very highly, rating scores of 9 or 10

¹⁰⁶ MacDonald D, Chang H, et al. Drug Therapy Problem Identification and Resolution by Clinical Pharmacists in a Family Medicine Residency Clinic. 2018. <https://pubs.lib.umn.edu/index.php/innovations/article/view/971>

¹⁰⁷ Westberg SM, Derr SK, et al. Drug Therapy Problems Identified by Pharmacists Through Comprehensive Medication Management Following Hospital Discharge. Journal of Pharmacy Technology. June 2017. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5998417/>

¹⁰⁸ Newman TV, Hernandez I, et al. Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations. J Manag Care Spec Pharm. 2019 Sep;25(9):995-1000. doi: 10.18553/jmcp.2019.25.9.995. <https://www.ncbi.nlm.nih.gov/pubmed/31456493>

¹⁰⁹ Campbell AM, Corbo JM, et al. Pharmacist-Led Drug Therapy Problem Management in an Interprofessional Geriatric Care Continuum: A subset of the PIVOTS Group. American Health and Drug Benefits. December 2018. <http://www.ahdonline.com/issues/2018/december-2018-vol-11-no-9/2678-pharmacist-led-drug-therapy-problem-management-in-an-interprofessional-geriatric-care-continuum-a-subset-of-the-pivots-group>

out of 10 (See Appendix 7 for Additional Collaborative Chronic Care Management Examples). Providing pharmacists in Virginia the opportunity to resolve drug therapy problems through greater authority to initiate, modify, and discontinue therapy creates the opportunity for similar interventions to be offered broadly at the population level to improve patient care across Virginia.

- ***Statins in patients with diabetes:*** CMS recently adopted the Statin Use in Persons with Diabetes (SUPD) quality measure for inclusion in the Part D star ratings in 2019.¹¹⁰ This national quality measure is also recognized as an NQF measure, MIPS Quality measure, ACO measure, HEDIS measure and a CPC+ measure.^{111,112} The measure builds off of the evidence-based recommendation of the American College of Cardiology and the American Heart Association that diabetic patients receive cholesterol-lowering statins to decrease the risk of heart disease irrespective of whether cholesterol levels are elevated.¹¹³

Despite these recommendations underpinned by decades of supportive evidence, statins are often overlooked and not started in patients who need this therapy. NCQA shared that only 46% of patients with commercial health plans, and 71% of Medicare patients were dispensed any statin in an analysis of commercial and Medicare Advantage health plans' diabetes populations aged 40-75 years of age.¹¹⁵ Thus, there is significant room for quality improvement.

Pharmacist Authority	States Permissible
Authority to Furnish Statins Outside of CPA ¹¹⁴ (2 states/provinces)	Idaho Alberta, Canada

The key barrier to closing this care gap typically is not pharmacists. Rather, pharmacists strive to achieve quality metrics under federal and commercial contracts, which generally includes statin medication for diabetics. In so doing, pharmacists communicate with the patients' physician to initiate a statin via telephone or fax based on the evidence-based quality recommendation. However, in many states, the pharmacy must wait for the provider to respond to the inquiry – specifically, the physician needs to send a statin prescription, delaying the implementation of this important intervention. In fact, according to a 2017 study, for approximately every 13 prescribers contacted, only 1 statin prescription was obtained and dispensed to a patient, yielding an abysmal 7.7% success rate.¹¹⁶ As pharmacists have access to patients' diagnosis and/or medication history

¹¹⁰ Medicare 2019 Part C & D Star Ratings Technical Notes. March 2019. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2019-Technical-Notes.pdf>

¹¹¹ Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2019_Measure_438_MIPSCQM.pdf

¹¹² 2019 HEDIS Measures: Statin Therapy for Patients with Diabetes.

<https://www.aetnabetterhealth.com/pennsylvania/assets/pdf/provider/notices/quality-improvement/ABH%20-%202019%20Statin%20Therapy%20for%20Patients%20With%20Diabetes%20SPD.pdf>

¹¹³ American College of Cardiology/American Heart Association. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease. March 2019.

¹¹⁴ Idaho State Legislature. [Section 54-1704](#): Practice of Pharmacy. Idaho State Board of Pharmacy Newsletter September 2018.

Yuksel N, Eberhart G, Bungard T. Prescribing by pharmacists in Alberta. Am J Health-Sys Pharm 2008;65:2126-32.

<https://www.ncbi.nlm.nih.gov/pubmed/18997141>

¹¹⁵ NCQA. Statin Therapy for Patients With Cardiovascular Disease and Diabetes. <https://www.ncqa.org/hedis/measures/statin-therapy-for-patients-with-cardiovascular-disease-and-diabetes/>

¹¹⁶ Vanderholm T, Renner HM, Stolpe SF, Adams AJ. An Innovative Approach to Improving the Proposed CMS Star Rating "Statin Use in Persons with Diabetes". J Manag Care Spec Pharm. 2018 Nov;24(11):1126-1129. doi:10.18553/jmcp.2018.24.11.1126.

<https://www.jmcp.org/doi/pdf/10.18553/jmcp.2018.24.11.1126>

records,¹¹⁷ they have the incentive and ability to identify diabetic patients who have not filled a statin or are not continuing statin therapy appropriately. Moreover, interventions by pharmacists have been shown to improve statin uptake and adherence.¹¹⁸ Thus, engagement of pharmacists with full scope of practice, who can initiate statins when clinically indicated, could help successfully address this critical gap in care. Idaho's current practice model provides the best opportunity for high-risk patients to receive statin therapy by becoming the first state to allow pharmacists to initiate and manage this medication without a protocol or collaborative practice agreement.¹¹⁹ The Commonwealth's current standard of practice for diabetic statin therapy (supervision under a collaborative practice agreement) as well as for other medications as described below is cumbersome and unnecessarily burdensome for physicians and pharmacies, impedes timely access to needed clinical care, and drives up system expenditures.

➤ **Hormonal contraceptives:**

There are currently 10 states that allow pharmacists to initiate contraceptives without a CPA, including: California, Colorado, District of Columbia, Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, and West Virginia.¹²²

In Oregon, pharmacists can autonomously prescribe hormonal contraceptives for patients, and one study showed that 73.8% of patients who received a prescription from their pharmacist had never previously had a contraceptive prescription, thereby expanding access to care. The study also showed that the safety profile of pharmacist initiation was equal to physician prescribing.¹²³

Pharmacist Authority	States Permissible
Initiate Hormonal Contraceptives (without CPA) ¹²¹ (9 states)	California, Colorado, Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, and West Virginia

➤ **Tobacco cessation products:**

As of 2019, 12 states have statutes or regulations in place authorizing pharmacists to prescribe the tobacco cessation aids without a CPA or local standing order (See Appendix 8 for NASPA Map on Prescribing Tobacco Cessation Aids).¹²⁴ A study conducted in New Mexico

Pharmacist Authority	States Permissible
Prescriptive Authority for Tobacco Cessation Aids ¹²⁰ (12 states)	All Nicotine-Replacement Products: Arkansas (statewide protocol authorized not yet issued), Arizona, California, Iowa (statewide protocol authorized not yet issued), Missouri All FDA-Approved Tobacco Cessation (TC) Aids: Colorado, Idaho, New Mexico, Indiana (statewide standing order), West Virginia (statewide standing order authorized not yet issued) Over the Counter Nicotine Replacement Products: Maine (regulations pending) Tobacco Cessation Prescribing: Oregon (addressed in statute)

¹¹⁷ Centers for Disease Control and Prevention. Select features of state pharmacist collaborative practice laws. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2013.

¹¹⁸ Bui A, Kwon J, Kim J, Lucas, A. Overcoming Barriers to Statin Adherence. June 2019. <https://www.uspharmacist.com/article/overcoming-barriers-to-statin-adherence>

¹¹⁹ Idaho State Legislature. Section 21-2401: Pharmacist Prescribing for Clinical Gaps in Care. https://bop.idaho.gov/wp-content/uploads/sites/99/code_rules/2018-07-02_2018_IDBOP_LawBook.pdf

¹²⁰ NASPA 2018, CDC 2017, JAPhA 2017, Arkansas State Legislature – Act 651, IDAPA 27 Title 01 Chapter 04 27.01.04 – Rules Governing Pharmacist Prescriptive Authority, Idaho State Board of Pharmacy Newsletter September 2018.

¹²¹ NASPA 2019. <https://naspa.us/resource/contraceptives/>

¹²² NASPA. Pharmacist Prescribing: Hormonal Contraceptives. May 2019. <https://naspa.us/resource/contraceptives/>

¹²³ Anderson L, Hartung DM, Middleton L, Rodriguez MI. Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population: Obstetrics & Gynecology. 2019;133(6):1231-1237. doi:10.1097/AOG.0000000000003286. <https://www.ncbi.nlm.nih.gov/pubmed/31135739>

¹²⁴ NASPA. Pharmacist Prescribing: Tobacco Cessation Aids. August 2019. <https://naspa.us/resource/tobacco-cessation/>

assessed tobacco quit rates among smokers who participated in a 6-month community pharmacist-based program. Patients were scheduled for an initial visit with a pharmacist and then seen for follow-up visits at 1 month, 3 months, and 6 months from the initial visit. Average quit rates were 25% at the end of 6 months, is comparable to similar programs headed by providers. The study concluded that a community pharmacist-led smoking cessation program with prescriptive authority is an effective approach to reduce smoking.¹²⁵ Allowing pharmacists to initiate all FDA-approved tobacco cessation products without the restrictions of a CPA or standing order is an important preventive care intervention, which offers substantial potential to improve patient health outcomes and quality of life.

- ***PrEP/PEP:*** These critical medications for HIV/AIDS prevention represent low risk, high value opportunities for pharmacists to better serve at-risk populations and expand the use of this important therapy. The use of PrEP has increased dramatically since 2012. However, the CDC has estimated that while 1.2 million people in the US could benefit from HIV prevention like PrEP, there were only 77,120 PrEP users in the US in 2016.¹²⁶ Further, in 2016 in Virginia, 21,565 people were living with HIV and in 2017, 868 people in Virginia were newly diagnosed with HIV.¹²⁷ This enormous gap in care can be filled by expanding the ability of pharmacists to provide these interventions via autonomous prescribing. These medications can be difficult for patients to obtain for many reasons, as individuals who need these medications may not have access to or be able to afford a visit to a provider. To combat this shortcoming, it is imperative that community pharmacists are able to provide these medications to patients who need them in a convenient and welcoming manner, which can lead to reduced HIV/AIDS transmission. Many states, including New Mexico, Iowa, and Washington, have piloted studies that show pharmacist-run, or pharmacist-involved, PrEP clinics are an effective way to increase uptake of the medication, which can then lead to decreased HIV transmission.^{128,129,130} To improve access to emergency PEP, New York allows pharmacists, through a non-specific patient order, to provide 7 days of PEP to patients without a prescription.¹³¹ This is an important factor given that the medication is more effective if started within 72 hours; thus, access to convenient, quality care, including at community pharmacies, is imperative through either an autonomous pharmacist's prescription or subject to a statewide protocol.

Lastly, and most importantly, Virginia already has a PrEP Clinic Resource Manual that could be easily adapted for use by pharmacists so this medication can be provided at community pharmacies throughout the state; thus, increasing the number of options patients have to

¹²⁵ Khan N, Anderson JR, et al. Smoking Cessation and Its Predictors: Results from a Community-Based Pharmacy Tobacco Cessation Program in New Mexico. *The Annals of Pharmacotherapy*. September 2012. <https://naspa.us/wp-content/uploads/2018/10/Khan.-Smoking-Cessation-New-Mexico.pdf>

¹²⁶ Mapping PrEP: First Ever Data on PrEP Users Across the US. AIDSvu- Emory University Rollins School of Public Health and Gilead Sciences. <https://aidsvu.org/prep/>

¹²⁷ Local Data: Virginia. AIDSvu- Emory University Rollins School of Public Health and Gilead Sciences. <https://aidsvu.org/local-data/united-states/south/virginia/>

¹²⁸ Ryan K, Lewis J, Sanchez D, et al. The Next Step in PrEP: Evaluating Outcomes of a Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic. ID Week 2018 Poster Abstract Session. Oct 2018. <https://idsa.confex.com/idsa/2018/webprogram/Paper72194.html>

¹²⁹ Hoth A, Shafer C, et al. Iowa TelePrEP: A Public-Health-Partnered Telehealth Model for HIV Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State. *Sexually Transmitted Diseases*. May 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31157732>

¹³⁰ Tung EL, Thomas A. Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. *Sex Health*. Nov 2018. <https://www.ncbi.nlm.nih.gov/pubmed/30401342>

¹³¹ New York State Education Department, Pharmacy Unit. §6801. Definition of practice of pharmacy. <http://www.op.nysed.gov/prof/pharm/article137.htm>

receive this medication.¹³² Given the fact that a negative HIV test is required for PrEP and PEP initiation, and given the success of Commonwealth’s pharmacy-administered HIV tests,¹³³ authorizing pharmacists to offer PrEP and PEP based on appropriate patient assessment, will provide more comprehensive and convenient access to this vital preventive care intervention.

- ***Medical devices:*** In 2018, pharmacists in Idaho were given category-specific prescribing authority for certain medical devices including inhalation spacers, nebulizers, and blood glucose testing supplies including pen needles.¹³⁴ Such devices help patients better manage their chronic disease; for example, spacers improve the likelihood that inhaled medication actually reaches the lungs when patients have poor inhaler coordination and timing, which is one of the most common mistakes during inhaler use.¹³⁵ This is important considering it has been estimated that patients incorrectly use their inhalers up to 90% of the time.¹³⁶ However, patients often do not realize a prescription is needed to purchase such devices if billing through insurance. At the point of dispensing and counseling, pharmacists know when these devices are needed, but often the prescriber must be reengaged for a prescription to dispense the requisite device, resulting in unnecessary delays in patient access. Alternatively, some patients may forgo the devices when they realize a protracted or inconvenient prescription process could ensue, leading to poor medication administration. Allowing pharmacists to timely fill basic gaps in therapy may help patients better manage chronic diseases and maximize medication therapy.

In sum, implementing innovations in pharmacy practice similar to the examples highlighted above would drive value and improve healthcare for patients across Virginia. The Commonwealth should aim to replicate and scale the success of innovation in federal programs by authorizing full pharmacist prescribing and coverage of pharmacy services to the broadest extent for the ultimate benefit of all Virginians. As scope expands, coverage and payment must also be modernized to support the sustainability of pharmacy care necessary to realize meaningful impacts on patient health. NACDS has provided suggestions for statutory language refinements beginning on page 30.

Alternative Action 1.2: Develop a broad list of statewide protocols for pharmacist prescribing in the Commonwealth as a means to advance health, including ability to initiate, monitor, modify, and discontinue therapy.

Autonomous prescribing is the most progressive and forward leaning means to modernize pharmacy care in the Commonwealth. In the alternative, the Commonwealth should consider issuing statewide protocols to provide the “most cost-effective and efficacious means to delivery of healthcare services so that the greatest number of Virginians receive quality healthcare.”¹³⁷ Statewide protocols are published by a state and set out specific pharmacy care criteria. Statewide

¹³² Virginia Department of Health. Pre-Exposure Prophylaxis: Clinic Resource Manual. 2019.

<http://www.vdh.virginia.gov/content/uploads/sites/10/2019/07/VDH-PrEP-Clinic-Resource-Manual-2019.pdf>

¹³³ Collins Bryan, Bronson H. The “No Wrong Door” Approach to HIV Testing: Results From a Statewide Retail Pharmacy–Based HIV Testing Program in Virginia, 2014-2016. Sage Journals. Nov 2018. <https://journals.sagepub.com/doi/full/10.1177/0033354918801026>

¹³⁴ Idaho State Board of Pharmacy. Pharmacy Law. 54-1752: Definitions. https://bop.idaho.gov/wp-content/uploads/sites/99/code_rules/2018-07-02_2018_IDBOP_LawBook.pdf

¹³⁵ Sanchis J, Gich I, et al. Systematic Review of Errors in Inhaler Use. CHEST Journal. August 2016. [https://journal.chestnet.org/article/S0012-3692\(16\)47571-9/fulltext](https://journal.chestnet.org/article/S0012-3692(16)47571-9/fulltext)

¹³⁶ Lavorini F, Magnan A, et al. Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD. Journal of Respiratory Medicine. April 2008. [https://linkinghub.elsevier.com/retrieve/pii/S0954-6111\(07\)00447-7](https://linkinghub.elsevier.com/retrieve/pii/S0954-6111(07)00447-7)

¹³⁷ Code of Virginia §§ 30-168 through 170.

protocols are typically used by many states to address preventive or acute care, or self-limiting conditions, that require no diagnosis or are easily diagnosed. The primary difference between autonomous, category-specific prescribing (Priority Action 1.1) and prescribing via statewide protocol is that the clinical protocol is set by a Board of Pharmacy or the state's Department of Health to provide care to citizens if they meet the protocol inclusion criteria. For example, in Kentucky, the Board of Pharmacy has authorized pharmacists to execute clinical protocols and prescribe medications for several conditions, including:¹³⁸

- (1) Acute influenza infection pursuant to recommendations by the Centers for Disease Control and Prevention (CDC);
- (2) Acute streptococcal pharyngitis infection;
- (3) Acute, uncomplicated urinary tract infection;
- (4) Acute mucocutaneous fungal infection;
- (5) Allergic rhinitis;
- (6) Anaphylaxis;
- (7) HIV infection prevention through pre-exposure prophylaxis pursuant to recommendations by the CDC;
- (8) Nutritional supplementation with vitamins and minerals;
- (9) Opioid use disorder pursuant to recommendations by the American Society of Addiction Medicine;
- (10) Tobacco use disorder;
- (11) Travelers health pursuant to recommendations by the CDC;
- (12) Tuberculosis prevention and control through skin testing, and referral as necessary, pursuant to recommendations by the CDC; and
- (13) Self-care conditions appropriately treated with over-the-counter medications and products.¹³⁹

To reiterate, implementing Priority Action 1.1 for prescriptive authority is preferred; however, statewide protocol implementation is the next best option to achieve broad state health goals and objectives (See Appendix 9 for Kentucky's protocols). In addition, health and care access goals can be achieved via statewide protocols, which include:

- *Test and treat patients (seasonal influenza treatment/prophylaxis and Group A streptococcal pharyngitis (strep throat);*
- *Treat uncomplicated minor ailments;*
- *Chronic care management programs:*
- *Statins in patients with diabetes;*
- *Hormonal contraceptives;*
- *Tobacco cessation products;*
- *PrEP/PEP; and*
- *Medical devices.*

Several other states have begun to use statewide protocols as well to expand access to patient care. In New Mexico, pharmacists have authority to prescribe, pursuant to statewide protocols, for smoking cessation products, hormonal contraception, emergency contraception, immunizations

¹³⁸ Kentucky Board of Pharmacy. Board Approved Protocols. <https://pharmacy.ky.gov/Pages/Board-Approved-Protocols.aspx>

¹³⁹ Kentucky Board of Pharmacy. 201 KAR 2:380. Board authorized protocols. <https://pharmacy.ky.gov/Documents/Kentucky%20Pharmacy%20Lawbook.pdf>

and tuberculosis (TB) testing.¹⁴⁰ Likewise, in Colorado, pharmacists have the authority to prescribe subject to statewide protocols for hormonal contraception and smoking cessation products (See Appendix 10 for Colorado Hormonal Contraceptives Protocol).¹⁴¹ These protocols are implemented statewide, thus bringing an additional benefit of consistency as well as convenience for patients to receive services regardless of the location within the state.¹⁴² Adopting a model for pharmacist prescribing without the burden of protocols is our priority action; however, in the event that is not adopted, the next best option to drive value and innovation in healthcare is to implement similar authority through statewide protocols.

