REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

The Dispensing of Drugs and Devices Pursuant to Pharmacy Collaborative Practice Agreements, Standing Orders, and Statewide Protocols (HJR 662, 2019)

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 2

COMMONWEALTH OF VIRGINIA
RICHMOND
2020

Code of Virginia § 30-168.

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor 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. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

JOINT COMMISSION ON HEALTH CARE MEMBERSHIP

Chair
The Honorable Rosalyn R. Dance

Vice-Chair
The Honorable T. Scott Garrett

Senate of Virginia
The Honorable George L. Barker
The Honorable Charles W. Carrico, Sr.
The Honorable Siobhan S. Dunnavant
The Honorable John S. Edwards
The Honorable L. Louise Lucas
The Honorable Glen H. Sturtevant, Jr.
The Honorable David R. Suetterlein

Virginia House of Delegates
The Honorable David L. Bulova
The Honorable Robert (Bob) Orrock
The Honorable C.E. (Cliff) Hayes, Jr.
The Honorable Patrick A. Hope
The Honorable Riley E. Ingram
The Honorable Kaye Kory
The Honorable Christopher K. Peace
The Honorable Christopher P. Stolle
The Honorable Roslyn C. Tyler

The Honorable Daniel Carey, M.D.
Secretary of Health and Human Resources, ex officio

Commission Staff

Michele L. Chesser, Ph.D.
Executive Director

Paula R. Margolis, Ph.D., MPH
Senior Health Policy Analyst

Andrew D. Mitchell, Sc.D.
Senior Health Policy Analyst

Stephen G. Weiss, M.P.A.
Senior Health Policy Analyst

Agnes Dymora
Executive Assistant/Office Manager

Preface

House Joint Resolution No. 662, introduced by Delegate Christopher P. Stolle, M.D. and Delegate Alfonso H. Lopez during the 2019 General Assembly session, mandated that the Joint Commission on Health Care (JCHC) study the dispensing of drugs and devices pursuant to pharmacy collaborative practice agreements (CPAs), standing orders and statewide protocols. The resolution specified that the JCHC: 1) evaluate laws and regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth pursuant to pharmacy CPAs, standing orders, and statewide protocols; 2) review the roles and responsibilities of pharmacists and other health care prescribing; 3) determine the legal liability of pharmacists and other health care providers pursuant to CPAs; 4) identify any changes to such laws or regulations governing the prescribing, dispensing and administration of drugs and devices pursuant to CPAs that would enhance patient access to health care in the Commonwealth; 5) develop specific proposals to implement changes identified, including amendments to laws and regulations necessary to implement such changes; and, 6) provide for stakeholder input from the Department of Health, the Department of Health Professions, the Medical Society of Virginia, the Virginia pharmacists Association.

Based on the study findings, eight policy options were presented for consideration by JCHC members who voted to introduce legislation to add independently practicing nurse practitioners and physician assistants as "practitioners" that can be parties to CPAs. In addition, the JCHC voted to request, by letter from the JCHC Chair, that the Boards of Pharmacy and Medicine convene a workgroup of expert stakeholders to determine if statewide standing orders can be expanded to include testing and dispensing drugs for conditions for which Clinical Laboratory Improvement Amendments (CLIA) waived tests exist, (e.g., antiviral medication for influenza, antibiotics for urinary tract infections, smoking cessation products, hormonal birth control, and others).