At a Bare Minimum, Adopted Alternative Action 1.3: Revise the Commonwealth's pharmacy collaborative practice requirements to allow:

- (a) multiple prescribers (MDs, DOs, NPs, and PAs) to enter into a CPA with multiple pharmacists;***
- (b) Prescribers to authorize pharmacists to prescribe, modify, discontinue, initiate, etc. medication therapies; and***
- (c) All licensed pharmacists to enter into CPAs, without specific certification or educational training requirements.***

A collaborative practice agreement (CPA) is an arrangement that enables a prescriber to enter into a voluntary relationship with a pharmacist and delegate to him or her the ability to prescribe products as specified in the agreement.¹⁴⁴

Generally, collaborative practice agreements can be formatted in different ways with the most benefit for comprehensive population health impact resulting from an agreement that allows for collaboration between a single provider or

numerous providers and multiple pharmacists across pharmacy locations (See Appendix 11 for NASPA CPA maps). *At a bare minimum*, the Commonwealth must remove the existing, constraining

Pharmacist Authority	States Permissible
CPA Requirements ¹⁴³ (36 states)	<p>Broad CPA: Alaska, Idaho, Illinois, Michigan, Minnesota, South Carolina, Tennessee, Utah, Washington, Wisconsin</p> <p>No site restrictions (Silent): Alaska, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, Wisconsin, Wyoming (33)</p> <p>All prescribers may participate: Alaska, Idaho, Nevada, New Hampshire, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Washington, Wyoming (12)</p>

¹⁴⁰ New Mexico Administrative Code. 16.19.26: Pharmacist Prescriptive Authority.

<https://www.nmpharmacy.org/resources/Documents/TITLE%2016-19-26%20-%20pharmacist%20prescribing%20protocol%20regulations.docx>

¹⁴¹ Colorado Department of Regulatory Agencies. State Board of Pharmacy: Collaborative Pharmacy Practice and Statewide Protocols.

https://www.colorado.gov/pacific/dora/Pharmacy_Protocols

¹⁴² Weaver KK. Policy 101: Statewide protocols increase patient access to public health services. Pharmacy Today. July 2016.

[https://www.pharmacytoday.org/article/S1042-0991\(16\)30537-0/pdf](https://www.pharmacytoday.org/article/S1042-0991(16)30537-0/pdf)

¹⁴³ Centers for Disease Control and Prevention. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017. <https://www.cdc.gov/dhds/pubs/docs/CPA-Team-Based-Care.pdf>

¹⁴⁴ Virginia Code. 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy. <https://law.lis.virginia.gov/vacode/title54.1/chapter33/section54.1-3300.1/>

CPA restrictions to enable pharmacists to provide a range of clinical patient care services.¹⁴⁵ Examples of other state broad CPAs are as follows:

- *Michigan and Wisconsin* - Physicians are permitted to delegate medical services that pharmacists can perform, similar to other mid-level practitioners.^{146,147}
- *Tennessee* – Multiple prescribers [Medical Doctors (MDs), Doctor of Osteopathic Medicine (DOs), Nurse Practitioners (NPs), and Physician Assistants (PAs,)] may enter agreements with multiple pharmacists. It also allows a medical director or the chief medical officer (CMO) to enter into the agreement on behalf of an organized medical practice. Physicians are permitted to authorize pharmacist to prescribe, modify, discontinue, start, etc. medication therapies; and they also may delegate preventive health, immunizations, naloxone, contraception, etc. to be managed by a pharmacist without requiring a diagnosis and individualized care plan from a prescriber¹⁴⁸ (See Appendix 12 for Tennessee’s Policy Statement on Preventive Care).
- *Washington* –Practitioners, who are characterized as a physician, dentist, veterinarian, nurse, or other professionals duly authorized to prescribe drugs may enter into a CPA with pharmacists, authorizing pharmacists to prescribe any legend drug in addition to controlled substances. There are no limitations on practice settings in which the CPA may operate, nor statutory requirement to communicate with the practitioner within a specified time frame.¹⁴⁹
- *Minnesota*- One or more practitioners may enter into a CPA with pharmacist(s) to initiate, manage, modify, and discontinue drug therapy according to a written protocol or collaborative practice agreement. Practitioners include dentists, optometrists, physicians, podiatrists, veterinarians, physician assistants or advanced practice nurses.¹⁵⁰
- *Utah* – Pharmacists and one or more practitioners may enter into a CPA for the purpose of drug therapy management and prevention of disease.¹⁵¹

Preventive Care

Recommendation 2: Drive coverage and breadth of pharmacy care to advance preventive health and population health, including improving access to immunizations and screenings within the Commonwealth, by authorizing and covering pharmacists to initiate and manage these services without requiring a diagnosis, prescription, or individualized plan of care from a prescriber.

¹⁴⁵ Weaver, KK. Collaborative Practice Agreements: Explaining the Basics. Pharmacy Today. March 2018.

[https://www.pharmacytoday.org/article/S1042-0991\(18\)30260-3/fulltext](https://www.pharmacytoday.org/article/S1042-0991(18)30260-3/fulltext)

¹⁴⁶ Select Features of State Pharmacist Collaborative Practice Laws. CDC. December 2012.

https://www.cdc.gov/dhds/pubs/docs/pharmacist_state_law.pdf

¹⁴⁷ Michigan Legislature. Public Health Code Act 368. Section 333.16215: Delegation of acts, tasks, or functions to licensed or unlicensed individual; supervision; rules; immunity; third party reimbursement or worker's compensation benefits.

[https://www.legislature.mi.gov/\(S\(dctaeipmo3bun2p1nal0dtgd\)\)/mileg.aspx?page=getobject&objectName=mcl-333-16215](https://www.legislature.mi.gov/(S(dctaeipmo3bun2p1nal0dtgd))/mileg.aspx?page=getobject&objectName=mcl-333-16215)

¹⁴⁸ Tennessee Code. § 63-10-217. Collaborative pharmacy practice agreements. Title 63 Chapter 10 Part 2.

<https://law.justia.com/codes/tennessee/2018/title-63/chapter-10/part-2/section-63-10-217/>

¹⁴⁹ Washington State Department of Health. Interim Guidance on Collaborative Drug Therapy. December 2018.

<https://www.doh.wa.gov/Portals/1/Documents/Pubs/690327.pdf>

¹⁵⁰ Minnesota Legislature. Section 151.01. Definitions. <https://www.revisor.mn.gov/statutes/cite/151.01>

¹⁵¹ Utah State Legislature. Section 58-17b-102. Definitions. https://le.utah.gov/xcode/Title58/Chapter17B/58-17b-S102.html?v=C58-17b-S102_2019051420190514

Priority Action 2.1: Remove constraining and unnecessary requirements for protocols and prescriptions for pharmacists to immunize patients of any age in the Commonwealth.

Preventive care avoids or delays the onset or progression of certain preventable diseases, conditions, and other illnesses in patients. Through preventive care, pharmacists can identify potentially serious health conditions and provide early treatment of those conditions. Pharmacists can take such actions safely without unnecessary, burdensome restrictions such as collaborative practice agreements or statewide protocols. Based on supportive evidence, the CDC recognizes pharmacists have successfully implemented a variety of USPSTF recommendations, through screening, education, and recommendations to patients (folic acid supplementation, tobacco use cessation) and screening and referrals to primary care providers for follow up testing and care (osteoporosis screening, HIV screening).¹⁵² Further, pharmacists have had a tremendous impact on improving immunization rates over the last decade;¹⁵³ but even greater healthcare value can be realized when needless pharmacy care restrictions related to preventive care are eliminated.

In 2016, CDC shared that the United States was well below national benchmarks for adult immunization goals. Despite modest gains in uptake for some vaccines, coverage rates did not improve for others and many adults remained unvaccinated.¹⁵⁴ As mentioned, community pharmacies provide a convenient, easily accessible option for patients to receive their vaccinations.

Vaccination Destination	
Vaccines Provided (2011-2012)	6.25 million
Off-Clinic Hours	30.0%
Weekends	17.4%
Evenings	10.2%
Holidays	2.9%

One study showed that in a one-year period from 2011-2012, community pharmacies administered more than 6.25 million vaccinations, of which 30.5% were provided during off-clinic hours: 17.4% were provided on weekends, 10.2% on evenings, and 2.9% on holidays.¹⁵⁵ Most recently, in 2018, approximately one-third of adults reported receiving their influenza vaccine at a pharmacy.¹⁵⁶

Unfortunately for patients, pharmacist authority to administer vaccines within the Commonwealth is extremely rigid and outdated as compared to other states (See Appendix 13 for Map on Pharmacist Immunization Authority), creating an untapped public health opportunity. Specifically, the Virginia Board of Health and the Board of Nursing issued a restrictive standing order “for the administration of the influenza vaccine to minors by licensed pharmacists.”¹⁵⁷ However, pharmacists may only vaccinate adults and children with non-flu ACIP vaccines pursuant to a valid prescription. Removal of age restrictions and prescription requirements would prove beneficial

¹⁵² Kelling SE, Rondon-Begazo A, DiPietro Mager NA, Murphy BL, Bright DR. Provision of Clinical Preventive Services by Community Pharmacists. [Addendum appears in Prev Chronic Dis 2016;13. http://www.cdc.gov/pcd/issues/2016/16_0232e.htm.] Prev Chronic Dis 2016;13:160232. DOI: <http://dx.doi.org/10.5888/pcd13.160232>

¹⁵³ Drozd EM, Miller L, et al. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States. Aug 2017. Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004. <https://www.ncbi.nlm.nih.gov/pubmed/28781217>

¹⁵⁴ Vaccination Coverage Among Adults in the United States, National Health Interview Survey, 2016. CDC. <https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html>

¹⁵⁵ Goad JA, Taitel MS, Fensterheim LE, Cannon AE. Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience. Ann Fam Med. 2013 Sep-Oct;11(5):429-36. doi: 10.1370/afm.1542. <https://www.ncbi.nlm.nih.gov/pubmed/24019274>

¹⁵⁶ General Population Early Season Vaccination Coverage. December 2018, <https://www.cdc.gov/flu/fluview/nifs-estimates-nov2018.htm>

¹⁵⁷ Virginia Department of Health. Standing Order for Administering Influenza Vaccines to Children and Adolescents. <http://www.vdh.virginia.gov/content/uploads/sites/11/2019/09/influenzaStandingOrders.pdf>

for patients and the state. Many states have more progressive laws related to pharmacist vaccination, such as Utah and New Mexico.

In addition, expanding authority in the Commonwealth, like Utah and New Mexico have done, to include all vaccines which have been FDA-approved and recommended by the Advisory Committee on Immunization Practices (ACIP) or the CDC is essential to drive public health, population health and emergency preparedness and response. Expanding the types of vaccines pharmacists are authorized to administer and eliminating the requirements for prescription and protocols could bridge the current gap in vaccine uptake. Such authority also accommodates the administration of vaccines under public health emergencies but have yet to go through the process of ACIP-recommendation (e.g. Zika vaccine, Swine flu, et al.). In public health emergencies, it is critical that pharmacists have the opportunity to work with the Department of Health to extend access to important vaccines in communities across the state. This is also true outside of emergencies where pharmacists can be a population health agent for the state by authorizing pharmacists to administer all FDA-approved vaccines subject to ACIP-recommendations.

Increasing access to preventive health services is critically important to enhancing the value of care and reducing downstream, preventable harms and costs. Allowing pharmacists the ability to provide preventive care, without unnecessary barriers such as a prescriber diagnosis, protocol, prescription, or CPA, would drive innovation and value by maximizing the capacity of pharmacists to provide comprehensive preventive care broadly to the communities and populations they serve.

(iii) Determine the legal liability of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices in the Commonwealth in accordance with laws and regulations, including the legal liability of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices pursuant to pharmacy collaborative practice, agreements, standing orders, and statewide protocols.

As healthcare providers, pharmacists are subject to, and must comply with, numerous state and federal laws, regulations, and policies with respect to dispensing activities. Consequent to this, pharmacists are subject to the enforcement authority of numerous federal and state entities, including at the state level from state Medicaid departments, state boards of pharmacy, state drug control agencies, state departments of health; and at the federal level from CMS, DEA, DoD, FDA, HHS, EPA, HRSA, HHS/OCR, and CPSC.

When providing expanded services, such as prescribing and administering drugs and devices, whether under autonomous authority, pharmacy collaborative practice agreements, standing orders, or statewide protocols, pharmacists understand that their legal responsibilities may also expand. However, pharmacists' legal liabilities should be no greater than that of health care practitioners that already provides these services. Moreover, when pharmacists are acting in a capacity under pharmacy collaborative practice agreements, standing orders, or statewide protocols, pharmacists' legal liabilities should be secondary to that of the delegating health care practitioners.

(iv) Identify any changes to such laws or regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth, including the prescribing, dispensing, and administration of drugs and devices by pharmacists and other health care providers pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols, that would enhance patient access to health care in the Commonwealth

The following statutory language recommendations are in accordance with NACDS' comments set forth in Section IV of this document, cited as Priority Action 1.1 with respect to chronic and acute pharmacy care. For the sake of clarification, we submit that to achieve true healthcare reform, recommendations on acute and chronic care should be combined with the recommendations on preventive care, found in Section IV of this document cited as Priority Action 2.1, forthcoming.

PRIORITY ACTION 1.1: PROPOSED REVISIONS TO VA CODE TO GIVING PHARMACISTS INDEPENDENT/AUTONOMOUS AUTHORITY TO FURNISH CERTAIN CATEGORIES OF MEDICATIONS:

Statutory Changes – Prescribing Certain Categories of Medications
--

VA Code Ann. § 54.1-3300 Definitions

...

“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 the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; **and the management of patient care under the terms of a collaborative agreement as defined in this section; and the prescribing and administration as appropriate of the following categories of drugs and devices in accordance with established standards of care:**

(A) Dietary fluoride supplements when prescribed according to the American dental association’s recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services’ recommended concentration;

(B) Opioid antagonists;

(C) Epinephrine auto-injectors;

(D) Tobacco cessation products;

(E) Tuberculin purified protein derivative products; and

(F) Products supporting chronic care management where there are clinical gaps in care, including but not limited to statins for patients with diabetes and short acting beta agonists for patients with asthma;

(G) Drugs, drug categories, or devices that are prescribed in accordance with the product’s federal food and drug administration-approved labeling and that are limited to conditions that:

- (1) Do not require a new diagnosis;**
- (2) Are minor and generally self-limiting;**
- (3) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or**
- (4) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be dispensed without delay, in which case the pharmacist may dispense a quantity sufficient to ensure that the patient has access to medication until the patient is able to be treated by another provider.**

PRIORITY ACTION 2.1: PROPOSED REVISIONS TO VA CODE AND REGULATIONS TO PROVIDE PHARMACISTS WITH INDEPENDENT/AUTONOMOUS AUTHORITY TO ADMINISTER IMMUNIZATIONS:

Statutory Changes – Immunization Authority

ELIMINATE VA Code Ann. § 54.1-3408 AS FOLLOWS:

~~VA Code Ann. § 54.1-3408. Professional use by practitioners. —~~

...

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

...

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

...

REPLACE WITH THE FOLLOWING MODIFICATIONS TO THE PRACTICE OF PHARMACY (Section A) AND THE PRACTICE OF NURSING (Section B):

A. VA Code Ann. § 54.1-3300 Definitions

...

“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 the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and

medicines and their therapeutic values and uses in the treatment and prevention of disease; **administration and prescriptive authority for immunizations that are listed on the US Food and Drug Administration's Vaccines Licensed for Use in the United States, and any rescue medications, including but not limited to epinephrine and diphenhydramine;** and the management of patient care under the terms of a collaborative agreement as defined in this section.

B. VA Code Ann. § 54.1-3000. Definitions.

...

"Professional nursing, ""registered nursing" or "registered professional nursing" means the performance for compensation of any nursing acts in the observation, care and counsel of individuals or groups who are ill, injured or experiencing changes in normal health processes or the maintenance of health; in the prevention of illness or disease; in the supervision and teaching of those who are or will be involved in nursing care; in the delegation of selected nursing tasks and procedures to appropriately trained unlicensed persons as determined by the Board; **or in the administration of medications and treatments as prescribed by any person authorized by law to prescribe such medications and treatment; or in the administration of immunizations that are listed on the US Food and Drug Administration's Vaccines Licensed for Use in the United States.** Professional nursing, registered nursing and registered professional nursing require specialized education, judgment, and skill based upon knowledge and application of principles from the biological, physical, social, behavioral and nursing sciences.

VA Code Ann. § 32.1-46. Immunization of patients against certain diseases.

A. The parent, guardian or person standing in loco parentis of each child within this Commonwealth shall cause such child to be immunized in accordance with the Immunization Schedule developed and published by the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The required immunizations for attendance at a public or private elementary, middle or secondary school, childcare center, nursery school, family day care home or developmental center shall be those set forth in the State Board of Health Regulations for the Immunization of School Children. The Board's regulations shall at a minimum require:

1. A minimum of three properly spaced doses of hepatitis B vaccine (HepB).
2. A minimum of three or more properly spaced doses of diphtheria toxoid. One dose shall be administered on or after the fourth birthday.
3. A minimum of three or more properly spaced doses of tetanus toxoid. One dose shall be administered on or after the fourth birthday.
4. A minimum of three or more properly spaced doses of acellular pertussis vaccine. One dose shall be administered on or after the fourth birthday. A booster dose shall be administered prior to entry into the seventh grade.
5. Two or three primary doses of Haemophilus influenzae type b (Hib) vaccine, depending on the manufacturer, for children up to 60 months of age.
6. Two properly spaced doses of live attenuated measles (rubeola) vaccine. The first dose shall be administered at age 12 months or older.
7. One dose of live attenuated rubella vaccine shall be administered at age 12 months or older.
8. One dose of live attenuated mumps vaccine shall be administered at age 12 months or older.
9. All children born on and after January 1, 1997, shall be required to have one dose of varicella vaccine on or after 12 months.

10. Three or more properly spaced doses of oral polio vaccine (OPV) or inactivated polio vaccine (IPV). One dose shall be administered on or after the fourth birthday. A fourth dose shall be required if the three dose primary series consisted of a combination of OPV and IPV.
11. One to four doses, dependent on age at first dose, of properly spaced pneumococcal conjugate (PCV) vaccine for children up to 60 months of age.
12. Three doses of properly spaced human papillomavirus (HPV) vaccine for females. The first dose shall be administered before the child enters the sixth grade.

The parent, guardian or person standing in loco parentis may have such child immunized by a physician, physician assistant, nurse practitioner, registered nurse, or licensed practical nurse, or a pharmacist **who administers pursuant to a valid prescription**, or may present the child to the appropriate local health department, which shall administer the vaccines required by the State Board of Health Regulations for the Immunization of School Children without charge to the parent or person standing in loco parentis to the child if (i) the child is eligible for the Vaccines for Children Program or (ii) the child is eligible for coverages issued pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare), Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid), Title XXI of the Social Security Act, 42 U.S.C. § 1397aa et seq. (CHIP), or 10 U.S.C. § 1071 et seq. (CHAMPUS). In all cases in which a child is covered by a health carrier, Medicare, Medicaid, CHIP, or CHAMPUS, the Department shall seek reimbursement from the health carrier, Medicare, Medicaid, CHIP, or CHAMPUS for all allowable costs associated with the provision of the vaccine. For the purposes of this section, the Department shall be deemed a participating provider with a managed care health insurance plan as defined in § [32.1-137.1](#).

...

Regulatory Changes – Immunization Authority
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ELIMINATE 18 VAC 90-21-50. AS FOLLOWS:

18 VAC 90-21-50. Requirements for protocols for administration of adult immunizations.

Pursuant to provisions of subsection I of § 54.1-3408 of the Code of Virginia, a protocol shall be submitted to and approved by the board prior to the administration of an adult immunization program that includes the following:

...