JCHC members and staff would like to acknowledge and thank those who assisted in this study including: Caroline D. Duran, Executive Director, Virginia Board of Pharmacy; William Harp, MD, DLFAPA, Executive Director, Virginia Board of Medicine; Elaine J. Yeatts, Senior Policy Analyst, Virginia Department of Health Professions; Donald C. Beatty, Deputy Commissioner, Virginia Bureau of Insurance (BOI); Julie Blauvelt, Deputy Commissioner Life & Health Division, Virginia BOI; Joseph Hilbert, Director of Government and Legislative Affairs, Virginia Department of Health (VDH); Lilian Peake, State Epidemiologist, VDH: Stephanie M. Wheawill, PharmD, Division of Pharmacy Services Director Office of Epidemiology, VDH; Christina Barrille, Executive Director, Virginia Pharmacists Association; Catherine Cary, PharmD, Bremo Pharmacy; Tana N. Kaefer, Pharm.D., Director of Clinical Services Bremo Pharmacies; Cynthia K. Kirkwood, PharmD, BCPP, Executive Associate Dean for Academic Affairs, Virginia Commonwealth University (VCU) School of Pharmacy; Joseph, Dean and Professor, VCU School of Pharmacy; Dave L. Dixon, PharmD, FACC, FCCP, FNLA, BPS, BCACP, CDE, CLS, Associate Professor and Vice Chair of Clinical Services, VCU School of Pharmacy; Jean-Venable Goode, Director of Community Pharmacy Practice and Residency

Program Professor, VCU School of Pharmacy; Craig A. Gill Director US Government Relations, Pfizer, Inc.; Howard P. Estes, Jr. Spotts Fain; Lauren Bates-Rowe, Assistant Vice President of Health Policy, Medical Society of Virginia (MSV); Clark Barrineau; Assistant Vice President of Government Affairs, MSV; Tara C. F. Ryan, Vice President State Government Affairs, Association for Accessible Medicines; Andrew T. Lamar, Principal, Lamar Consulting; Rebecca Snead, Executive Vice President and CEO, National Alliance of State Pharmacy Associations (NASPA); Allie Jo Shipman, PharmD, MBA, Director of State Policy, NASPA; Doug Gray, Executive Director Virginia Association of Health Plans.

The study and this report was assigned to and completed by Paula R. Margolis, Ph.D., MPH at the Joint Commission on Health Care. She may be contacted at pmargolis@jchc.virginia.gov.

Table of Contents

Executive Summary

House Joint Resolution (HJR) No. 662, introduced by Delegates Christopher P. Stolle, M.D. and Alfonso H. Lopez in the 2019 General Assembly session, directed the JCHC to study the dispensing of drugs and devices pursuant to prescriptions, pharmacy collaborative practice agreements (CPAs), standing orders, and statewide protocols in the Commonwealth. The Boards of Pharmacy and Medicine have oversight responsibility for CPAs. CPAs are agreements between a practitioner and a pharmacist and must include the condition that the pharmacist is authorized to address and protocols that are the accepted clinical standard of care.[i] If the parties to the agreement wish to use non-standard protocols, they must receive approval from the Boards. The Boards do not receive copies of CPAs, and oversight consists of responding to complaints. At the time of the study, the Boards had received no requests for approval of non-standard protocols nor complaints.

Presently in Virginia pharmacists may provide vaccines and dispense Naloxone without a physician prescription or being a party to a CPA. Several states have expanded the authority of pharmacists to provide certain medications without a physician's prescription, such as smoking cessation products, hormonal birth control, and anti-viral medication for influenza, and Colorado recently authorized autonomous dispensing authority to pharmacists. The Indian Health Service and Veterans Health Administration have allowed autonomous dispensing authority to pharmacists for several years. Expanding pharmacists dispensing authority may increase access to health services, promote public health goals, and reduce emergency department visits for conditions such as influenza.

Several policy options were offered for JCHC consideration, including expanding pharmacists dispensing authority, striking the requirement for the Boards of Pharmacy and Medicine to approve non-standard protocols, include physician assistants and independently practicing nurse practitioners to act as *practitioners* in CPAs, and requesting that the Boards of Pharmacy and Medicine convene a workgroup to provide recommendations to the JCHC for conditions and drugs that can be added to the current statewide standing orders (such as antiviral drugs for influenza and hormonal birth control pills). The JCHC elected to introduce legislation to include physician assistants and independent nurse practitioners as parties to CPAs and to request that a workgroup be convened to submit recommendations to the JCHC regarding expanded statewide standing orders.

[i] Defined in § 54.1-3300 of the *Code of Virginia as:* (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 and, (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... involved directly in patient care.

The Dispensing of Drugs and Devices Pursuant to Pharmacy Collaborative Practice Agreements, Standing Orders and Statewide Protocols

Introduction

House Joint Resolution No. 662, introduced by Delegate Christopher P. Stolle, M.D. and Delegate Alfonso H. Lopez, mandated that the Joint Commission on Health Care (JCHC) study the dispensing of drugs and devices pursuant to pharmacy collaborative practice agreements (CPAs), standing orders and statewide protocols. The resolution specified that the JCHC: 1) evaluate laws and regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth pursuant to pharmacy CPAs, standing orders, and statewide protocols; 2) review the roles and responsibilities of pharmacists and other health care prescribing; 3) determine the legal liability of pharmacists and other health care providers pursuant to CPAs; 4) identify any changes to such laws or regulations governing the prescribing, dispensing and administration of drugs and devices pursuant to CPAs that would enhance patient access to health care in the Commonwealth; 5) develop specific proposals to implement changes identified, including amendments to laws and regulations necessary to implement such changes; and, 6) provide for stakeholder input from the Department of Health, the Department of Health Professions, the Medical Society of Virginia, the Virginia pharmacists Association.

Background

CPAs are agreements between a *practitioner* (a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, and a physician assistant and nurse practitioner who has entered into a practice agreement with a patient care team physician) and a pharmacist and designated alternative pharmacist. Contents of a CPA must include the treatment protocol, disease state or conditions being treated, drugs or drug categories, laboratory tests, medical devices, substitutions authorized by the practitioner, authorized activities of the pharmacist, procedures for pharmacist documentation and periodic review. Patients must consent to be in an agreement and can opt out at any time, as can the practitioner and pharmacist.

A CPA must include protocols that are clinically accepted as the standard of care within the medical and pharmaceutical professions and include a statement by the practitioner that describes the activities the pharmacist is authorized to perform. If the practitioner and pharmacist intend to manage or treat a condition or disease state for which there is not a standard protocol, they must apply for approval to the Virginia Boards of Pharmacy (BOP) and Medicine (BOM) in accordance with the *Code of Virginia* §2.2-4019. The Boards do not receive, review or approve of CPAs that include standard protocols. At the time of the study, the BOP and BOM reported that no requests for approval of non-standard protocols had been received. The Boards respond to any complaints received in relation to a CPA, although at the time of the study, none had been received.

The terms, *protocol* and *standing order* are almost used interchangeably and allow someone other than the provider to enter, modify, or stop an order, on behalf of the provider. Standing

orders refer to orders that prescribe the actions to be taken in caring for patients related to specific conditions. They include dosage, route, and frequency of drug administration as well as administration of therapeutic procedures. The *Code of Virginia* allows the Commissioner of Health or their designee to issue standing orders for Naloxone and for routine vaccines. Several states have expanded standing orders to include anti-viral medications to treat influenza, smoking cessation aids, hormonal birth control, and other medications.

Medical protocols are sets of predetermined criteria that define appropriate nursing interventions and describe situations in which the nurse makes judgments relative to a course of action for effective management of common patient problems. Examples include: heparin administration, insulin infusion, wound care, pain management, and dietary management[ii]. Within a defined protocol, pharmacists are permitted to assume professional responsibility for performing patient assessments, counseling, making referrals, ordering laboratory tests, administering drugs, and selecting, initiating, monitoring and adjusting drug regimes.

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). Some laboratory tests are designated as *CLIA waived*. Waived tests employ relatively simple methodologies, and when they are performed properly, they are unlikely to yield erroneous results. Even when performed incorrectly, these tests are least likely to pose danger on the patients and can be performed by the patient at home. CLIA waived tests can be administered by a pharmacist, and if the results are positive the pharmacist may dispense appropriate drugs or refer the patient to a practitioner.

A study published in the journal of American pharmacists association demonstrated that testing for influenza and strep disease by pharmacists resulted in appropriate dispensing of anti-viral medication, and no patients were inappropriately given an antibiotic.[iii, iv]

Staff at the Virginia Department of Health (VDH) were asked to comment on the possibility of expanding pharmacist scope of practice to administer influenza tests and dispense anti-viral medication if the test is positive. VDH staff communicated concern that persons presenting with influenza symptoms at pharmacies may have more serious conditions, such as pneumonia which may go undetected. Pharmacists interviewed for this report expressed the opinion that they are trained to appropriately assess patients and refer them to medical practitioners when needed.