10. Qualification of immunization providers.

- a. Virginia licensure as a registered nurse, **or** licensed practical nurse, **or** pharmacist.

See Appendix 14 for additional suggested statutory changes.

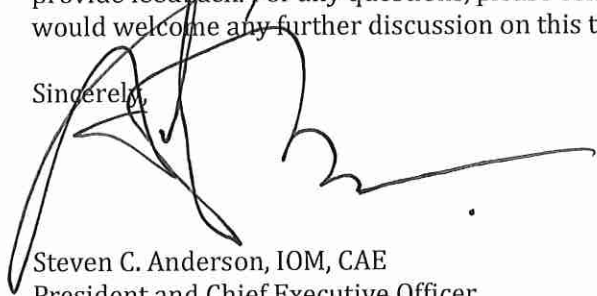
(v) develop specific proposals to implement changes identified, including proposed amendments to laws and regulations necessary to implement such changes. In conducting its study, the Joint Commission on Health Care shall provide for stakeholder input from the Department of Health, the Department of Health Professions, the Medical Society of Virginia, and the Virginia Pharmacists Association.

V. Conclusion

NACDS strongly supports and appreciates the JCHC's directive to study the roles and responsibility of pharmacies within Virginia, as well as areas of opportunity to expand pharmacist authority for the benefit of the Commonwealth's population. The Commonwealth has a strong history of

interprofessional education and coordinated, high-quality, and innovative care delivery models. Our recommendations seek to modernize statutory and regulatory language based on evidence-based models to drive value for the Commonwealth and all Virginians through a full pharmacist scope of practice. As medication experts, community pharmacists stand ready to meet the needs of patients in today's healthcare environment – in concert with other healthcare professionals – to provide high quality and continuous care to the communities they serve across the Commonwealth and beyond. We greatly appreciate the consideration of our recommendations and the opportunity to provide feedback. For any questions, please contact Kathleen Jaeger (kjaeger@nacds.org). We would welcome any further discussion on this topic.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steven C. Anderson', with a long horizontal flourish extending to the right.

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer

Table 1. Continuum of Pharmacist Prescriptive Authority.

Term Used in This Report	Definition	Level of Restriction
Collaborative prescribing		Most restrictive
<ul style="list-style-type: none"> • Collaborative practice agreement (CPA): An agreement between one or more prescribers and one or more pharmacists who work within the context of a defined protocol that is site and practice specific. • The CPA permits the pharmacist to assume responsibility for performing certain services that are otherwise outside of his or her scope of practice, including selecting, initiating, monitoring, continuing, and adjusting medication regimens 		↑
1. Patient-specific collaborative practice agreement	<ul style="list-style-type: none"> • A relationship exists between the participating patient, his or her provider(s), and the pharmacist, and services are limited to such patients • Typically used for chronic disease management for specific patients 	
2. Population-specific collaborative practice agreement	<ul style="list-style-type: none"> • A relationship exists between the participating provider(s) and the pharmacist, and services may be provided for broad patient populations regardless of if they were previously a patient of the collaborating providers • Typically used for acute care and chronic disease management for patients 	
Autonomous prescribing		
1. Statewide protocol	<ul style="list-style-type: none"> • A protocol published by an empowered state body that may be followed by any pharmacist who meets the qualifying criteria specified in the protocol. The protocol is the same for all qualified pharmacists in the state, and thus is not site or practice specific • The statewide protocol permits the pharmacist to prescribe medications that are used for preventive care or for acute or self-limiting conditions that require no diagnosis or are easily diagnosed • Services are not provided under the direct supervision of a collaborating physician 	
2. Unrestricted category-specific authority	The authority to autonomously prescribe a medication without the supervision of a collaborating physician, for legitimate medical purposes and within the pharmacist's usual course of professional practice	Least restrictive

Excerpt from NACDS Comments re: Health Care Innovation Caucus RFI August 2018

Examples of Value-based Models in Pharmacy

1. Wellmark Blue Cross Blue Shield Value Based Pharmacy Program (VBPP)

Payor: Medicare, Medicaid, and Commercial

Background: In July 2016, Wellmark identified high performing independent and chain pharmacies in Iowa and South Dakota to participate in a new value-based model, focused on better serving patients with asthma, diabetes, hyperlipidemia, and depression. Goals of this program include ensuring that the patient is on the right drug and is adherent, and in the longer-term, to reduce emergency department visits, hospital readmissions, and total cost of care.

Program Details: For inclusion in the network, participating pharmacies must offer multiple clinical services (e.g. year-round immunization program, comprehensive medication reviews, health screenings, and medication synchronization appointments). Participating pharmacies are also required to formally document services delivered and actively communicate information to patients' providers, provide adequate space for private or semi-private consultations, develop a service plan based on community-specific needs, establish formal immunization protocol and/or collaborative practice agreement(s), and ongoing pharmacist training.

Eligible members for the program include those with ≥ 1 chronic medication or diagnosed with a chronic condition. Example metrics to evaluate pharmacy performance vary by disease state and include:

- Diabetes – blood sugar control and blood pressure control
- Depression - remission
- Cardiovascular risk - cholesterol goals, is patient on correct statin intensity?
- Asthma - assess how often patient is utilizing rescue inhaler

Payment Structure: Wellmark's VBPP network is structured outside of the Pharmacy Benefit Manager (PBM) relationship. VBPP payment structure is per member per month (PMPM) with bonuses. Bonus from shared savings is received based on Wellmark's evaluation of costs.

Preliminary Results: As of July 2018, researchers are collecting and analyzing VBPP data to determine the impacts of this program. However, the **Continuous Medication Monitoring (CoMM) pharmacy pilot**, which informed the creation of the ongoing Wellmark VBPP model, had significant results. Specifically, the CoMM pilot was designed to assess the effects of continuous medication monitoring (CoMM) on total costs of care, proportion of days covered (PDC) rates and the use of high-risk medications by elderly patients. The pilot results demonstrated lower total costs of care and meaningfully better medication adherence. *Per member per month (PMPM) costs were approximately*

*\$300 lower for patients who received medications only from the pharmacy offering the CoMM program as compared to patients receiving medications from other pharmacies. This pilot validated that paying pharmacists to proactively address the safety, effectiveness, and adherence of medications at the time of dispensing can support optimization of medication therapy and decrease costs.*¹⁵

2. *Wisconsin Pharmacy Quality Collaborative (WPQC)*¹⁶

Payors: Medicaid, Medicare Part D, Medicare, Commercial, and SeniorCare

Background: Established in 2008, the WPQC is an initiative of the Pharmacy Society of Wisconsin (PSW), which connects community pharmacists with patients, physicians, and health plans to improve the quality and reduce the cost of medication use across Wisconsin. In 2012 the PSW received a \$4.1 million Health Care Innovation Award from the Centers for Medicare & Medicaid Services (CMS) to expand the WPQC statewide. Currently, over 500 pharmacists are actively certified through WPQC. Current health plan partners include the Wisconsin Medicaid and SeniorCare programs and the United Way of Dane County, representing approximately 20% of the state population, or over 1 million Wisconsin lives.

Program Details: WPQC is a network of pharmacies with pharmacists who provide medication therapy management (MTM) services, such as comprehensive medication reviews (CMRs) to complex, high-risk patients. This model leverages pharmacists to reduce medication complexity and errors, improve adherence, and empower patients to safely manage their medication regimens. WPQC and its health plan partners facilitate the provision of MTM services for patients taking multiple medications to treat chronic conditions, those at risk of falls and adverse drug events (ADEs), and those recently discharged from the hospital. The UWDC CMR program supports community and senior center case managers to identify older adults at risk of falls and ADEs, and intervene by scheduling WPQC-provided CMRs and offering home falls safety assessments. Services can also be provided at the pharmacy or the patient's residence. Similarly, a partnership in Milwaukee between WPQC pharmacies and UniteMKE trains community health workers in medication adherence screening. The community health workers then make CMR referrals to WPQC pharmacies.

Eligible patients must meet at least one of the following criteria to receive WPQC CMR services: take four or more prescription medications to treat/prevent two or more chronic conditions, diagnosis of diabetes, have multiple prescribers, or low health literacy. Patients also qualify for a CMR in the 14 days following discharge from a hospital or long-term care facility to prevent a readmission to the

¹⁵ Pilot: While some of the pharmacy services promoted and measured are different between the current Wellmark Blue Cross Blue Shield VBPP and the CoMM pilot, in the CoMM, pharmacists assessed each of the medications being dispensed, identified, and resolved any medication-related problems, and then documented their actions. Examples of drug therapy problems include doses too high or low, duplicate therapy, omissions in drug therapy, etc.

Doucette, William R, et al.; "Pharmacy performance while providing continuous medication monitoring.", *Journal of the American Pharmacists Association*; Volume 57, Issue 6, 692-697. [https://www.japha.org/article/S1544-3191\(17\)30788-4/fulltext](https://www.japha.org/article/S1544-3191(17)30788-4/fulltext)

¹⁶ <http://www.pswi.org/wpqc>

<http://www.pswi.org/WPQC/About-WPQC/About-WPQC>

<https://www.dhs.wisconsin.gov/publications/p01558.pdf>

<http://www.pswi.org/WPQC/WPQC-Payers/Benefits-to-Payers>

hospital. Additionally, a referral from a prescriber automatically qualifies any patient covered by a participating health plan for WPQC services.

Preliminary Results: In 2016, the Wisconsin Department of Health Services Division of Health Care Access and Accountability completed an evaluation of the project work. The evaluation showed that patients who received a CMR at some point prior to hospitalization exhibited a decrease of \$524 in inpatient costs per hospitalized patient in comparison with a control group that had not received a CMR. This finding suggests that CMRs provided through WPQC may have been impacting health care utilization between 2012-15. Results from the pilot phase of WPQC (2008-2010), which included Unity Health Insurance and Group Health Cooperative of South Central Wisconsin showed:

- 1) 10:1 Return on Investment (ROI) for services which directly impacted medication cost;
- 2) ROI was maintained at 2.5:1 when combining services which directly impacted medication cost and comprehensive medication reviews; and
- 3) Facilitating the use of health plan formularies to ensure the least expensive equivalent medication, pharmacists can save payers and patients 3-4 times the cost of medications.

Payment Structure: Compensation for the CMR service is provided by participating health plans on a fee-for-service basis and includes one initial visit and three follow-up visits with the pharmacist annually at no cost to the patient.

3. Community Care of North Carolina – Enhanced Pharmacy Services Network¹⁷

Payor: Medicare and Medicaid Innovation Grant

Background: In 2014, Community Care of North Carolina (CCNC) was awarded a 3-year grant from the CMS Center for Medicare & Medicaid Innovation (CMMI) to test payment reform in community pharmacies for Medicaid, Medicare, and dually eligible Medicare-Medicaid and NC Health Choice beneficiaries by using a collaborative care model where community pharmacy is part of the medical home team.

Program Details: Participating pharmacies are given access to CCNC information that allows pharmacists to review prescription claims data, adherence data, and population management tools. Pharmacies are allowed to participate in the CPESN-NC framework as long as they deliver enhanced services, document interventions, and meet minimum established criteria. CPESN-NC pharmacies must provide a proactive waste management program that prevents medication waste by verifying patient need prior to each fill, patient counseling and adherence coaching, and assistance with

¹⁷ <https://www.communitycarenc.org/>
<https://www.cpesn.com/>
https://issuu.com/iowapharmacyassociation/docs/2016q2_journal_web
<https://cpesn.com/payors>

medication reconciliation especially after hospital discharge.

Preliminary Results: Outcomes from this grant have not been published yet. Based upon preliminary results, high-risk Medicaid patients supported by CPESN pharmacies are:

- 45% less likely to have an inpatient hospitalization admission,
- 35% less likely to have a preventable hospital admission or readmission,
- 15% less likely to experience an emergency department visit,
- 25% more likely to engage their primary care provider (PCP), and
- 20% more adherent to their medications.

Primary goals of this grant were to improve quality and reduce costs while enhancing the ability of the primary care provider (PCP) to improve care outcomes for patients with chronic diseases.

Payment Structure: The payment structure is per member per month (PMPM) based on the patient risk or complexity and pharmacy performance score. Pharmacy performance score is based upon the following metrics: risk-adjusted total cost of care, risk-adjusted inpatient hospitalizations, risk-adjusted emergency department visits, adherence to antihypertensive medications, adherence to statins, adherences to DM medications, and patients' adherence to multiple chronic medications. Payment is based on current Medicare Chronic Care Management codes.

Patients must have high preventable risks. For example, a patient with high preventable risk is a 55-year-old with diabetes and high cholesterol who has a history of two previous ER visits and is nonadherent to their cholesterol medication. A pharmacist can help this patient become more adherent to the cholesterol medication and reduce the likelihood of a \$3,000 or significantly higher ER visit.

4. Community Pharmacy Enhanced Services Network of United States of America (CPESN-USA)¹⁸

Results of the CMMI grant have informed the creation of CPESN-USA, which is made up of 1,600 pharmacies and owned by a partnership of the National Community Pharmacists Association (NCPA) and Community Care of North Carolina (CCNC). Goals are to encourage state networks of pharmacies to provide enhanced services such as Medication Therapy Management, adherence packing, and more, and to offer guidance on establishing value-based payment contracts. The company contains a growing network of 35 local networks in 32 different states in varying stages of implementation or pre-implementation. One example of a functional state-based networks participating in CPESN, USA is CPESN-Iowa.

¹⁸ <https://www.cpesn.com/>

5. Community Pharmacy Enhanced Services Network of Iowa (CPESN-IA) ²⁰

Payors: Medicare, and others

Background: CPESN-IA was the second state to join CPESN-USA after CPESN-NC. As of July 2018, CPESN-IA consists of 91 pharmacies across Iowa including independently owned, small chains, and large chains, and has a core service set that every pharmacy must agree to provide as part of the network.

Program Details: The Iowa CPESN core service set includes medication reconciliation, clinical medication synchronization, adherence packaging, immunizations, and complete medication reviews with chronic care management.

Payment Structure: CPESN-IA has local contracts with Tabula Rasa and with ClaritasPSM. For the Tabula Rasa contract, pharmacists utilize their MedWise Advisor Platform to assess patients' regimens and complete Medication Safety Reviews. The ClaritasPSM contracts with preferred pharmacies to provide enhanced services to hospice patients. Core services are available to all patients who utilize CPESN-IA pharmacies. Patients enrolled in Medicare Blue Rx Part D plan are eligible for the Tabula Rasa EMTM program. Eligible patients for ClaritasPSM are hospice patients for whom ClaritasPSM is the claims processor.

CPESN-IA is a fee-for-service payment structure with bonuses. There are 2 bonus pools - if the pharmacy reaches 50% approval on doctor recommendations and/or 70% positive patient satisfaction based on brief survey. CPESN-IA mainly focuses on patient safety. Metrics include the following: patient recognizes enhanced service based on a survey, factors that require patients to spend more time with pharmacists, reduction in emergency department visits and hospital admissions, assuring the patient is taking medication at the correct time of day, reducing medication side effects, and confirm patient is on a safe therapy regimen.

Preliminary Data: Data outcomes are not yet available as of July 2018.

6. Inland Empire Health Plan (IEHP) Pharmacy P4P Program¹⁹

Payors: Medi-Cal and Medicare

Background: In 2013, IEHP, a Medi-Cal and Medicare health plan that provides managed care for more than 1.2 million California residents, developed the IEHP Pharmacy Pay-For-Performance (P4P) Program – one of the first programs of its kind – designed to improve pharmacy services through IEHP's 450 community pharmacy providers. The main focus of the program aimed to validate the roles of community pharmacies in promoting healthcare quality and define a pharmacy payment model for outcome-based services while improving members' health, reducing costs, and increasing the plan's star rating. IEHP has a Pharmacy Quality Star Ratings system created to help IEHP members

¹⁹ <https://ww3.iehph.org/en/providers/pharmaceutical-services/pharmacy-p4p-program>

locate high-quality pharmacies based on data collected. The searchable system displays the rating of each participating pharmacy. The ratings range from 1 to 5 stars, with 5 stars being the best.

Program Details: The initiative began with a focus on pharmacist review of member's Proportion of Days Covered (PDC), which is a measure of medication adherence. Pharmacists worked to achieve members' adherence goal of PDC ≥80%. In a later phase, the Pharmacy Home Program began, which provided reimbursement for pharmacies that reached PDC member adherence goals, and included medication therapy management (MTM) services to provide care for diabetes, high blood pressure, high cholesterol, and/or asthma. The most recent phase of the program, Safe Rx Network, commenced with a focus on medication safety, and requires pharmacists to review all relevant drug utilization review (DURs) alerts, and determine the most appropriate interventions. DUR alerts and appropriate intervention can mitigate the risk of adverse or medication-related events. There are four DUR alert categories in the program: drug-drug interactions, high dose exceeding maximum recommended dose, therapeutic and ingredient duplication, and high-risk medications for the elderly. To evaluate the program, IEHP measures DUR interventions, percentage (%) of total processed claims with safety DUR alerts, and percentage (%) of overall inappropriate claims avoided. IEHP is preparing to expand their quality-focused initiatives with a Point-of-Care (POC) MTM Pharmacy Program with expected launch date in 2019.

Preliminary Results: Prior to current phase of the DUR program, pharmacists were able to significantly increase medication adherence rates. Likewise, based on current DUR program data collection and calculations, overridden DUR alerts are trending down from baseline. Therefore, pharmacists are intervening on DUR alerts more often: this process helps to optimize medication therapy and ensure that only safe and effective medications reach patients.

Payment Structure: Pharmacies are paid a certain amount of dollars per prescription claim that is processed with an overridden DUR alert providing that a payable PSC code is included. The P4P payment per claim will be determined based on final paid prescription volume. Furthermore, there is a bonus payment associated with not filling a prescription after receiving a DUR notification or alert. A pharmacy will receive bonus payment if the percentage of paid prescription volume associated with overridden DUR alerts of the total paid prescription is lower than IEHP threshold. Pharmacies can also earn payment for participating in a Text Message Incentive Program. Monetary support will be allocated to encourage pharmacies to implement a text message system to provide notification to IEHP members. For pharmacies to meet the requirement for opt-in, IEHP members much opt-in >50%. Pharmacies may also earn payment based on member satisfaction survey results.

7. *Express Scripts Performance-based Retail Pharmacy Network*²⁰

The Express Scripts Performance-based Retail Pharmacy Network is a 12-month pilot that will be launched in the fall of 2018. The pilot will examine the impact of rewarding pharmacies that fill prescriptions for Express Scripts members and demonstrate a positive improvement on individual

²⁰ <https://www.prnewswire.com/news-releases/express-scripts-launches-innovative-pilot-program-for-performance-based-retail-pharmacy-network-for-commercial-plans-300628608>.

members' medication adherence for conditions such as diabetes, hypertension, and asthma. It is designed to optimize medication therapy, improve medication adherence, and promote better outcomes. Participating pharmacies will be able to track their own performance and identify gaps in care via a web portal. For this pilot, participating plan sponsors, such as employers and health plans, will have the ability to select the four therapy classes where they would like to see an improvement in medication adherence - for example, diabetes, cholesterol, hypertension or asthma - which will be used to measure each pharmacy's performance.

In addition to those already listed above, other payors who have started to engage in limited innovative value-based models include United Healthcare, SCAN, Health First, Aetna, Anthem, and BlueCross BlueShield, among others.

Moving forward, when establishing value-based agreements, both private sector and public-sector healthcare payors should recognize the cost savings and patient care benefits of pharmacist provided services and recommendations for cost-effective prescription drug treatment. Payors should also recognize that services provided by community pharmacists help to lower prescription drug costs and reduce overall healthcare costs by decreasing the use of more costly services such as avoidable emergency room visits and hospitalizations.

In sum, despite promising examples, more must be done to incorporate community pharmacist care into innovative payment and delivery models. Current barriers include the lack of recognition of pharmacists as healthcare providers, misaligned system incentives, lack of patient care coordination, lack of transparency between payors and providers and medication cost sharing, and increased DIR fines where money is unjustly retracted from pharmacies, all of which makes advancing a patient care business in pharmacy increasingly difficult.

NACDS therefore urges the Caucus to encourage the Centers for Medicare & Medicaid Innovation to advance community pharmacy participation in innovative care delivery and care coordination models, including aligning incentives to ensure patient care across the care continuum.

²¹ http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

²² <http://content.healthaffairs.org/content/32/11/1963.full>; https://www.ncqa.org/Portals/0/Homepage/The_Future_of_PCMH.pdf

VA Interprofessional Collaborative Efforts

- **Virginia Commonwealth University (VCU):** The VCU Center for Interprofessional Education and Collaborative Care is a model aiming to transform care communities and healthcare through innovations in education, scholarship and practice focused on increasing interprofessional care. Through this, VCU has created initiatives such as the Richmond Health and Wellness Program and the Center for Healthy Hearts which incorporates students from various disciplines to provide valuable care to surrounding communities.¹
 - The Richmond Health and Wellness Program is a community-based care coordination initiative that provides care to elderly, disabled, and low-income residents who have limited access to care. Through collaboration with the VCU Schools of Nursing, Pharmacy, Medicine, Social Work, Occupational Therapy, and the Department of Psychology, students provide coordinated care services to those in need.²
 - The Center for Healthy Hearts is a free clinic that provides primary care and chronic disease management for the uninsured population. Specifically, pharmacists lead chronic disease management for indigent populations, while the physicians support the pharmacists through evaluation of complex patients via a referral mechanism.³
 - The VCU School of Pharmacy's Center for Pharmacy Practice Innovation in collaboration with VCU Health also launched a project to help people across the state prevent diabetes and heart disease. The five-year, \$1.3 million, community-based project grant will utilize telemedicine, remote monitoring, and one-on-one coaching to improve participants' health. The School of Pharmacy faculty and VCU Health dieticians will lead a 16-week CDC-developed Diabetes Prevention program to educate participants. This program has shown to reduce the risk of Type 2 Diabetes by approximately 50 percent. Future phases will expand to include the monitoring and treatment of high blood pressure. Community pharmacies will give out Bluetooth-enabled blood pressure devices, provided by the VCU Office of Telemedicine, to monitor and coach high-risk participants. In addition to this program, VCU is currently exploring an opportunity to collaborate with VA Premier to develop and implement a community pharmacy-based high blood pressure monitoring program.
- **Virginia Tech⁴:** The Virginia Tech Carilion School of Medicine with Jefferson College of Health Sciences at Carilion Clinic is the first medical school in the country to integrate interprofessional efforts and initiatives within their entire curriculum. Starting from Year 1, medical, nursing, physician assistant, and allied health students work together through cases and patient simulations to gain awareness and appreciation of the various roles within the healthcare community.
- **Eastern Virginia Medical School (EVMS):** In 2015, EVMS won a \$1.75 million grant, awarded by HHS' Health Resources and Services Administration (HRSA), to fund the Transformative Education Advancing Community Health (TEACH) project. Solely one of a kind within the state, this project will bring together regional health-care providers to collaborate on improving population health and reducing healthcare disparities. Project partners include EVMS

¹ <https://ipe.vcu.edu/>

² <https://ipe.vcu.edu/clinical-programs/>

³ <http://www.centerforhealthyhearts.org/>

⁴ <https://medicine.vtc.vt.edu/academics/value-domain-interprofessionalism.html>

Departments of Pediatrics, Internal Medicine, and Family and Community Medicine; EVMS' PA program; Old Dominion University; several local hospitals; and specific free clinics. Project Director Dr. Bruce Britton describes the grant as an opportunity to, "enable us to create a clinically integrated network that will reduce disparities in health care especially for people who have chronic diseases but no health insurance."⁵ In 2017, medical students and residents will train along with EVMS' PA students and students from Old Dominion University (ODU)'s dental hygiene, counseling, and nursing programs to provide quality patient care within clinic settings.⁶

- **University of Virginia (UVA):** The UVA Center for Interprofessional Collaborations, previously known as the Center for Academic Strategic Partnerships for Interprofessional Research and Education (ASPIRE) was created by the UVA Schools of Nursing and Medicine with a strong focus on interdisciplinary care. The focus of this program is to touch upon interprofessional and education competencies with overlap on three curricular content areas: Practical Tools, Leadership, and Relational Factors. In addition, UVA is currently working on an initiative, 4VA, to develop interprofessional team-based models which utilize telehealth and additional resources from University of Virginia, James Madison University, Old Dominion University, and Virginia Tech to address key challenges related to the opioid crisis.⁷
- **SBIRT:** Effective April 2017, Virginia requires that screening, brief intervention, and referral to treatment (SBIRT) be covered for reimbursement through Medicaid across all settings. SBIRT is an evidence-based community health practice designed to identify, reduce and prevent problematic substance use disorders. Specifically, pharmacists and other healthcare providers assess a patient for risky substance use behaviors using standardized screening tools in a variety of care settings. If the patient demonstrates risky substance use behavior, pharmacists engage in a short conversation, providing feedback, advice and as appropriate, provides referral for follow up care with another partnering provider.⁸ Virginia is leading the way for innovation and sustainability of SBIRT through Medicaid's support of pharmacists and others as members of the healthcare team to drive screening and linkage to treatment during this critical public health epidemic.

⁵https://www.evms.edu/about_evms/administrative_offices/marketing_communications/publications/issue8_1/evms-wins-grant.php

⁶https://www.evms.edu/community/spencer_foreman_award_entry/supporting_documents/Spencer-Foreman-Application-Narrative.pdf

⁷<https://ipe.virginia.edu/innovations/>

⁸<https://www.integration.samhsa.gov/resource/sbirt-resource-page>

Strand MA, Eukel H, Burck S. Moving opioid misuse prevention upstream: A pilot study of community pharmacists screening for opioid misuse risk. *Research in Social and Administrative Pharmacy*. Volume 15, Issue 8, August 2019, Pages 1032-1036.

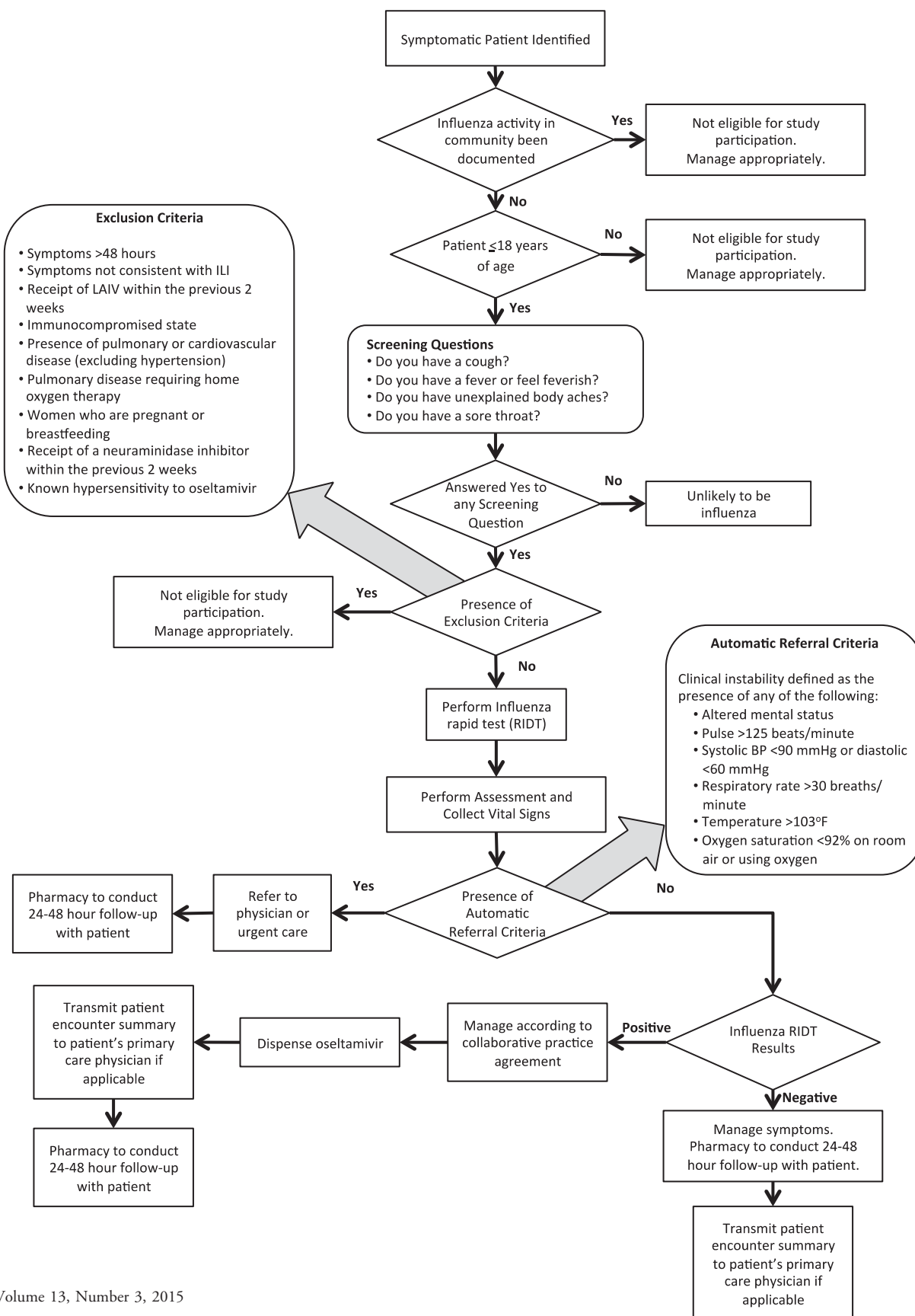
<https://www.sciencedirect.com/science/article/abs/pii/S1551741118302195?via%3Dihub>

<https://www.finance.senate.gov/download/virginia-department-of-medical-assistance-services>

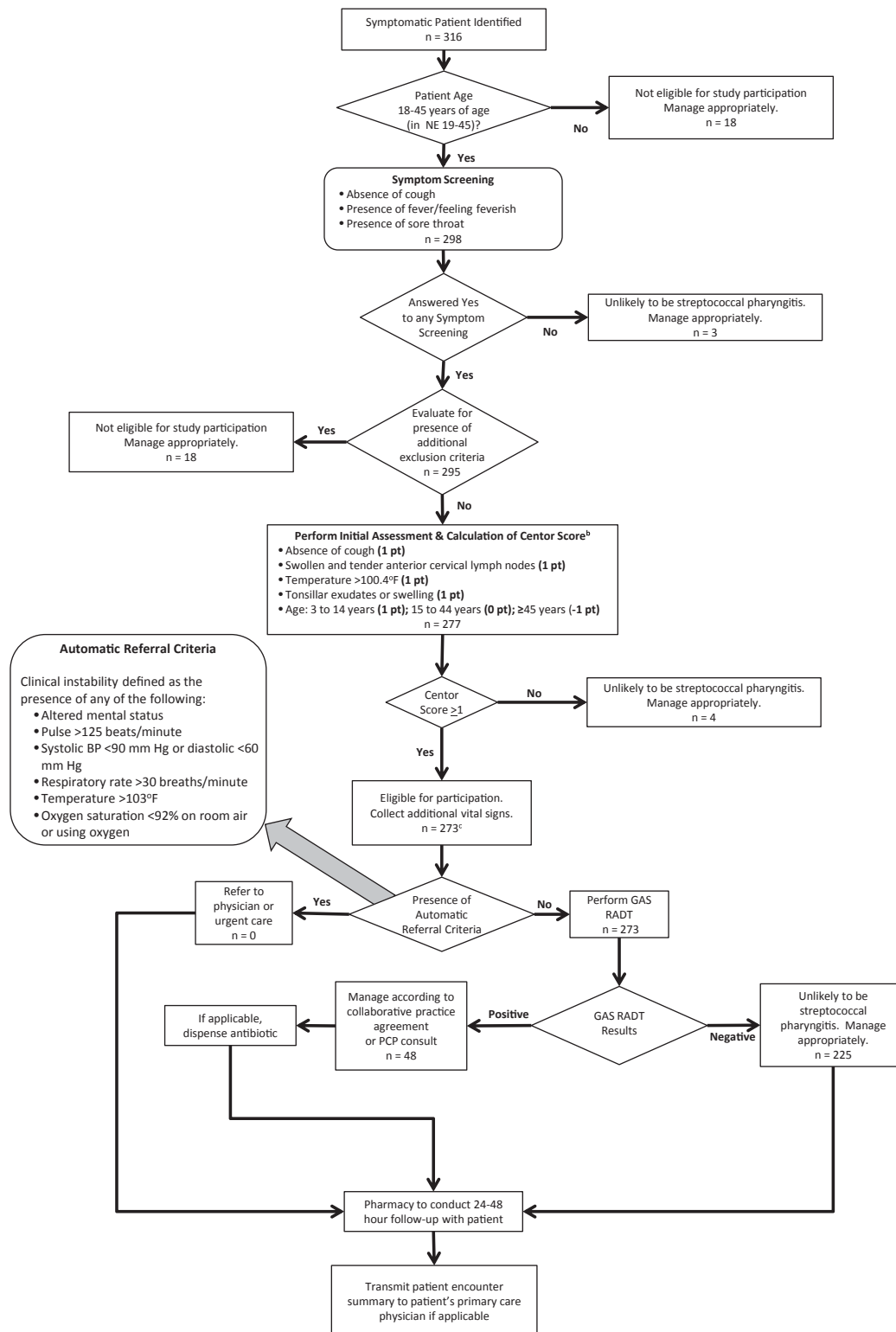
<https://www.sbirt.pitt.edu/>

Study Protocols

KLEPSER ET AL.

Figure 1. Community-Based Influenza Disease Management Program¹³

Volume 13, Number 3, 2015



(a) Adapted from reference 17

(b) References 11 and 12

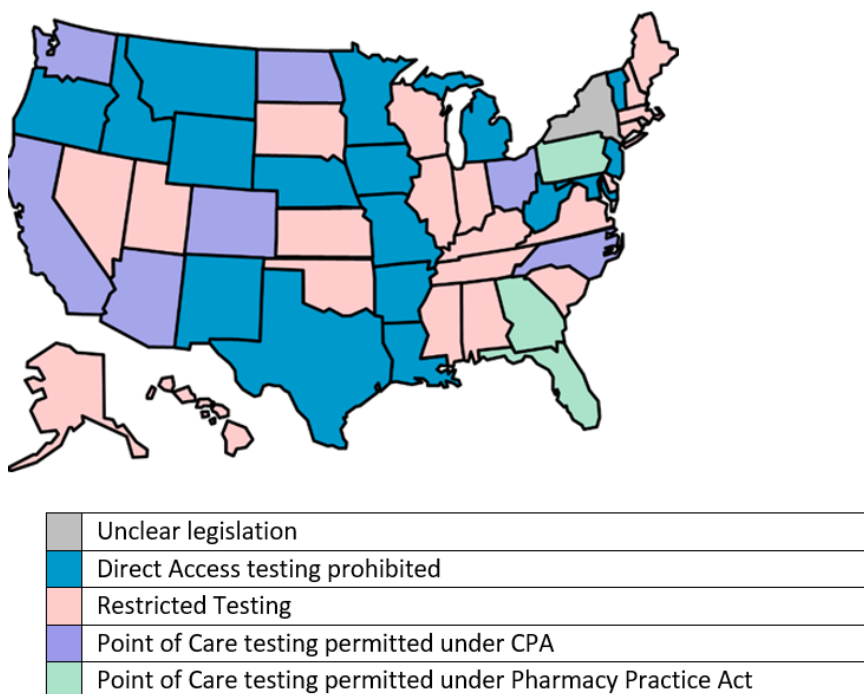
(c) Of patients eligible for participation, 118/273 (43.2%) did not have a primary care provider and 120/273 (43.9%) were seen at the pharmacy outside regular clinic office hours.

Figure 1. Workflow and patient totals for community pharmacy–physician collaborative group A streptococcal pharyngitis management program.

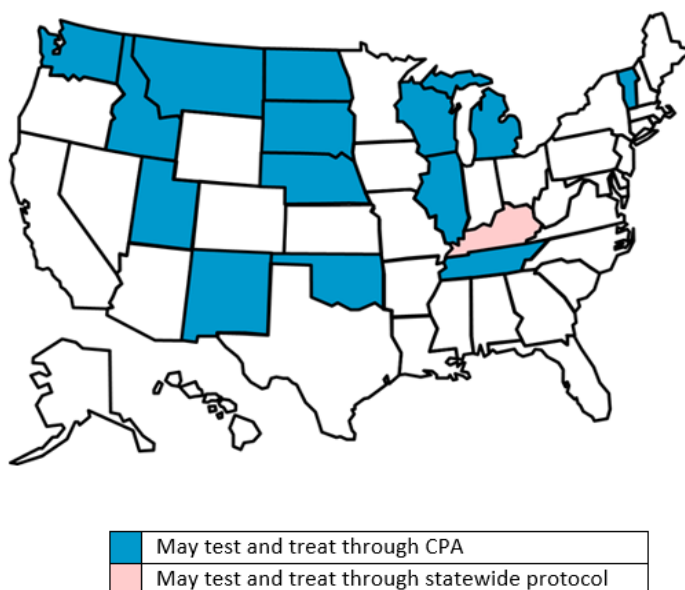
^aAdapted from Klepser et al., *Health Security*. 2015;13(3);166–173.¹⁷ ^bSee references Centor et al.¹¹ and McIsaac et al.¹² ^cOf the patients eligible for participation, 118/273 (43.2%) did not have a primary care provider and 120/273 (43.9%) were seen at the pharmacy outside regular clinic office hours.

CLIA- Waived and Test and Treat Map

Pharmacy CLIA-waived Testing Authority



Test and Treat as a Result of CLIA-waived Test¹



¹ APhA Policy (2016), Research in Social and Administrative Pharmacy (2016), CDC (2017), NASPA (2019)

TITLE 54
PROFESSIONS, VOCATIONS, AND BUSINESSES
CHAPTER 17
PHARMACISTS

- 54-1704. PRACTICE OF PHARMACY. "Practice of pharmacy" means:
- (1) The interpretation, evaluation and dispensing of prescription drug orders;
 - (2) Participation in drug and device selection, drug administration, prospective and retrospective drug reviews and drug or drug-related research;
 - (3) The provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care;
 - (4) The responsibility for:
 - (a) Compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager or distributor of nonprescription drugs and commercially packaged legend drugs and devices;
 - (b) Proper and safe storage of drugs and devices, and maintenance of proper records for them; and
 - (c) The offering or performing of those acts, services, operations or transactions necessary to the conduct, operation, management and control of pharmacy;
 - (5) The prescribing of:
 - (a) Dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
 - (b) Agents for active immunization when prescribed for susceptible persons six (6) years of age or older for the protection from communicable disease;
 - (c) Opioid antagonists pursuant to section [54-1733B](#), Idaho Code;
 - (d) Epinephrine auto-injectors pursuant to sections [54-1733C](#) and [54-1733D](#), Idaho Code;
 - (e) Tobacco cessation products pursuant to section [54-1733E](#), Idaho Code;
 - (f) Tuberculin purified protein derivative products pursuant to section [54-1733F](#), Idaho Code; and
 - (g) Drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:
 - (i) Do not require a new diagnosis;
 - (ii) Are minor and generally self-limiting;
 - (iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or
 - (iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases,

only sufficient quantity may be provided until the patient is able to be seen by another provider.