Pharmacist Education

Current national pharmacy education standards require that students complete a four-year course of study, earning a doctoral degree in pharmacy (*PharmD*). There is a national trend to phase out Bachelor level degrees. Students training at the Virginia Commonwealth University (VCU) School of Pharmacy must first complete 73 credit hours of prerequisites that include biology, chemistry, physics, anatomy, physiology, microbiology, biochemistry, calculus, statistics, communications, and biomedical science courses, such as genetics, molecular biology, immunology, and cell biology. The VCU PharmD program requires completion of 155.5 credit

[ii] https://www.hcpro.com/HIM-315444-865/Patient-care-ordersprotocols-What-do-the-regulations-say.html.
[iii] https://www.japha.org/article/S1544-3191(19)30349-8/pdf
[iv] This is important for addressing the overuse of antibiotics which can lead to antibiotic resistant infections.

hours over 4 years; courses include pharmacognosy, pharmaceutical calculations and biopharmaceutics, clinical therapeutics, pharmacokinetics, practice management, courses focused on each of the body systems, such as cardiovascular, endocrinology, infectious diseases, psychiatry, and hematology/oncology among others. Courses provide students with patient assessment skills necessary in patient-centered pharmacy practice and trains students in skills such as basic physical assessment techniques, interpretation of findings from laboratory tests or physical examinations, and documenting findings from patient assessments. Laboratory time is used to practice various assessment skills. One stakeholder interviewed during this study indicated that pharmacists don't need a doctoral degree to simply fill pill bottles. Expanding pharmacists' authorities could help increase access to people without insurance, people living in rural areas, and pharmacies that are open 24 hours allowing for more rapid treatment of common conditions.

Liability

The Code of Virginia, Title 8.0. Civil Remedies and Procedures Chapter 21.1 Medical Malpractice, defines the term *health care provider* and includes pharmacists in the definition. Section 8.01.581.15 specifies a schedule of the dollar amount of required liability insurance that a health care provider must maintain. The amount increases periodically, and the schedule goes through 2031. None of the individuals consulted for this study (including key stakeholders) indicated that liability was an issue for CPAs and did not feel it was a barrier to CPA participation.

Payment

Payment to pharmacists for services for assessments and medication management that are beyond the drug ingredient cost and dispensing fee are not consistently paid. Medicare Part D requires that insurers pay pharmacists for medication management, and the Virginia Medicaid program requires contracted managed care organizations to follow Medicare Part D rules regarding payment for pharmacist services. But the Department of Medical Assistance Services (DMAS) does not classify pharmacists as *providers*, (although pharmacists are classified as health care providers in other sections of the *Code of Virginia)*. Because DMAS does not classify pharmacists as *providers*, there is no authority or mechanism for DMAS to pay pharmacists for medication management outside of the managed care organization contracts (i.e., in the fee-for-service programs).

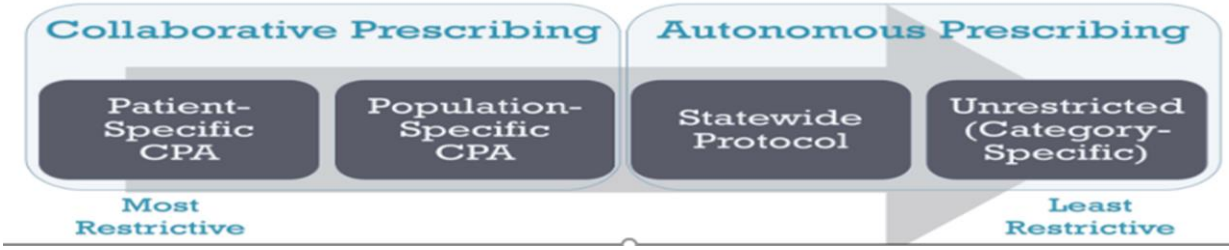
Actions in Other States

The scope of pharmacist practice can be visualized as a continuum from most restrictive to least restrictive (see Exhibit 1). Virginia's regulations fall midway on this continuum. A number of states have taken action to authorize more autonomy on the part of pharmacists. For example, as of August 2019, several states have statutes or regulations addressing pharmacist prescribing of tobacco cessation aids including Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Maine, New Mexico and West Virginia.[v] As of May 2019, ten states have statutes or regulations