The board shall not adopt any rules authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product.

History:

[54-1704, added 1979, ch. 131, sec. 3, p. 404; am. 1992, ch. 179, sec. 1, p. 565; am. 1993, ch. 49, sec. 1, p. 126.; am. 2009, ch. 244, sec. 2, p. 748; am. 2011, ch. 264, sec. 1, p. 709; am. 2013, ch. 28, sec. 4, p. 52; am. 2015, ch. 88, sec. 1, p. 217; am. 2016, ch. 62, sec. 1, p. 198; am. 2016, ch. 264, sec. 1, p. 693; am. 2017, ch. 23, sec. 1, p. 42; am. 2017, ch. 25, sec. 1, p. 45; am. 2017, ch. 143, sec. 1, p. 339; am. 2018, ch. 169, sec. 18, p. 368; am. 2019, ch. 141, sec. 1, p. 488.]

Additional Examples of Chronic Care Management

- **University of California, San Diego Health:** This interdisciplinary health system uses a pharmacist-physician collaborative practice in three family medicine clinics to improve care for hypertension and/or diabetes. Pharmacists help to optimize patient health and medication outcomes via collaborative, team-based care. Patients with uncontrolled chronic conditions are identified in primary care visits and referred to pharmacists by physicians. Pharmacists collect information about the patient's knowledge of their conditions, control of disease, and goals, assesses their health status, lifestyle behaviors, adherence, immunization records and side effects, develops a patient-centered plan to set and meet treatment goals, implements the plan and follows-up with the patient to monitor the safety and efficacy of therapy every 1-2 weeks until at goal then every 3-6 months, making necessary modifications as necessary. So far, the program has served 375 patients across 3 clinics. Among patients served by pharmacists, 85% have blood pressure under 140/90 mm HG and 69% have blood pressure under 130/80 mm Hg. Further analyses are still underway, but unplanned clinic visits, ER visits and hospitalizations with also be assessed.¹
- **Michigan Medicine:** As one of the largest health care systems in Michigan, Michigan Medicine helps patients control their blood pressure through integration of pharmacists in 14 clinics and 2 community pharmacy sites with shared electronic medical records to improve access to care. Similar to the previously mentioned examples, pharmacists provide disease management services through collaborative practice agreements between pharmacists and physicians to initiate, modify, and discontinue therapy using protocols. In 2017, 1,332 patients were served by clinic pharmacists and 514 were served by the community sites. Expected outcomes include improve blood pressure control, improved access to pharmacists and other providers, and decreased cardiovascular disease.²
- **State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health (CDC state funding opportunity):** Three grantees examined the role of pharmacists in diabetes management. **Colorado Department of Public Health and Environment** is supporting pharmacy students to provide Medicaid patients with hypertension and/or diabetes with medication adherence support and disease testing and management services via select Medicaid Accountable Care Organizations with pharmacies in high-risk areas. As part of the pilot project, the ACOs enroll Medicaid beneficiaries into the program at preferred pharmacies, then pharmacy students provide disease-specific services, update the patient information on the electronic data tracking system, share information with the patients' primary care physicians who use the pharmacy-entered data to help inform clinical decisions.³ The **Iowa Department of Public Health** initiated a team-based care strategy to improve care for hypertension where the University of Iowa's College of Pharmacy recruits providers and pharmacists who are interested, guides/facilitates the partnership

¹ https://www.cdc.gov/dhdsp/docs/UCSD_Field_Notes-508.pdf

² https://www.cdc.gov/dhdsp/docs/Michigan_Medicine_Field-Notes-508.pdf

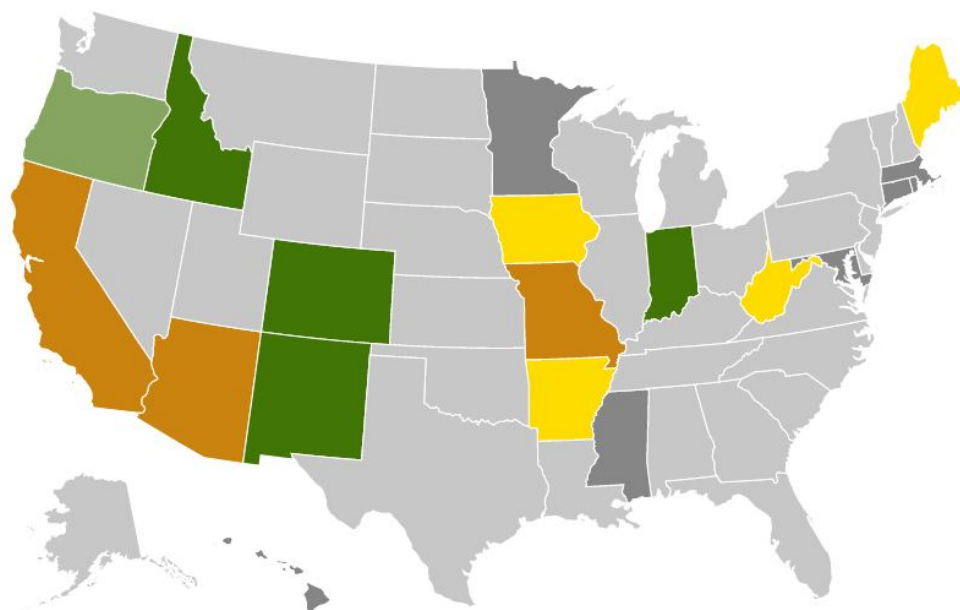
³ https://www.cdc.gov/diabetes/pdfs/programs/stateandlocal/emerging_practices-work_with_pharmacists.pdf

with resources to facilitate implementation of care coordination, then the participating providers refer patients with high blood pressure or diabetes who are newly diagnosed or uncontrolled to work with partnering pharmacists to provide education, discuss adherence and recommend the addition, discontinuation or modification of therapy.⁴ The **Ohio Department of Health** engaged three federally qualified health centers to measure the impact of pharmacist-delivered medication therapy management services on chronic disease. At 6 months into the program, over 44.8% of patients who initially had A1c >9% had a controlled A1c, and nearly 68.6% of patients with blood pressure over or equal to 140/90 had gained control.⁵

⁴ https://www.cdc.gov/diabetes/pdfs/programs/stateandlocal/emerging_practices-work_with_pharmacists.pdf

⁵ https://www.cdc.gov/diabetes/pdfs/programs/stateandlocal/emerging_practices-work_with_pharmacists.pdf

Tobacco Cessation Prescribing Map



Updated 8.5.19

	All Nicotine Replacement Products (AZ, CA, MO)
	Statute addresses tobacco cessation prescribing. Rules currently being considered (OR)
	All FDA-approved tobacco cessation products (CO, ID, NM) Statewide standing order; all FDA- approved tobacco cessation products (IN)
	Statewide protocol can be issued by the Board of Pharmacy for nicotine replacement products, but not yet issued (IA, AR) Statewide standing order is authorized to be issued by Commissioner of Bureau of Public Health for all FDA-approved tobacco cessation products, but not yet issued (WV) Regulations pending for authority for over-the-counter nicotine replacement products (ME)
	Proposed legislation (CT/MA/MD/MI/MN/RI)

**Borrowed from NASPA*

Kentucky Protocols

ACUTE INFLUENZA INFECTION: CHEMOPROPHYLAXIS PROTOCOL**Approved 9/12/18****PURPOSE**

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antiviral therapies to prevent influenza infection. The purpose of this protocol is to ensure appropriate and timely antiviral therapy for individuals at risk for influenza infection after exposure to a person with known or suspected influenza infection.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of antiviral therapy under this protocol, pharmacist(s) must have received education and training in influenza chemoprophylaxis 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 chemoprophylaxis of influenza.¹

Provider of Training: _____

Date Training Completed: _____

CRITERIA

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

Ambulatory Settings

Inclusion criteria:

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

- Family or close contact of person(s) with known or suspected influenza infection
- Exposed to person(s) with known or suspected influenza infection within the past 48 hours
- Unvaccinated against the influenza virus strains circulating at the time of exposure
- At high risk for influenza complications as evidenced by one or more of the following:
 - aged 65 or older
 - chronic pulmonary disease
 - immunosuppression
 - aged <19 years who are receiving long term aspirin therapy

¹ *Antiviral Drugs: Information for Health Care Professionals*. Available at <https://www.cdc.gov/flu/professionals/antivirals/index.htm>

- morbidly obese

Exclusion criteria:

- Age < 5 years (should be referred to pediatrician)
- Pregnant (should be referred to OBGYN or PCP)

Healthcare Institutional Settings

Inclusion criteria:

- Resident of long-term care facility where a case of acute influenza has been identified
- Unvaccinated employee of a long-term care facility where a case of acute influenza has been identified
- Employee of a long-term care facility, regardless of influenza vaccination status, if the outbreak is caused by a strain of influenza virus that is not well-matched by the vaccine

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 in ambulatory settings:

- **Adults:** 75 mg once a day for 7 days following last exposure
- **Children:** (current weight determined using pharmacy's scale) for 7 days following last exposure
 - **15 kg or less:** 30 mg once a day
 - **>15 to 23 kg:** 45 mg once a day
 - **>23 to 40 kg:** 60 mg once a day
 - **> 40 kg:** 75 mg once a day
 -

Oral oseltamivir dosing in institutional settings:

- **Adults:** 75 mg once a day for a minimum of 14 days, continuing up to 1 week after last known identified case
- **Children:** (current weight) for a minimum of 14 days, continuing up to 1 week after last known identified case
 - **15 kg or less:** 30 mg once a day
 - **>15 to 23 kg:** 45 mg once a day
 - **>23 to 40 kg:** 60 mg once a day
 - **> 40 kg:** 75 mg once a day

Inhaled zanamivir dosing in ambulatory settings:

- **Adults:** 10mg (two 5mg inhalations) once a day x 7 days following last exposure
- **Children:** 10mg (two 5mg inhalations) once a day x 7 days following last exposure

Inhaled zanamivir dosing in institutional settings:

- **Adults:** 10mg (two 5mg inhalations) once a day x 14 days for up to 1 week after last known identified case
- **Children:** 10mg (two 5mg inhalations) once a day x 14 days for up to 1 week after last known identified case

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.

Relevant Medical and Social History

- Past medical history
- Current medications
- Allergies and hypersensitivities

Contraindications and Precautions

- Known hypersensitivity to oseltamivir or zanamivir
- Underlying respiratory disease or asthma (zanamivir)
- Severe renal dysfunction (est. CrCl < 30 ml/min, oseltamivir)
- Fructose/sorbitol intolerance (oseltamivir)

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Pharmacist will follow-up within 36-72 hours for evaluation of therapy, adverse effects, and possible need of referral in case of onset of symptoms consistent with influenza or medication adverse effects severe enough to warrant discontinuation of therapy.

EDUCATION REQUIREMENTS

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

- Medication counseling consistent with state and federal requirements for prescription drug products
- That prophylaxis lowers but does not eliminate the risk for influenza
- That susceptibility to influenza returns once the antiviral medication is stopped
- That the influenza vaccine is recommended if eligible
- Instructions to seek medical care as soon as they develop signs and symptoms of the flu
- Instructions on signs or symptoms that warrant emergent medical care

DOCUMENTATION

Pharmacist(s) will document via prescription record each individual eligible for influenza chemoprophylaxis under this protocol, including:

- Documentation of parental consent for individuals under age 18
- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual received the education required by this

protocol

NOTIFICATION

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

[If directed by the authorizing physician, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing physician 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

ACUTE INFLUENZA INFECTION: ANTIVIRAL THERAPY PROTOCOL v2

Approved 12-12-18

PURPOSE

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

PHARMACIST EDUCATION AND TRAINING

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

Provider of Training: _____

Date Training Completed: _____

CRITERIA

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

Inclusion criteria:

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

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

Exclusion criteria:

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

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

¹ <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>

- Long-term aspirin therapy in individuals younger than 19 years of age
- Antiviral agent prescribed currently or within the previous 2 weeks
- Any condition requiring home oxygen therapy
- Known hypersensitivity to oseltamivir or other antiviral therapy or any 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 physician or urgent/emergent treatment facility if clinically appropriate.

MEDICATIONS

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

Oral Oseltamivir dosing:

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

Oral baloxavir dosing:

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

Inhaled Zanamivir dosing:

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

PROCEDURES FOR INITIATION OF THERAPY

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

Relevant Medical and Social History

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

Contraindications and Precautions

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

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

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

EDUCATION REQUIREMENTS

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

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

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Telephone follow-up by a pharmacist within 36 to 72 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, onset of new symptoms, and medication adverse effects. Referral to a primary care physician 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 physician or urgent/emergent treatment facility as clinically appropriate. Referral will be made when the pharmacist has high suspicion of a false-negative result (i.e. when influenza activity in the community is high and person has clear signs and symptoms of influenza infection), determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

DOCUMENTATION

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

- Documentation of the presenting signs and symptoms that warranted influenza testing
- Documentation of parental consent for individuals under age 18
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care RIDT 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 physician, the pharmacist will provide that physician 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 physician, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing physician 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

ACUTE GROUP A STREPTOCOCCAL PHARYNGITIS INFECTION PROTOCOL

Approved 5-16-18

PURPOSE

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

PHARMACIST EDUCATION AND TRAINING

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

Provider of Training: _____

Date Training Completed: _____

CRITERIA

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

Inclusion criteria:

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

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

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)

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

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

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

MEDICATIONS

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

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

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

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

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

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

- 3a. Azithromycin PO 12 mg/kg (max 500 mg) once daily for 5 days**
- 3b. Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days**
- 3c. Clarithromycin PO 7.5 mg/kg/dose (max 250 mg/dose) twice daily for 10 days**

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

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

PROCEDURES FOR INITIATION OF THERAPY

Perform RADT to determine between acute GAS and viral pharyngitis

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

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 physician or urgent/emergent treatment facility will occur if any of the following are reported:

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

- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on:

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

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

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

DOCUMENTATION

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

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care RADT 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 physician, the pharmacist will provide that physician 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 physician, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing physician 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

Approved March 27, 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
- 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

¹Gupta 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)

²Treatment 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)
- No previous history of uncomplicated UTI
- 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:

1. **Nitrofurantoin monohydrate/macrocystals 100 mg PO BID for 5 days**
OR
2. **Trimethoprim-sulfamethoxazole 160/800 mg PO BID for 3 days**
OR
3. **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 physician, the pharmacist will provide that physician 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

Practitioner/Prescriber Name

Date

Practitioner/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.

STATE OF COLORADO
DEPARTMENT OF REGULATORY AGENCIES

Colorado State Board of Pharmacy Approved Statewide Protocol for Prescribing Hormonal Contraceptive Patches and Oral Contraceptives

(Appendix A)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to perform the pertinent physical assessments and prescribe hormonal contraceptive patches and oral contraceptives under the conditions of this protocol and according to and in compliance with all applicable state and federal laws and rules.

Definitions

- (1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.
- (2) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.
- (3) "Oral hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

Training Program

Only a Colorado-licensed pharmacist, who has completed an Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may dispense hormonal contraceptive patches and oral hormonal contraceptives to a patient. In addition, pharmacists shall comply with the most current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as adopted by the U.S. Centers for Disease Control and Prevention (CDC).

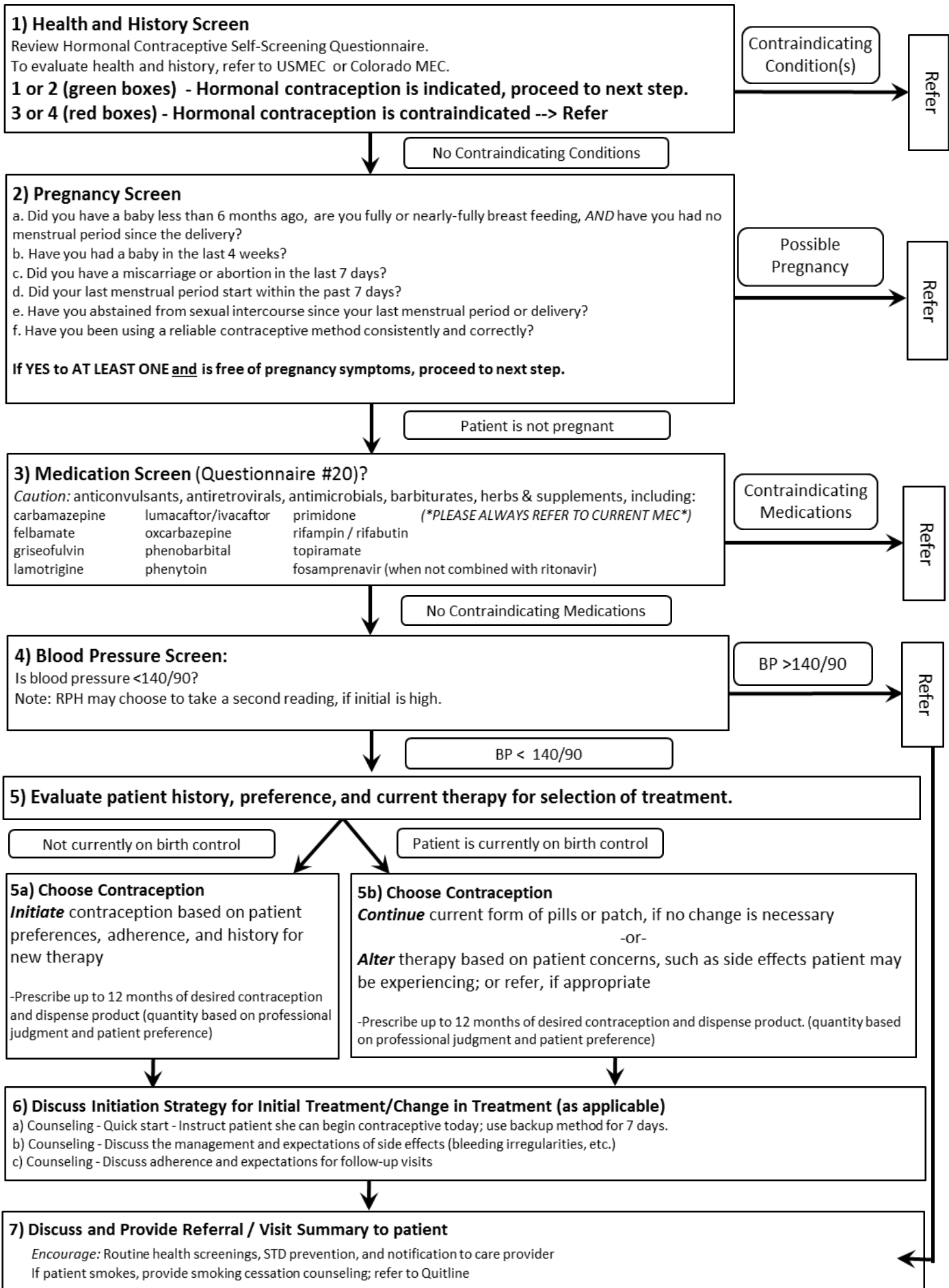
Age Requirements

A pharmacist may prescribe hormonal contraceptive patches and self-administered oral hormonal contraceptives to a person who is at least 18 years of age.

Further Conditions

- (1) For each new patient requesting a contraceptive service and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:
 - (a) Obtain a completed Colorado Self-Screening Risk Assessment Questionnaire;
 - (b) Utilize and follow the Colorado Standard Procedures Algorithm to perform the patient assessment;
 - (c) Prescribe, if clinically appropriate, the hormonal contraceptive patch or self-administered oral hormonal contraceptive, or refer to a healthcare practitioner;
 - (d) Provide the patient with a Visit Summary;
 - (e) Advise the patient to consult with a primary care practitioner or women's health care practitioner;
 - (f) Refer any patient that may be subject to abuse to an appropriate social services agency; and
 - (g) Ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality.
- (2) If the hormonal contraceptive patch or self-administered oral hormonal contraceptive is dispensed, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.
- (3) A pharmacist must not:
 - (a) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive;
 - (b) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit; or
 - (c) Prescribe in instances that the Colorado Standard Procedures Algorithm requires referral to a provider.
- (4) Records:
 - (a) Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.
 - (b) Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

STANDARD PROCEDURES ALGORITHM FOR COLORADO RPH PRESCRIBING OF CONTRACEPTIVES



Hormonal Contraceptive Self-Screening Questionnaire (form updated Nov16)

Name _____ Health Care Provider's Name _____ Date _____
 Date of Birth _____ Age* _____ Weight _____ Do you have health insurance? Yes / No
 What was the date of your last women's health clinical visit? _____
 Any Allergies to Medications? Yes / No If yes, list them here: _____

Background Information:

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	____/____/____
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Medical History:

6	Have you given birth within 21 days? If yes, how long ago?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you get migraine headaches? If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	
20	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	
21	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	

Do you have a preferred method of birth control that you would like to use?

☐ **A pill you take each day** ☐ **A patch that you change weekly** ☐ **Other (ring, injectable, implant, or IUD)**

Internal use only <input type="checkbox"/> verified DOB* with valid photo ID <input type="checkbox"/> BP Reading _____/_____ Pharmacist Name _____ Pharmacist Signature _____ <input type="checkbox"/> Drug Prescribed _____ Rx# _____ -or- <input type="checkbox"/> Patient Referred-circle reason(s) Sig: _____ (Pharmacy Phone _____ Address _____) Notes: _____	
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Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use



Pages 1,2Color coded in the left column to match the corresponding question of the Oregon Hormonal Contraception Self-Screening Tool Questionnaire.
 Pages 3,4 Arranged alphabetically by disease state

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

Updated November 2016. This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

Corresponding to the order of the Colorado Hormonal Contraception Self Screening Tool Questionnaire:

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Age		Initiating	Continuing	Initiating	Continuing	
	Menarche to <40=1			Menarche to <18=1		Yes
	≥40=2			18-45=1		Yes
Smoking	a) Age < 35	2		>45=1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3				Yes
	c) Age ≥ 35, ≥15 cigarettes/day	4				Yes
Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA*
Postpartum (see also Breastfeeding)	a) < 21 days	4		1		Yes
	b) 21 days to 42 days:					
	(i) with other risk factors for VTE	3*		1		Yes
	(ii) without other risk factors for VTE	2		1		Yes
	c) > 42 days	1		1		Yes
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		Yes
	b) 1 month or more postpartum	2*		1*		Yes
Diabetes mellitus (DM)	a) History of gestational DM only	1		1		Yes
	b) Non-vascular disease					
	b) Other abnormalities:					
	(i) non-insulin dependent	2		2		Yes
	(ii) insulin dependent‡	2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		Yes
Headaches	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		Yes
	a) Non-migrainous	1*	2*	1*	1*	Yes
	b) Migraine:					
	i) without aura, age <35	2*	3*	1*	2*	Yes
	ii) without aura, age ≥35	3*	4*	1*	2*	Yes
Hypertension	iii) with aura, any age	4*	4*	2*	3*	Yes
	a) Adequately controlled hypertension	3*		1*		Yes
	b) Elevated blood pressure levels (properly taken measurements):					
	(i) systolic 140-159 or diastolic 90-99	3		1		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4		2		Yes
History of high blood pressure during pregnancy	c) Vascular disease	4		2		Yes
		2		1		Yes
Hyperlipidemias		2/3*		2*		Yes
	Peripartum cardiomyopathy‡					
	a) Normal or mildly impaired cardiac function:					
	(i) < 6 months	4		1		Yes
	(ii) ≥ 6 months	3		1		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
		Initiating	Continuing	Initiating	Continuing	
	b) Moderately or severely impaired cardiac function	4		2		Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		Yes
Ischemic heart disease‡	Current and history of	4		2	3	Yes
Valvular heart disease	a) Uncomplicated	2		1		Yes
	b) Complicated‡	4		1		Yes
Stroke‡	History of cerebrovascular accident	4		2	3	Yes
Thrombogenic mutations‡		4*		2*		Yes
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy					
	i) higher risk for recurrent DVT/PE	4		2		Yes
	ii) lower risk for recurrent DVT/PE	3		2		Yes
	b) Acute DVT/PE	4		2		Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months					
	i) higher risk for recurrent DVT/PE	4*		2		Yes
	ii) lower risk for recurrent DVT/PE	3*		2		Yes
	d) Family history (first-degree relatives)	2		1		Yes
	e) Major surgery					
	(i) with prolonged immobilization	4		2		Yes
	(ii) without prolonged immobilization	2		1		Yes
	f) Minor surgery without immobilization	1		1		Yes
History of bariatric surgery‡	a) Restrictive procedures	1		1		Yes
	b) Malabsorptive procedures	COCs: 3		3		Yes
Breast disease/ Breast Cancer	a) Undiagnosed mass	2*		2*		Yes
	b) Benign breast disease	1		1		Yes
	c) Family history of cancer	1		1		Yes
	d) Breast cancer:‡					
	i) current	4		4		Yes
	ii) past and no evidence of current disease for 5 years	3		3		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Viral hepatitis	a) Acute or flare	3/4*	2	1		Yes
	b) Carrier/Chronic	1	1	1		Yes
Cirrhosis	a) Mild (compensated)	1		1		Yes
	b) Severe‡ (decompensated)	4		3		Yes
Liver tumors	a) Benign:					
	i) Focal nodular hyperplasia	2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		Yes
	b) Malignant‡	4		3		Yes
Gallbladder disease	a) Symptomatic:					
	(i) treated by cholecystectomy	2		2		Yes
	(ii) medically treated	3		2		Yes
	(iii) current	3		2		Yes
	b) Asymptomatic	2		2		Yes
History of Cholestasis	a) Pregnancy-related	2		1		Yes
	b) Past COC-related	3		2		Yes
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4		3		Yes
	b) Severe thrombocytopenia	2		2		Yes
	c) Immunosuppressive treatment	2		2		Yes
	d) None of the above	2		2		Yes
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		Yes
	b) Not on immunosuppressive therapy	2		1		Yes
Blood Conditions?						
Epilepsy‡	(see also Drug Interactions)	1*		1*		Yes
Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		Yes
	b) Pelvic	1*		1*		Yes
HIV	High risk	1		1		Yes
	HIV infected (see also Drug Interactions)‡	1*		1*		Yes
	AIDS (see also Drug Interactions) ‡	1*		1*		Yes
	Clinically well on therapy	If on treatment, see Drug Interactions.				
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*		1		Yes
	b) Non-nucleoside reverse transcriptase inhibitors	2*		2*		Yes
	c) Ritonavir-boosted protease inhibitors	3*		3*		Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		Yes
	b) Lamotrigine	3*		1		Yes
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		Yes
	b) Antifungals	1		1		Yes
	c) Antiparasitics	1		1		Yes
	d) Rifampicin or rifabutin therapy	3*		3*		Yes

Alphabetical Listing of USMEC Contraceptive Eligibility By Disease State

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Breast disease/ Breast Cancer	a) Undiagnosed mass	2*	2*			Yes
	b) Benign breast disease	1	1			Yes
	c) Family history of cancer	1	1			Yes
	d) Breast cancer‡					
	i) current	4	4			Yes
Breastfeeding (see also Postpartum)	ii) past and no evidence of current disease for 5 years	3	3			Yes
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*	2*			Yes
	b) 1 month or more postpartum	2*	1*			Yes
Cervical cancer	Awaiting treatment	2	1			Yes
Cervical ectropion		1	1			Yes
Cervical intraepithelial neoplasia		2	1			Yes
Cirrhosis	a) Mild (compensated)	1	1			Yes
	b) Severe‡ (decompensated)	4	3			Yes
Cystic Fibrosis		1*	1*			Yes
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy					
	i) higher risk for recurrent DVT/PE	4	2			Yes
	ii) lower risk for recurrent DVT/PE	3	2			Yes
	b) Acute DVT/PE	4	2			Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months					
	i) higher risk for recurrent DVT/PE	4*	2			Yes
	ii) lower risk for recurrent DVT/PE	3*	2			Yes
	d) Family history (first-degree relatives)	2	1			Yes
	e) Major surgery					
	(i) with prolonged immobilization	4	2			Yes
	(ii) without prolonged immobilization	2	1			Yes
	f) Minor surgery without immobilization	1	1			Yes
Depressive disorders		1*	1*			Yes
Diabetes mellitus (DM)	a) History of gestational DM only	1	1			Yes
	b) Non-vascular disease					
Diabetes mellitus (cont.)	(i) non-insulin dependent	2	2			Yes
	(ii) insulin dependent‡	2	2			Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*	2			Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*	2			Yes
Endometrial cancer‡		1	1			Yes
Endometrial hyperplasia		1	1			Yes
Endometriosis		1	1			Yes
Epilepsy‡	(see also Drug Interactions)	1*	1*			Yes
Gallbladder disease	a) Symptomatic					
	(i) treated by cholecystectomy	2	2			Yes
	(ii) medically treated	3	2			Yes
	(iii) current	3	2			Yes

	b) Asymptomatic	2		2		Yes
	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Gestational trophoblastic disease	a) Decreasing or undetectable β-hCG levels	1		1		Yes
	b) Persistently elevated β-hCG levels or malignant disease‡	1		1		Yes
Headaches	a) Non-migrainous	1*	2*	1*	1*	Yes
	b) Migraine					
	i) without aura, age <35	2*	3*	1*	2*	Yes
	ii) without aura, age ≥35	3*	4*	1*	2*	Yes
	iii) with aura, any age	4*	4*	2*	3*	Yes
History of bariatric surgery‡	a) Restrictive procedures	1		1		Yes
	b) Malabsorptive procedures	COCs: 3 P/R: 1		3		Yes
History of cholestasis	a) Pregnancy-related	2		1		Yes
	b) Past COC-related	3		2		Yes
History of high blood pressure during pregnancy		2		1		Yes
History of pelvic surgery		1		1		Yes
HIV	High risk	1		1		Yes
	HIV infected (see also Drug Interactions)‡	1*		1*		Yes
	AIDS (see also Drug Interactions) ‡	1*		1*		Yes
	Clinically well on therapy	If on treatment, see Drug Interactions.				
Hyperlipidemias		2/3*		2*		Yes
Hypertension	a) Adequately controlled hypertension	3*		1*		Yes
	b) Elevated blood pressure levels (properly taken measurements)					
	(i) systolic 140-159 or diastolic 90-99	3		1		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4		2		Yes
	c) Vascular disease	4		2		Yes
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		Yes
Ischemic heart disease‡	Current and history of	4		2	3	Yes
Liver tumors	a) Benign					
	i) Focal nodular hyperplasia	2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		Yes
	b) Malignant‡	4		3		Yes
Malaria		1		1		Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		Yes
Obesity	a) ≥30 kg/m² body mass index (BMI)	2		1		Yes
	b) Menarche to < 18 years and ≥ 30 kg/m² BMI	2		1		Yes
Ovarian cancer‡		1		1		Yes
Parity	a) Nulliparous	1		1		Yes
	b) Parous	1		1		Yes
Past ectopic pregnancy		1		2		Yes

Alphabetical Listing of USMEC Contraceptive Eligibility By Disease State

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)					
	(i) with subsequent pregnancy	1		1		Yes
	(ii) without subsequent pregnancy	1		1		Yes
	b) Current	1		1		Yes
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function					
	(i) < 6 months	4		1		Yes
	(ii) ≥ 6 months	3		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		Yes
Postabortion	a) First trimester	1*		1*		Yes
	b) Second trimester	1*		1*		Yes
	c) Immediately post-septic abortion	1*		1*		Yes
Postpartum (see also Breastfeeding)	a) < 21 days	4		1		Yes
	b) 21 days to 42 days					
	(i) with other risk factors for VTE	3*		1		Yes
	(ii) without other risk factors for VTE	2		1		Yes
Postpartum (in breastfeeding or non-breastfeeding women, including post-caesarean section)	c) > 42 days	1		1		Yes
	a) < 10 minutes after delivery of the placenta					
	b) 10 minutes after delivery of the placenta to < 4 weeks					
	c) ≥ 4 weeks					
Pregnancy	d) Puerperal sepsis					
		NA*		NA*		NA*
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		Yes
	b) Not on immunosuppressive therapy	2		1		Yes
Schistosomiasis	a) Uncomplicated	1		1		Yes
	b) Fibrosis of the liver‡	1		1		Yes
Severe dysmenorrhea		1		1		Yes
Sexually transmitted infections (STIs)	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1		1		Yes
	b) Other STIs (excluding HIV and hepatitis)	1		1		Yes
Sexually transmitted infections (cont.)	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1		1		Yes
	d) Increased risk of STIs	1		1		Yes
Smoking	a) Age < 35	2		1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3		1		Yes
	c) Age ≥ 35, ≥ 15 cigarettes/day	4		1		Yes
Solid organ transplantation‡	a) Complicated	4		2		Yes
	b) Uncomplicated	2*		2		Yes
Stroke‡	History of cerebrovascular accident	4		2	3	Yes
Superficial venous thrombosis	a) Varicose veins	1		1		Yes
	b) Superficial thrombophlebitis	2		1		Yes
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4		3		Yes
	b) Severe thrombocytopenia	2		2		Yes
	c) Immunosuppressive treatment	2		2		Yes
	d) None of the above	2		2		Yes
Thrombogenic mutations‡		4*		2*		Yes

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
Thyroid disorders	Simple goiter/hyperthyroid/hypothyroid.	1		1		Yes
Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		Yes
	b) Pelvic (suspicious for serious condition) before evaluation	1*		1*		Yes
Unexplained vaginal bleeding		2*		2*		Yes
Uterine fibroids		1		1		Yes
Valvular heart disease	a) Uncomplicated	2		1		Yes
	b) Complicated‡	4		1		Yes
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		2		Yes
	b) Heavy or prolonged bleeding	1*		2*		Yes
Viral hepatitis	a) Acute or flare	3/4*	2	1		Yes
	b) Carrier/Chronic	1	1	1		Yes
Antiretroviral therapy (All other ARVs are 1 or 2 for all methods)	Fosamprenavir (FPV)	3*		2*		Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		Yes
	b) Lamotrigine	3*		1		Yes
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		Yes
	b) Antifungals	1		1		Yes
	c) Antiparasitics	1		1		Yes
	d) Rifampicin or rifabutin therapy	3*		3*		Yes
SSRIs		1		1		Yes
St. John's Wort		2		2		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable

* Please see the complete guidance for a clarification to this classification:

www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

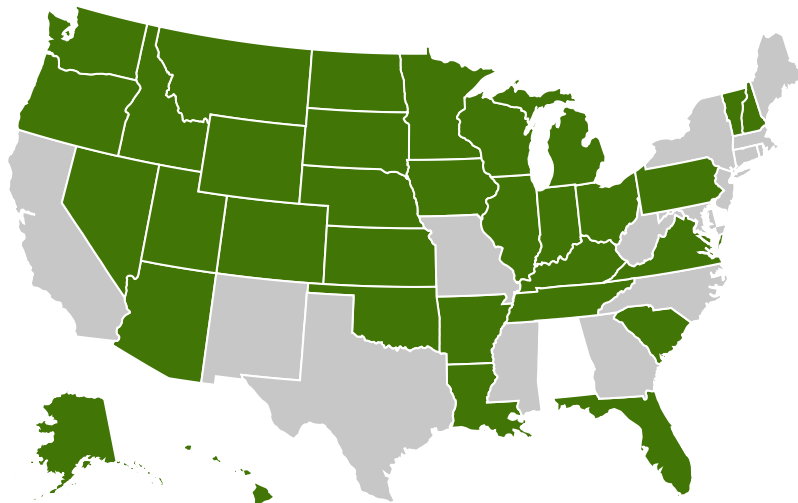
Collaborative Practice Agreements

**Borrowed from NASPA*

States Allowing All Pharmacists to Participate in CPAs

33 states allow any licensed pharmacist, in any practice setting, to participate in a CPA. This means there are no state-mandated requirements for extra training for the pharmacist. Note that practitioners always have the ability to include added qualifications as prerequisites for specific services within a CPA's terms.

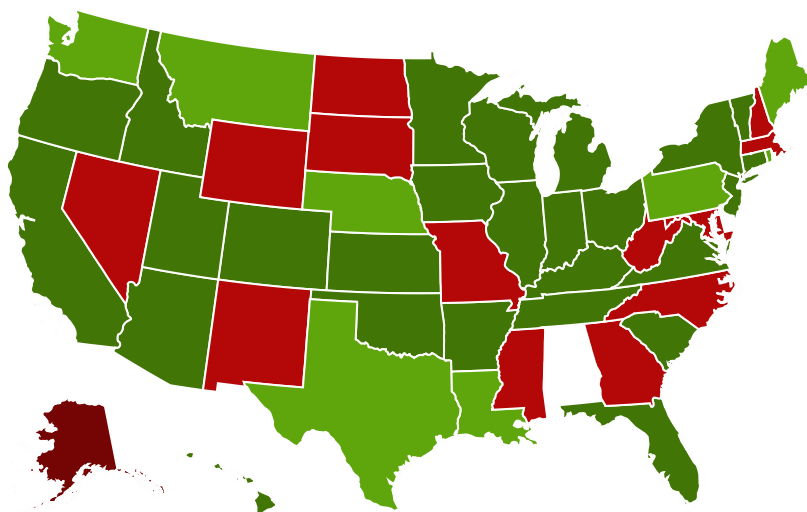
All pharmacists:
AK, AR, AZ, CO, DC, FL, HI, IA, ID, IL, IN, KS, KY, LA, MI, MN, MT, ND, NE, NH, NV, OH, OK, OR, PA, SC, SD, TN, UT, VA, VT, WA, WI, WY



Board Involvement in Individual Agreements

States that require a state regulatory body to approve the CPA before its use and states that require CPAs be filed with a state regulatory body.

- Board approves pharmacist and agreement:** AK
- Board approves agreements:** MS, ND, NV, SD, WV, WY
- Board approves pharmacist, submit agreements to the board:** MD, MO, NM
- Board approves pharmacist:** GA, MA, NC
- CPAs must include quality metrics that are reported to the board annually:** NH
- Submit agreements to the board:** ME, MT, NE, PA, RI, TX, WA
- Pharmacist must register with the board:** LA. In the remaining states, pharmacists should keep a copy on file for inspection



Based on NASPA research. This information is intended to be used for informational purposes only and does not constitute legal advice.

Single or Multiple Pharmacists and Physicians

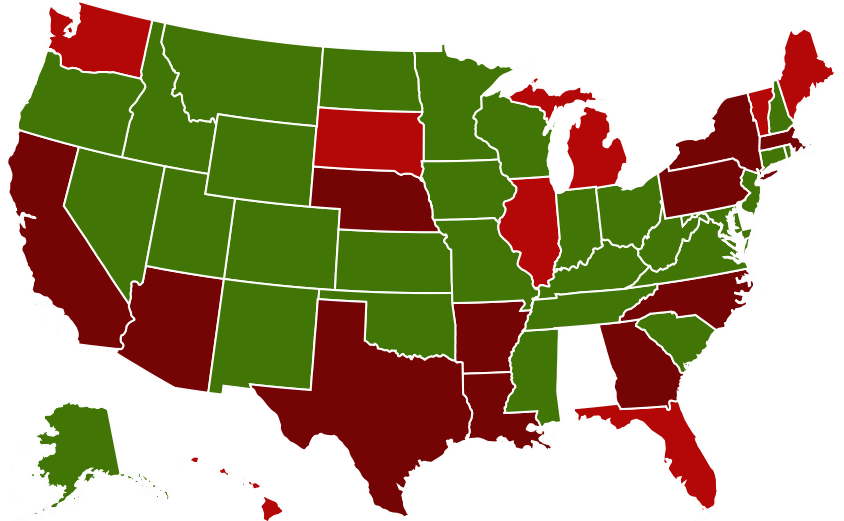
States that allow multiple or single pharmacists and multiple or single physicians to be parties on a particular collaborative practice agreement.