[v] https://www.drugtopics.com/latest/six-new-clinical-services-pharmacists/page/0/4

that allow pharmacists to prescribe contraceptives without a CPA, including California, Colorado, District of Columbia, Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, and West Virginia.[vi]

Exhibit 1: Continuum of Pharmacy Practice.



Policy Options, JCHC Actions and Public Comments

Eight policy options were presented to the JCHC for consideration. The JCHC voted to adopt Options 4 and 7.

Table 1: Policy Options

1. Take no action
2. Introduce legislation, and accompanying budget amendment if needed, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of *provider*.
3. Introduce legislation striking the requirement that parties to a CPA must get approval for agreements containing non-standard protocols.
4. Introduce legislation to add Nurse Practitioners and Physician Assistants with prescription authority as practitioners that can participate in CPAs.
5. Introduce legislation to expand statewide standing orders to include some, or all of Streptococcus, influenza, urinary tract infections, hormonal birth control, smoking cessation aids, and tuberculosis testing.
6. Introduce legislation to allow pharmacists limited prescriptive authority, (e.g., for smoking cessation drugs, anti-viral drugs, birth control).
7. By letter from the JCHC Chair, request that the Boards of Pharmacy and Medicine convene a workgroup of expert stakeholders to determine if statewide standing orders can be expanded to other drugs (e.g., CLIA Waived tests).
8. Introduce legislation to amend 18VAC110-40-40 to allow the practitioner to determine *all* protocols and pharmacists' roles without the Boards' approval.

[vi] https://naspa.us/tag/pharmacist-prescriging/

Public Comments

The study mandate included obtaining comments from specific entities. In addition, public comment was received during a three-week public comment period. Comments from mandated stakeholders are below:

The Virginia Department of Health - VDH has no position on the issue of standing orders and deferred to the Department of Health Professions. VDH staff conveyed that standing orders are limited to those for vaccines and Naloxone, and for those designated by the Secretary during an emergency. The issue of health care workers being able to reach out to identified contacts of persons diagnosed with a sexually transmitted disease was discussed, particularly in relation to a contact who refuses to see a physician. The contact must be assessed for allergies and contraindications for drugs that may be prescribed. Currently, only a Health Department physician may reach out to a contact.

Virginia Commonwealth University School of Pharmacy - "Graduate students in the Department of Pharmaceutics are required to complete a common core of entry-level graduate courses, including statistics, physical pharmacy, biopharmaceutics, drug metabolism, pharmacokinetics, pharmaceutical analysis and seminars in drug development. Building upon this core, students then specialize, through advanced coursework and meritorious research, in an area of concentration within the department. Training includes patient assessment/history, and exam skills. They recommend expanding the scope of standing orders to include common infectious diseases (urinary tract, influenza, Strep throat, other CLIA waivered conditions), and smoking cessation (Ziban, Chantix)." VCU representatives also discussed establishing a committee to develop statewide protocols for conditions such as hypertension, diabetes, renal disease, that would not require a CPA. Payment for expanded services is a significant barrier. Most, if not all, pharmacists working under a CPA are working in clinics; very few, if any, work in a community pharmacy.

National Alliance of State Pharmacy Associations (NASPA) - There are conditions where a diagnosis is not needed, e.g., someone using tobacco products. Pharmacists could dispense smoking cessation drugs. Although there is a Statewide Standing Order for Naloxone, if an insurance company requires pre-authorization, the State Health Commissioner is not going to provide information needed by the health plan – pharmacists' prescriptive authority would remove that barrier." NASPA supports several of the policy options presented to the Commission and encourages Commission members to take action on the following:

Option 2. Introduce legislation, and accompanying budget amendment, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of provider (enactment of legislation will depend on BA approval) (Option.