Multiple pharmacists, multiple physicians: AK, CO, CT, DC, IA, ID, IN, KS, KY, MD, MN, MO, MS, MT, ND, NH, NJ, NM, NV, OH, OK, OR, RI, SC, TN, UT, VA, WI, WV, WY

Multiple pharmacists, single physician: FL, HI, IL, ME, MI, SD, WA

Single pharmacist, multiple physicians: VT

Single pharmacist, single physician: AR, AZ, CA, GA, LA, MA, NC, NE, NY, PA, TX



Other Prescribers May Be a Party to a CPA

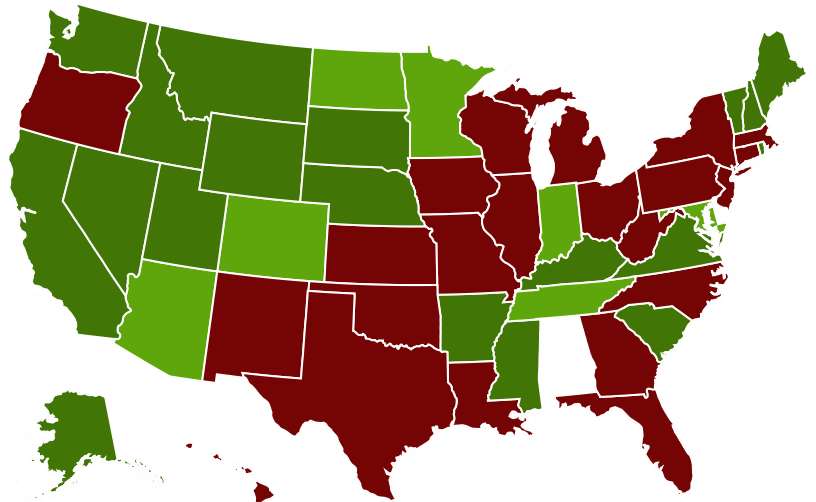
In some states, prescribers other than physicians may partner with pharmacists on a collaborative practice agreement. These states rationalize that other prescribers should also have the benefit of a medication expert as a formal collaborator. In addition to physicians, these states also allow:

All prescribers: AK, AR, CA, DC, ID, KY, ME, MS, MT, NE, NH, NV, RI, SC, SD, TN, UT, VA, VT, WA, WY

Nurse practitioners and physician assistants: IN, TN

Nurse practitioners: AZ, CO, MD, MN, ND

Physicians only: CT, FL, GA, HI, IA, IL, KS, LA, MA, MI, MO, MT, NC, NE, NJ, NM, NY, OH, OK, OR, PA, TX, WI, WV



Tennessee Board of Pharmacy Policy Statement on Preventive Care

This Tennessee Board of Pharmacy policy is intended to provide guidance to pharmacists regarding collaborative pharmacy practice agreements with prescribers authorizing the provision of preventive care which promotes patient health and does not require diagnosis appropriately made and documented by the physician, advanced practice nurse or physician assistant, as identified in Tennessee Board of Pharmacy Rule 1140-03-.17 (5)(b). Under this Board rule “all care and services provided, except immunizations, opioid antagonists, and preventive care, must be pursuant to a diagnosis appropriately made and documented by the physician, advanced practice nurse or physician assistant.” In addition to immunizations, opioid antagonists, and preventive care identified in this Board rule, Tennessee Board of Pharmacy Rule 1140-15 authorizes pharmacists to prescribe and dispense hormonal contraceptives through non-patient specific collaborative pharmacy practice agreements, which does not require a diagnosis, with prescribers.

Preventive care maintains patients’ health to avoid or delay the onset or progression of certain preventable diseases, conditions, and other illnesses. Specific to this Board rule, pharmacists are authorized to provide preventive care, including the identification of potentially serious health conditions and provision of early treatment of those conditions, pursuant to collaborative pharmacy practice agreements with prescribers which do not require a diagnosis. Pharmacist-provided preventive care under this rule may include screening and identification, performing CLIA-waived laboratory tests, ordering laboratory tests, treatment, clinical interventions, medication optimization services (including the prescribing, administration, and therapeutic optimization of medications and non-medication therapies), and initiation of patient referrals to physicians, advanced practice nurses, and physician assistants.

Under this Board policy, the Tennessee Board of Pharmacy provides the following policy statement regarding preventive care in Board Rule 1140-03-.17. Preventive care may include, but is not limited to:

- Emergency allergic reactions
- Seasonal and chronic allergic rhinitis
- Travel health
- Smoking cessation
- Screening, prevention, and treatment of influenza and streptococcal infections
- Herpes and herpes-related conditions
- Tuberculosis
- Dermatologic conditions
- Reduction in therapeutic gaps in care for chronic conditions (such as diabetes, hypertension, hyperlipidemia, chronic heart failure, chronic lung disease)
- Alcohol and drug abuse
- Lifestyle modifications and weight loss management
- Mental health and depression
- Prevention of falls
- Osteoporosis and bone health
- Medication-related clinical guideline optimization (such as BEERS and STOPP/START criteria, reduction of duplicate meds, discontinuation of unnecessary or potentially inappropriate medication therapies)

- Acid reflux, gastroesophageal reflux disease, and heartburn
- Anticoagulation
- Migraines
- Lice and scabies
- Vitamins and supplements (such as folic acid, prenatal vitamins for fetal health, vitamin B12, Vitamin D)
- Penicillin skin testing
- Prophylaxis of cytomegalovirus, pneumocystis jiroveci pneumonia, and other common infections in immunocompromised patients
- Prophylaxis of urinary tract infections
- Prophylaxis of meningitis
- Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)

This policy is not intended to change or conflict with pharmacist-provided care and services currently authorized under a pharmacist's scope of practice in Tennessee Code Annotated 63-10-204(39)(a) and (b).

This policy does not supersede or replace any requirement or obligation listed in statutes or rules pertaining to collaborative pharmacy practice. This policy defines preventative care as excluding the requirement for a patient-specific diagnosis. All other requirements of collaborative pharmacy practice remain in place.

ADOPTED BY THE TENNESSEE BOARD OF PHARMACY ON March 12, 2019.

TCA 63-10-204(39)(a) and (b) “Practice of Pharmacy”

(39) (A) "Practice of pharmacy" means a patient-oriented health service profession in which pharmacists interact and consult with patients and other health care professionals to enhance patients' wellness, prevent illness, and optimize outcomes. The practice involves:

- (i) Interpretation, evaluation and implementation of medical orders and prescription orders;
- (ii) Responsibility for compounding and dispensing prescription orders, including radioactive substances;
- (iii) Participation in drug, dietary supplement and device selection, storage, distribution and administration;
- (iv) Drug evaluation, utilization or regimen review;
- (v) Maintenance of patient profiles and other pharmacy records;
- (vi) Provision of patient education and counseling;
- (vii) Provision of patient care services and activities pursuant to a collaborative pharmacy practice agreement;
- (viii) Drug or drug-related research; and
- (ix) Those professional acts, professional decisions or professional services necessary to maintain all areas of a patient's pharmacist-provided care;

(B) Nothing in this chapter authorizes a pharmacist to order laboratory tests or prescribe any prescription drugs except pursuant to a medical order by the attending prescriber for each patient or pursuant to a collaborative pharmacy practice agreement jointly agreed upon by a pharmacist or pharmacists and a prescriber or prescribers; provided, that pharmacists are authorized to conduct and assist patients with tests approved for home use. Pharmacists may convey orders for laboratory tests when authorized by the attending prescriber and may prescribe prescription drugs when required to carry out a medical order or perform activities pursuant to a collaborative pharmacy practice agreement when authorized by the attending prescriber;

Background/Rationale

Emergency Allergic Reaction

Rationale: Preventing the worsening of an allergic reaction and/or death prior to the arrival of emergency medical services by utilizing emergency medications for patients who are experiencing acute anaphylaxis.

Examples/Model States:

- Idaho
 - If in an emergency, after contacting emergency medical services, a situation exists that, in the professional judgment of the pharmacist, threatens the health or safety of the patient, a pharmacist may prescribe the following FDA approved drugs in the minimum quantity necessary until the patient is able to be seen by another provider.
 - Diphenhydramine
 - Epinephrine
 - SABAs

Seasonal and Chronic Allergic Rhinitis

Rationale: Preventing seasonal and chronic allergic rhinitis from worsening and/or continuing without treatment.

Examples/Model States:

- Florida allows prescribing of certain antihistamines and decongestants.
- Could include additional medications used to prevent seasonal and chronic allergic rhinitis

Travel health

Rationale: Preventing future illness in patients related to travel

Examples/Model States:

- California: §1746.5 Pharmacists Furnishing Travel Medications
- Idaho: A pharmacist who successfully completes an accredited CPE or CME course on travel medicine may prescribe any non-controlled drug recommended for individuals traveling outside the United States that are specifically listed in the federal CDC Health Information for International Travel (e.g., Yellow Book). The pharmacist may only prescribe drugs that are indicated for the patient's intended destination for travel.

Smoking Cessation

Rationale: Preventing smoking and future complications from smoking in patients

Examples/Model States:

- California: §1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products
- New Mexico Protocol
 - Pharmacists may prescribe:

- Nicotine replacement therapies
- Patch
- Gum
- Inhaler
- Lozenge
- nasal spray
- Bupropion
- Other FDA approved products for tobacco cessation.
- General recommendations:
 - Pharmacists will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline – Treating Tobacco Use and Dependence.
 - Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco.
 - Pharmacists will include an education component including both face to face and telephonic/electronic interventions to patients of 90 minutes.
 - Referral
 - Pregnancy
 - Current seizure disorder for bupropion therapy.
 - Current eating disorder for bupropion therapy
 - Full protocol:
 - <https://www.nmpharmacy.org/Resources/Documents/rx%20authority/protocol-tobacco.pdf>

Identification, Prevention, and Treatment of Influenza and Streptococcal Infections

Rationale: Preventing the spread of influenza and streptococcal infections in patients and communities

Examples/Model States:

- Washington Influenza Treatment or Prophylaxis Protocol
 - http://www.nwcphp.org/documents/training/cdta_flu_template.pdf
- Idaho Influenza Treatment Protocol
 - Provides accessible and timely treatment of influenza for low-risk patients in consideration of the clinical guidelines of the Infectious Diseases Society of America (IDSA).
 - Patients Eligible for Neuraminidase Treatment Under this Protocol (Inclusion Criteria):
 - Patients 6 years of age or older exhibiting signs of influenza-like illness (e.g., fever, cough, sore throat, nasal congestion, muscle/body aches, etc.) for 48 hours or less who test positive to a CLIA-waived test indicated for influenza.
 - Patients Ineligible for Neuraminidase Treatment Under this Protocol (Exclusion and Referral Criteria):
 - Patients exhibiting signs of influenza-like illness (ILI) 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 <100mgHg

- Tachypnea >25 breaths/min (>20 breaths per minute for patients <18 years)
 - Tachycardia >100 beats/min (>119 beats/min for patients <18 years)
 - Oxygenation <90% via pulse oximetry
 - Body temperature >103OF (>102OF for patients <18 years)
 - Patients who report any of the following:
 - History of renal dysfunction
 - History of allergic reaction to any previous neuraminidase therapy
 - History of psychologic side effects from any previous neuraminidase therapy
 - Use of antiviral therapy in past 4 weeks
 - Follow-up within 48 hours after initial interaction to determine efficacy of treatment initiated or need for referral.
- Idaho Influenza Prophylaxis Protocol
 - Provides prophylactic therapy to high-risk household contacts of a patient being treated for active influenza in a timely and accessible fashion in accordance with guidelines of the Centers for Disease Control and Prevention.
 - Patients Eligible for Neuraminidase Prophylaxis Under this Protocol (Inclusion Criteria):
 - Patients who are 6 years of age or older who meet at least one of the following criteria:
 - Has asthma or other chronic pulmonary disease
 - Has diabetes mellitus
 - Has congestive heart failure or coronary artery disease
 - Is immunocompromised by medication or condition
 - Has HIV
 - Has sickle cell anemia or other hemoglobinopathies
 - Has chronic renal dysfunction
 - Has cancer
 - Has neuromuscular disorders, seizure disorders, or cognitive dysfunction that may compromise handling of respiratory secretions
 - Has not yet received influenza vaccine during this influenza season
 - Is age 65 years or older
 - Patients Ineligible for Neuraminidase Prophylaxis Under this Protocol (Exclusion and Referral Criteria):
 - Patients under the age of 6
 - Patients who are pregnant or breastfeeding
 - Patients with current symptoms of influenza-like illness
 - Patients who report any of the following:
 - History of allergic reaction to any previous neuraminidase therapy
 - History of psychologic side effects from any previous neuraminidase therapy
 - Use of antiviral therapy in past 4 weeks
- Idaho Streptococcal Pharyngitis Protocol

- Provides timely and accessible treatment of group A streptococcal (GAS) pharyngitis for low-risk, symptomatic patients in consideration of the clinical guidelines established by the Infectious Diseases Society of America (IDSA).
 - Patients Eligible for Antibiotic Therapy Under this Protocol (Inclusion Criteria):
 - Symptomatic patients between the ages of 6 and 45 who score a 2 or higher on the Centor Score and then test positive to a CLIA-waived test indicated for GAS pharyngitis.
 - Patients Ineligible for Antibiotic Therapy Under this Protocol (Exclusion and Referral Criteria):
 - Patients younger than 6 years of age or older than 45 years
 - 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 mgHg
 - Tachypnea >25 breaths/min (>20 breaths per minute for patients <18 years)
 - Tachycardia >100 beats/min (>119 beats/min for patients <18 years)
 - Oxygenation <90% via pulse oximetry
 - Body temperature >103OF (>102OF for patients <18 years)
 - History of renal dysfunction
 - Follow-up within 48 hours after initial interaction to determine efficacy of treatment initiated or need for referral.

Herpes and Herpes-Related Conditions

Rationale: Preventing the worsening of herpes infection and the spread of herpes infection throughout the community.

Examples/Model States:

- Idaho Protocol
 - Provides timely and accessible treatment for low-risk patients with recurrent herpes labialis, including episodic treatment and short-term prevention.
 - Patients Eligible for Treatment Under This Protocol (Inclusion Criteria):
 - Patients 6 years of age or older who report a previous history of cold sores and who present with:
 - Prodromal symptoms that are typical of a cold sore or a lesion that is typical of a cold sore that has lasted <48 hours.
 - Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria):
 - Patients under the age of 6 years
 - Patients who report no prior history of having a cold sore
 - Patients who have one or more of the following:
 - Lesion appears excessively red, swollen, or contains pus
 - Lesion appears on area other than around the mouth and lips
 - Lesions have not healed from a prior episode o

- Reports symptoms of systemic illness are present (fever, swollen glands, malaise)
- Reports being immunocompromised by medication or condition
- Reports that lesions have occurred more than 6 times in the past 12 months
- Follow-Up to Assess Need for Referral
 - Follow-up in 7 days. Referral needed if lesions spread or persist without improvement despite treatment.

Tuberculosis

Rationale: Preventing the spread of tuberculosis infection throughout the community, and current tuberculosis infection from continuing unidentified and untreated.

Examples/Model States:

- New Mexico TB skin testing protocol
 - https://www.nmpharmacy.org/Resources/Documents/rx%20authority/TB_BOP_Rules-Protocol.pdf

Dermatologic Conditions

Rationale: Preventing the worsening of dermatologic conditions.

Examples/Model States:

- Florida allows prescribing of certain topical medications on a formulary
 - <https://www.flrules.org/gateway/RuleNo.asp?title=PHARMACY%20PRACTICE&ID=64B16-27.220>

Reduction in therapeutic gaps in care for chronic conditions (such as diabetes, hypertension, hyperlipidemia, chronic heart failure, chronic lung disease)

Rationale: Prevention of morbidity and mortality related to chronic conditions by addressing therapeutic gaps in care based on current guidelines, untreated previously diagnosed chronic conditions based on current guidelines, worsening of patients' chronic conditions lasting greater than three months which cannot be prevented by immunizations or cured by medications due to lack of access to medications, and poor adherence caused by lack of access to medications.

Examples/Model States:

- Idaho Statins for Patients w/ Diabetes Protocol
 - Reduces cardiovascular (CV) risk in patients with diabetes and promote optimal patient care in accordance with the guidelines of the American College of Cardiology/American Heart Association.
 - Patients Eligible for Treatment under This Protocol (Inclusion Criteria):
 - Patients between the ages of 40 and 75 years who report a previous diagnosis of diabetes.
 - Patients who must be referred by the pharmacist to a more appropriate venue of care (Exclusion and Referral Criteria):
 - Patients younger than 40 years or older than 75 years
 - Patients who do not report a previous diagnosis of diabetes

- Patients who report they are pregnant, may become pregnant, or are breastfeeding
 - Patients who have or report one or more of the following:
 - Active liver disease
 - Unexplained elevated hepatic transaminase levels (ALT) >3 times upper limit of normal
 - History of statin-induced rhabdomyolysis
 - On hemodialysis or peritoneal dialysis
 - Hypersensitivity to any component of a statin
 - The pharmacist should investigate further the appropriateness of initiating statin therapy for patients who report one or more of the following:
 - NHYA class II-IV ischemic systolic Heart Failure
 - History of cognitive impairment
 - Previous statin intolerance
 - Follow-Up to Assess Need for Referral
 - Follow-up 4 to 12 weeks after initiation of a statin to assess medication adherence and to assess the safety and tolerability of statin therapy.
 - Notify the patient's provider of record within five business days of any clinically significant information collected upon follow-up.
- California: 4052.6. Advanced Practice Pharmacist; Permitted Procedures (Must have 1) Earn certification in a relevant area of practice; 2) Complete a postgraduate residency program; 3) Have provided clinical services to patients for one year under a collaborative practice agreement or protocol with a physician, APP pharmacist, CDTM pharmacist, or health system)
 - (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
 - (1) Perform patient assessments.
 - (2) Order and interpret drug therapy related tests.
 - (3) Refer patients to other health care providers.
 - (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
 - (5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.
- Iowa: 657—39.13 (155A) Collaborative drug therapy management.
 - Both in the community and in the hospital setting
- Idaho Short-Acting Beta Agonists Refill Renewal Protocol
 - Fills a gap in care for low-risk asthma patients who run out of refills of their short-acting beta agonist (SABA) rescue inhaler prescription in consideration of the National Heart, Lung, and Blood Institute clinical guidelines.
 - Patients Eligible for Treatment Under this Protocol (Inclusion Criteria)
 - Patients with asthma over the age of 6 years old who meet all of the following conditions:
 - Reports a previous prescription for a SABA rescue inhaler that is out of refills; and
 - Reports a current prescription for a long-term asthma control medication (e.g., inhaled corticosteroid, long-acting beta agonist, etc.);
 - Reports a previous medical office visit in the past fifteen (15) months.

- Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria)
 - Patients under the age of 6 years
 - Patients who report no previous diagnosis of asthma
 - Patients who report no previous SABA prescription
 - Patients who report no current prescription for a long-term asthma control medication
 - Patients who report no medical office visit in the past fifteen (15) months
 - Patients who report or present with one or more of the following:
 - Current shortness of breath, chest pain, or other acute symptoms; or
 - Current productive cough (e.g. colored mucus); or
 - Pregnancy or breastfeeding; or
 - Evidence of SABA overuse (e.g., use >2 days/week for >4 weeks) or more than 2 inhalers in the past month for no explainable reason (e.g., recent travel loss)
 - Has already received two albuterol inhalers through independent pharmacist prescribing in the past twelve (12) months
- California: 4052.6. Advanced Practice Pharmacist; Permitted Procedures (Must 1) Earn certification in a relevant area of practice; 2) Complete a postgraduate residency program; 3) Have provided clinical services to patients for one year under a collaborative practice agreement or protocol with a physician, APP pharmacist, CDTM pharmacist, or health system)
 - (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
 - (1) Perform patient assessments.
 - (2) Order and interpret drug therapy related tests.
 - (3) Refer patients to other health care providers.
 - (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
 - (5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

Alcohol and Drug Abuse

Rationale: Preventing future alcohol and drug abuse by utilizing drug screenings, as well as preventing current alcohol and drug abuse from continuing unidentified and untreated.

Examples/Model States:

- California: 4052.(a)(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber
 - Includes drug screenings

Lifestyle Modifications and Obesity

Rationale: Preventing the worsening of obesity individually and in the community by providing billable lifestyle modification counseling.

Examples/Model States:

- Pharmacists can provide education and care related to obesity prevention and lifestyle modification

Mental Health and Depression

Rationale: Preventing the worsening of mental health issues and depression, including suicide, by utilizing mental health screenings. Mental health screenings can also prevent current mental health issues and depression from continuing unidentified and untreated.

Examples/Model States:

- California: 4052.(a)(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber
 - Includes depression screenings

Prevention of Falls

Rationale: Prevention of falls in patients

Examples/Model States:

- A pharmacist can order medical equipment to assist in the prevention of falls such as canes or walkers.
- A pharmacist can discontinue unnecessary or potentially inappropriate medications that may increase the risk of falls (see Medication-related clinical guideline optimization below)

Osteoporosis and Bone Health

Rationale: Preventing future osteoporosis and the worsening of bone health by utilizing lab tests and bone density screenings. Also prevent current osteoporosis from continuing unidentified and untreated.

Examples/Model States:

- California: 4052.(a)(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber
 - Includes bone density testing
- A pharmacist can evaluate patients based on their lab values and prescribe bisphosphonates for patients that meet the criteria per guidelines.
- A pharmacist can recommend OTC calcium and vitamin D supplements for patients based on their lab values

Medication-related Clinical Guideline Optimization (such as BEERS and STOPP/START criteria, reduction of duplicate meds, discontinuation of unnecessary or potentially inappropriate medication therapies)

Rationale: Prevention of medication-related adverse events in patients

Examples/Model States:

- California: 4052.6. Advanced Practice Pharmacist; Permitted Procedures (Must 1) Earn certification in a relevant area of practice; 2) Complete a postgraduate residency program; 3) Have provided clinical services to patients for one year under a collaborative practice agreement or protocol with a physician, APP pharmacist, CDTM pharmacist, or health system)
 - (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
 - (1) Perform patient assessments.
 - (2) Order and interpret drug therapy related tests.
 - (3) Refer patients to other health care providers.
 - (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
 - (5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

Acid Reflux, Gastroesophageal Reflux Disease, and Heartburn

Rationale: Preventing acid reflux, GERD, and heartburn from worsening and/or continuing without treatment.

Examples/Model States:

- Florida allows prescribing of certain H2 antagonists
 - <https://www.flrules.org/gateway/RuleNo.asp?title=PHARMACY%20PRACTICE&ID=64B16-27.220>

Anticoagulation

Rationale: Preventing adverse effects such as bleeding events from anticoagulation therapy by utilizing lab tests such as INR. These lab tests can also be used to prevent thromboembolic events from the lack of anticoagulation therapy.

Examples/Model States:

- California: 4052.(a)(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber
 - Includes INR among other tests
- Iowa: 657—39.13 (155A) Collaborative drug therapy management.
 - Both in the community and in the hospital setting

Migraines

Rationale: Preventing future migraine attacks from occurring with migraine prophylaxis drugs in eligible patients based on current guidelines. Also preventing acute migraine attacks from worsening by prescribing triptan medications.

Examples/Model States:

- A pharmacist can prescribe migraine prophylaxis drugs based on guidelines if the patient meets specific criteria.
- A pharmacist can evaluate a patient having an acute migraine and prescribe a triptan medication to treat that acute attack.

Lice and Scabies

Rationale: Preventing the spread of lice and scabies throughout the community.

Examples/Model States:

- Idaho allows pharmacists to prescribe drugs approved by the FDA for Lice treatment
- Florida allows pharmacists to prescribe medicinal drug shampoos containing Lindane. The pharmacist shall:
 - Limit the order to the treatment of head lice only;
 - Order no more than four (4) ounces per person; and,
 - Provide the patient with the appropriate instructions and precautions for use.

Vitamins and Supplements (such as folic acid, prenatal vitamins for fetal health, vitamin B12, Vitamin D)

Rationale: Preventing the adverse effects of vitamin deficiencies by prescribing prescription vitamins. Preventing future fetal abnormalities through prescribing of prescription prenatal vitamins.

Examples/Model States:

- A pharmacist can assess a patient and their lab values and determine if they need Prescription Vitamins or Prenatal Vitamins. A pharmacist can prescribe these and bill for them.
 - A pharmacist can suggest OTC vitamins to patients seeking help or information.

Penicillin Skin Testing

Rationale: Preventing possible allergic reactions from occurring in patients with a penicillin allergy who are prescribed a penicillin antibiotic.

Examples/Model States:

- A pharmacist can do penicillin skin testing as part of a protocol in a hospital
- Related links:
 - <https://mopa.memberclicks.net/assets/SpeakerPresentations/Harmon%20Presentation.pdf>
 - [https://www.jaci-inpractice.org/article/S2213-2198\(16\)30499-8/pdf](https://www.jaci-inpractice.org/article/S2213-2198(16)30499-8/pdf)
 - https://academic.oup.com/ofid/article/3/suppl_1/1857/2636073

Prophylaxis of Cytomegalovirus, Pneumocystis Jiroveci Pneumonia, and Other Common Infections in Immunocompromised Patients

Rationale: Prevention of common infections in immunocompromised patients that have higher susceptibility to infection based on current guidelines.

Examples/Model States:

- A pharmacist can assess a patient's lab values like a CD4 count and determine if a patient needs prophylaxis for PCP, *Toxoplasma gondii*, Cytomegalovirus and *Mycobacterium avium* and then prescribe them based on existing HIV and ID guidelines.

Prophylaxis of Uncomplicated Urinary Tract Infections

Rationale: Prevention of future uncomplicated UTIs in patients with a history of recurrent UTIs based on current guidelines.

Examples/Model States:

- Idaho Uncomplicated UTI Protocol
 - Purpose: To provide timely and accessible treatment of uncomplicated urinary tract infections (UTI) for low-risk patients in accordance with the clinical guidelines of the Infectious Disease Society of America or the American Congress of Obstetricians and Gynecologists.
 - Patients Eligible for Treatment Under This Protocol (Inclusion Criteria):
 - Women aged 18 or older who present with at least two of the following symptoms: dysuria, urinary frequency, urinary urgency, or suprapubic pain.
 - Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria):
 - Men
 - Women who meet or report one or more of the following:
 - Under the age of 18
 - Pregnant
 - Post-menopausal
 - Immunosuppressed by medication or condition
 - No previous history of uncomplicated UTI
 - Has had previous antibiotic therapy within the past 4 weeks
 - Has had surgical changes or birth defects relevant to the urinary tract
 - Has undergone urinary tract instrumentation in the past 4 weeks or has any current catheterization
 - Has or reports any symptoms suggestive of systemic illness, including:
 - Fever
 - Sweating
 - Flank pain
 - Shaking chills
 - Nausea
 - Vomiting
 - Systolic hypotension <100mgHg
 - Tachypnea >25breaths/min
 - Tachycardia >100beats/min
 - Oxygenation <90% via pulse oximetry
 - Body temperature >103OF
 - Abnormal vaginal discharge or other symptom suggestive of a sexually transmitted infection
 - Poorly controlled diabetes

Prophylaxis of Meningitis

Rationale: Preventing the spread of meningococcal disease in patients and the community

Examples/Model States:

- A pharmacist can administer the meningococcal vaccine to eligible patients based on CDC guidelines.
- New Mexico Protocol
 - A pharmacist can prescribe antimicrobial chemoprophylaxis for close contacts of sporadic cases of meningococcal disease per guidelines. The rate of secondary disease is highest during the first few days after onset of disease in the primary patient, so antimicrobial chemoprophylaxis should be administered as soon as possible (ideally within 24 hours). Pharmacists can assist with ensuring close contacts of meningococcal disease cases receive antimicrobial chemoprophylaxis as soon as possible.
 - Antimicrobial chemoprophylaxis options include rifampin, ciprofloxacin, or ceftriaxone.

Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PEP) and Post-Exposure Prophylaxis (PrEP)

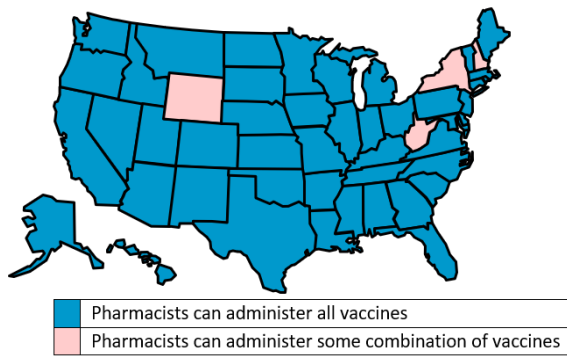
Rationale: Preventing future HIV infection in an individual and the spread of infection in the community

Examples/Model States:

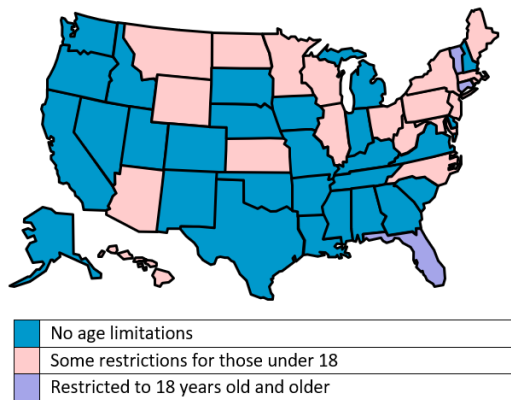
- Washington- “One-step PReP” pilot done under a collaborative practice agreement at Kelly Ross Pharmacy. Also has PEP for emergencies.
 - <https://www.kelley-ross.com/polyclinic/prep/>

Map on Immunization Authority

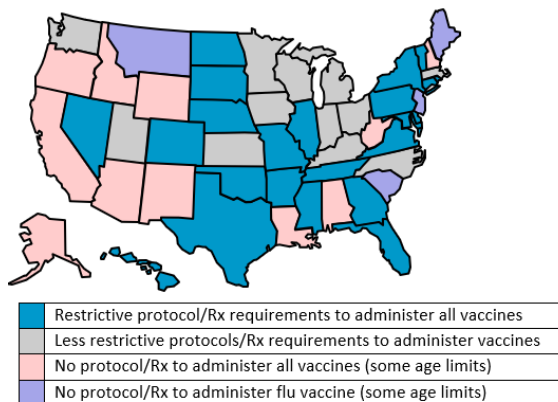
Pharmacist Authority to Vaccinate¹



Patient Age Restrictions for Pharmacist-Administered Vaccination²



Protocol or Rx Needed to Vaccinate³



¹ APhA/NASPA Survey of State Laws/Rules presentation (2019); State immunization laws (2018)

² APhA/NASPA Survey of State Laws/Rules presentation (2019); State immunization laws (2018)

³ APhA/NASPA Survey of State Laws/Rules presentation (2019); State immunization laws (2018)

ADDITIONAL RECOMMENDATIONS FOR SECTION IV

ALTERNATIVE ACTION 1.2:

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

Statutory Changes – Statewide Protocols
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VA Code Ann. § 54.1-3300 Definitions

...

“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 the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; ~~and~~ the management of patient care under the terms of a collaborative agreement as defined in this section; **and implementing Board authorized protocols for initiating the dispensing of drugs and devices or providing other patient care services.**

“Protocol” means an order for a predetermined course of treatment that is signed and dated by a prescriber and pharmacist(s) authorizing the pharmacist(s) to initiate the dispensing of medications, over-the-counter medications, or other professional services. The protocol shall direct the care, based on current clinical guidelines and standards of care, for treating authorized conditions, and meets the following requirements:

B. Protocols shall contain the following elements:

- 1. Criteria for identifying persons eligible to receive medication therapies or other professional services under the protocol, and referral to an appropriate prescriber if the patient is high-risk or treatment is contraindicated;**
- 2. A list of the medications, including name, dose, route, frequency of administration, and refills authorized to be dispensed under the protocol;**
- 3. Procedures for how the medications are to be initiated and monitored, including a care plan implemented in accordance with clinical guidelines;**
- 4. Education to be provided to the person receiving the dispensed medications, including aftercare instructions, if appropriate;**
- 5. Length of time protocol is in effect;**
- 6. Date and signature of prescriber approving the protocol;**
- 7. Dates and signatures of pharmacists authorized to initiate dispensing of medications or other professional services under the protocol; and**

C. Protocols may authorize dispensing and administration as appropriate of the following categories of drugs and devices in accordance with established standards of care:

- 1. Dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;**
- 2. Opioid antagonists;**
- 3. Epinephrine auto-injectors;**
- 4. Tobacco cessation products;**
- 5. Tuberculin purified protein derivative products; and**
- 6. Products supporting chronic care management where there are clinical gaps in care;**
- 7. Drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:**
 - a. Do not require a new diagnosis;**
 - b. Are minor and generally self-limiting;**
 - c. Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or**
 - d. In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.**

ALTERNATIVE ACTION 1.3: PROPOSED REVISIONS TO VA CODE TO BROADEN PHARMACISTS' AUTHORITY TO PERFORM DELEGATED ACTS AND PROVIDE POPULATION-LEVEL PATIENT CARE SERVICES UNDER COLLABORATIVE PRACTICE AGREEMENTS:

Statutory Changes – Collaborative Practice

VA Code Ann. § 54.1-3300. Definitions.

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

...

"Collaborative agreement" means a voluntary, written, or electronic arrangement between **one pharmacist and his designated alternate multiple** pharmacists involved directly in patient care **at a single physical location where patients receive services** and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health

Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, **involved directly in patient care** which authorizes **pharmacists to perform any patient care service delegated to the pharmacist(s) by 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.

...

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

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

No patient shall be required to **obtain a service from a pharmacist provided under a collaborative practice agreement participate in a collaborative procedure without such patient's consent.** A patient who **is referred to a pharmacist by a prescriber to obtain a service under a collaborative practice agreement and** chooses to not **obtain such service participate in a collaborative procedure** shall notify the prescriber of his refusal to participate in such collaborative procedure. **A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.**

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No **such** collaborative agreement shall exceed the scope of practice of the

respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

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

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303. 1999, cc. 895, 1011; 2013, c. 192; 2018, c. 776.

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

...

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

reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of § 38.2-3407.7.

VA Code Ann. § 38.2-4221. Services of certain practitioners other than physicians to be covered

...

B. If a subscription contract provides reimbursement for a service that may be legally performed by a licensed pharmacist, reimbursement under the subscription contract by the nonstock corporation shall not be denied because the service is rendered by the licensed pharmacist provided that (i) the service is performed for a subscriber for a condition under the terms of **pharmacist prescriptive authority, protocols or** a collaborative agreement, as defined in § 54.1-3300, between a pharmacist and the physician with whom the subscriber is undergoing a course of treatment or (ii) the service is for the administration of vaccines for immunization. Notwithstanding the provisions of § 38.2-4209, the nonstock corporation may require the pharmacist, any pharmacy or provider that may employ such pharmacist, or the collaborating physician to enter into a written agreement with the nonstock corporation as a condition for reimbursement for such services. **In addition, reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of § 38.2-4209.1.**

Regulatory Changes – Collaborative Practice

18 VAC 110-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

“Agreement” means a collaborative practice agreement as defined in § 54.1-3300 of the Code of Virginia.

“Committee” means an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members of the Board of Medicine.

“Pharmacist” means a pharmacist who holds an active license to practice pharmacy from the Virginia Board of Pharmacy.

“Practitioner” means a person authorized to have an agreement with a pharmacist and his designated alternative pharmacists as prescribed in the definition of a collaborative agreement in § 54.1-3300 of the Code of Virginia.

18 VAC 110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner involved directly in patient care and a pharmacist involved directly in patient care. Within the agreement, the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care **at a single physical location** where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. Documented informed consent from the

patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

1. The patient may decline to participate or withdraw from participation at any time.
2. Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.
3. As part of the informed consent Where applicable, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

18 VAC 110-40-30. Approval of protocols outside the standard of care.

A. If a practitioner and a pharmacist intend to manage or treat a condition or disease state for which there is not a guideline protocol that is clinically accepted as the standard of care, the practitioner and pharmacist shall apply for approval. The committee shall, in accordance with § 2.2-4019 of the Code of Virginia, receive and review the proposed treatment protocol and recommend approval or disapproval to the boards.

B. Application and approval are not needed for treatment of conditions for which there is an accepted standard of care, but for which the practitioner wants to increase the monitoring and oversight of the condition over what the protocol recommends.

C. In order to apply for approval of a protocol outside the standard of care, the practitioner and the pharmacist shall submit:

1. An application and required fee of \$750;
2. A copy of the proposed protocol; and
3. Supporting documentation that the protocol is safe and effective for the particular condition or disease state for which the practitioner and the pharmacist intend to manage or treat through an agreement.

18 VAC 110-40-40. Content of an agreement and treatment protocol.

A. An agreement shall contain treatment protocols that are clinically accepted as the standard of care within the medical and pharmaceutical professions.

B. The treatment protocol shall describe the disease state or condition to be managed or treated or the patient care service a pharmacist is otherwise authorized to provide, and shall include details such as drugs or drug categories, drug therapies, laboratory tests, medical devices, and substitutions authorized by the practitioner, or any other acts that the practitioner has delegated authority to the pharmacist to perform.

C. The treatment protocol shall contain a statement by the practitioner that describes the activities the pharmacist is authorized to engage in, including:

1. The procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management;
2. The procedures the pharmacist shall follow for documentation; and
3. The procedures the pharmacist shall follow for reporting activities and results to the practitioner.

D. The signatories shall implement a procedure for periodically reviewing and, if necessary, revising the procedures and protocols of a collaborative agreement.

E. If either the practitioner or the pharmacist who is a party to the agreement has a change of **location or** change of ownership, that person shall notify the other party and all patients who are participants in the collaborative agreement.

18 VAC 110-40-50. Record retention.

A. Signatories to an agreement shall keep a copy of the agreement on file at their primary places of practice.

~~B. An order for a specific patient from the prescribing practitioner authorizing the implementation of drug therapy management pursuant to the agreement shall be noted in the patient's medical record and kept on file by the pharmacist.~~

~~C. The patient's documented informed consent shall be retained by the practitioner in the patient record.~~

18 VAC 110-40-60. Rescindment or alteration of the agreement.

A. A signatory may rescind **or a patient may withdraw from** an agreement at any time.

B. A practitioner may override the collaborative agreement whenever he deems such action necessary or appropriate for a specific patient.

18 VAC 110-40-70. Compliance with statutes and regulations.

Any collaborative agreement or referral under an agreement governed by this chapter shall be in compliance with the requirements of the Practitioner Self-Referral Act (§ 54.1-2410 et seq. of the Code of Virginia) and with Chapters 29 (§ 54.1-2900 et seq.), 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and regulations promulgated pursuant thereto.