Option 3. Introduce legislation striking the requirement that parties to a CPA must get approval from Boards of Physicians and Medicine for agreements containing non-standard protocols.

Option 4. Introduce legislation to add independent nurse practitioners and physician assistants as the practitioner (as defined in CPA regulations) in a CPA.

Option 6. Introduce legislation to allow pharmacists limited prescriptive authority, (e.g., for smoking cessation drugs, anti-viral drugs, birth control).

Option 8. Introduce legislation to amend 18VAC110-40-40 to allow the practitioner to determine all protocols and pharmacists' roles without the Boards' approval.

In addition, NASPA encourages Commission members to introduce legislation clarifying that collaborative practice agreements are not patient-specific and that a separate CPA is not needed for each patient.

National Association of Chain Drug Stores (NACDS) – "Given the national imperative to improve healthcare quality, the entire healthcare continuum must be evaluated to advance, improve, and innovate. A myriad of compelling evidence demonstrates that greater inclusion of pharmacists in direct patient care is scalable and leads to less administrative burden on other providers, increased cost efficiency, more cohesive teams, and most importantly, improved patient outcomes. Community pharmacists, as the most accessible and frequently visited healthcare team member, complement care provided by others through facilitation of convenient access to affordable, high-quality preventive, chronic and acute care. In fact, the role of community pharmacists has evolved rapidly over the last two decades to include immunizations, screenings, health and wellness, treatment for minor illnesses, medication optimization, chronic care management, and more. Such services are often tethered synergistically to others in the healthcare community to improve care coordination.

Given the evolving healthcare needs of Virginians, we urge the Commission to modernize, innovate, and harmonize the Commonwealth's outdated pharmacy care laws and policies by removing unwarranted and burdensome restrictions placed on pharmacists, which dampen capacity to fully leverage their clinical expertise and thereby deprive patients of necessary advancements in transformational care services and delivery. Our recommendations are set forth in the NACDS Position Matrix. We also included additional supporting documentation/evidence (for full context, please refer to NACDS' October 1st letter that has been incorporated by reference herein). NACDS greatly values the opportunity to provide support for the reformation of pharmacy practice within the Commonwealth, and we appreciate the Commission's consideration of our recommendations on the proposed policy options."

The NACDS submitted a 103-page document including a wide variety of information addressing the issues covered in the study. In summary, the NACDS favors expanding the scope of pharmacy practice and implementing less restrictive rules than are current in Virginia. "NACDS strongly urges the commission to adopt our Priority Recommendation to Advance Patient Care and our Additional Recommendation to Advance Immunizations as well as alternative, secondary options if our two priority recommendations are not adopted." Their recommendations are found below:

Priority Recommendation to Advance Patient Care – Prescriptive Authority First Preference-Adopt Policy Option #6: Introduce legislation to allow pharmacists limited prescriptive authority (with suggestion to strike and replace "limited prescriptive authority" with "unrestricted,

category-specific prescriptive authority"), (e.g. for smoking cessation drugs, anti-viral drugs, birth control). Alternate Recommendation– Statewide Standing Orders:

Second Preference- Policy Option #5: Introduce legislation to expand statewide standing orders (with suggestion to strike and replace "statewide standing order" with "statewide protocols") to include some, or all of Streptococcus, Influenza, Urinary Tract Infections, hormonal birth control, smoking cessation aids, and tuberculosis testing. Recommendation to Modernize Collaborative Practice Agreements, implemented concurrently with priority recommendation above:

Third Preference- Policy Option #3: Introduce legislation striking the requirement that parties to a CPA must get approval from Boards of Pharmacy and Medicine for agreements containing non-standard protocols.

Fourth Preference- Policy Option #8: Introduce legislation to amend 18VAC110-40-40 to allow the practitioners to determine all protocols and pharmacists' roles without the Boards' approval.

Policy Option #4: Introduce legislation to add independent nurse practitioners and physician assistants as the practitioner (as defined in CPA regulations) in a CPA. Additional CPA Suggestions: (a) Allow prescribers to authorize pharmacists to prescribe, modify, discontinue, initiate, etc. medication therapies; and (b) Permit all licensed pharmacists to enter into CPAs, without specific certification or educational training requirements. Recommendation for Coverage of Pharmacy Services:

Fifth Preference- Adopt Policy Option #2: Introduce legislation, and accompanying budget amendment, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of *provider*.

Additional Recommendation to Advance Immunizations– New Policy Option: Suggest Creation of a 9th Policy Option for Inclusion in Decision Matrix: Remove constraining and unnecessary requirements for protocols and prescriptions for pharmacists to immunize patients of any age in the Commonwealth.

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 (e.g., 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; 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.

The Virginia Pharmacists Association (VPhA) - Pharmacists are the most accessible healthcare provider and play a large role in reducing the burdens of access, quality and costs. With this in mind, VPhA endorses the following policy options from the Commission's study presented on October 4: Policy Option 2: Introduce legislation, and accompanying budget amendment, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of provider (enactment legislation will depend on BA approval). An aging population and provider shortfalls contribute to health care access problems. There are several areas of the state where the provider to citizen ratio falls significantly below the recommended level to achieve balance and optimal outcomes. For DMAS to add pharmacists to the list of DMAS providers would improve access to the most at need population with some of the worst provider to citizen ratio. In DMAS' recognition of pharmacists as providers for billing services, the payments must reflect the effort and time involved in following the patient from the beginning to the end of the encounter. Pharmacists provide effective and efficient care: Research shows that pharmacists patient care services result in significant cost savings. Allowing patients to access care from pharmacists can help DMAS realize cost savings.

Policy Option 5: Introduce legislation to expand statewide standing orders (prefer to refer to this option as statewide protocols) to include all CLIA waivered tests. Statewide standing orders are easy to develop and modify, and there is precedent with the Naloxone standing order. The Board of Pharmacy also has experience with issuing statewide standing orders. In response to VDH's concern about pharmacists' level of training to assess/differentiate influenza from pneumonia and other conditions, pharmacists already assess and refer patients on many conditions and will continue to do so. A statewide protocol allowing pharmacists to test and treat if positive for influenza and Streptococcus would allow for accurate and timely treatment. Patients who either do not have a primary care provider or cannot visit one during their established office hours would receive care with appropriate follow up. Pharmacists are available 24/7. All licensed pharmacists, whether clinical or retail, meet the required certification needed to implement any protocol, including performing physical assessments. While some may prefer to only give clinical pharmacists authority, clinical pharmacists make up only 6% of the established practice settings. This practice setting alone would not address the challenge of access and improved outcomes.

Policy Option 6: Introduce legislation to allow pharmacists limited prescriptive authority (e.g., for smoking cessation drugs, anti-viral drugs, birth control). Pharmacists are appropriately trained and capable of practicing autonomously including post-diagnostic prescribing and prescribing for preventive treatments and treatments for conditions that are easily identified. Autonomous pharmacist prescribing is authorized in many states today and pharmacists are thoroughly trained to select and optimize mediation regimens. Cumberland County recently experienced a scabies outbreak. Many clinics and offices refused to see the patients due to contagious circumstances. Cumberland Pharmacy had plenty permethrin, but no ability to

dispense it without a provider. If the pharmacy had prescriptive authority, and maybe an emergency prescriptive authority in this instance, it could have prevented many more cases and treated existing ones. In conclusion, pharmacists are highly trained professionals who are capable, like other providers, of exercising appropriate judgment regarding prescribing and treatment. With the decrease in Family Practice providers and the expansion of Medicaid, the underserved population is growing quickly. Adequately prepared pharmacists can help fill this deficit in care. Pharmacists should not be subjected to more burdensome restrictions than other non-physician prescribers. Excessive regulations increase the cost of healthcare by creating inefficiencies and decreasing access to affordable, effective care.

JCHC Staff for this Report

Paula R. Margolis, Ph.D., MPH
Senior Health Policy Analyst