THE DISPENSING OF DRUGS AND DEVICES PURSUANT TO PHARMACY COLLABORATIVE PRACTICE AGREEMENTS, STANDING ORDERS, AND STATEWIDE PROTOCOLS

Joint Commission on Health Care
October 4, 2019 Meeting

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STUDY MANDATE – HOUSE JOINT RESOLUTION NO. 662

STUDY THE DISPENSING OF DRUGS AND DEVICES PURSUANT TO PRESCRIPTIONS, PHARMACY COLLABORATIVE PRACTICE AGREEMENTS (CPA), STANDING ORDERS, AND STATEWIDE PROTOCOLS

- Roles and responsibilities of pharmacists.
- Pharmacy laws and regulations including legal liability of pharmacists and providers in a CPA
- Standing orders and protocols and scope of practice.
- Identify changes to laws or regulations that would enhance patient access.

See Appendix I for HJR 662 language.

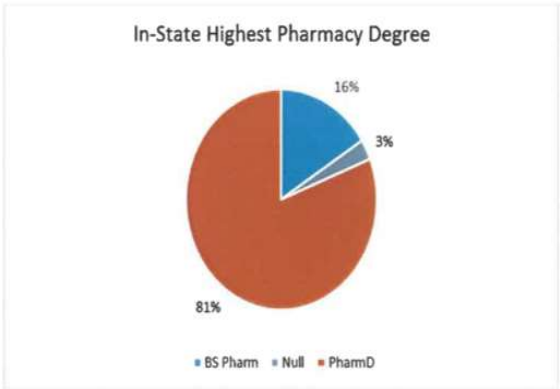
BACKGROUND

Characteristics of Virginia pharmacist workforce, 2019[1]

- Eighty-one percent of 478 survey respondents working in Virginia who indicated they participate in a CPA report having earned a PharmD (doctoral degree) and 16% have a BS degree.
- Three percent did not respond.
- Virginia Commonwealth University School of Pharmacy no longer offers a B.S. degree in pharmacy; only the PharmD program is offered, which is a national trend.

Highest Professional Degree

A large majority (81%) report having earned a PharmD and 16% a BS Pharmacy degree. 3 % did not respond to the question.

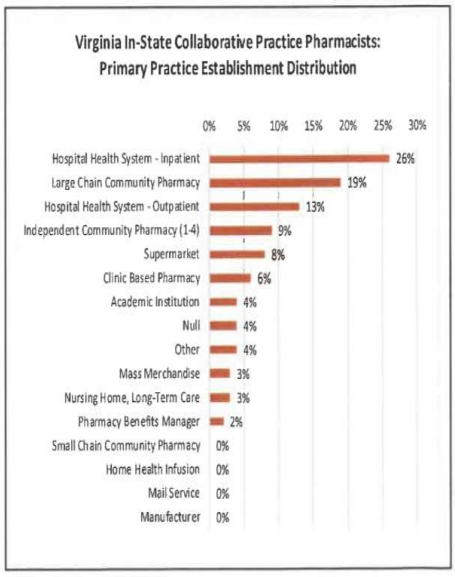


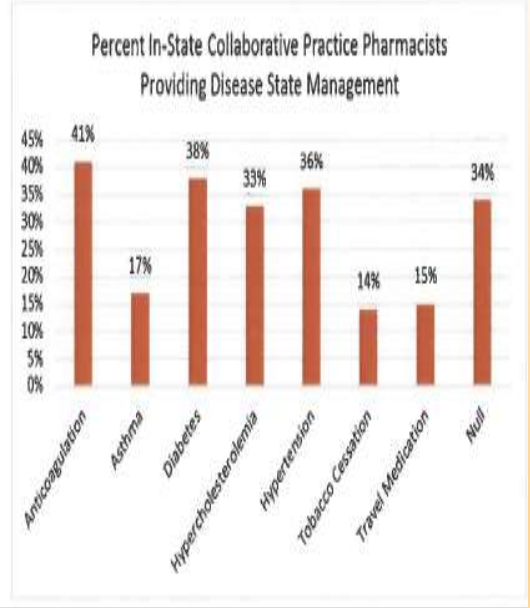
[1] Data Source: Virginia Department of Health Professions Collaborative Practice Analysis -2019 DRAFT.

Practice Establishment Setting

More than half report working in Hospital/Health Care settings and Large Chain Community Pharmacies as their Primary Practice Location.

The remaining establishment types with over 5% of practitioners are Independent Community Pharmacies, Supermarkets and Clinic Based Pharmacies.





[1] Virginia Department of Health Professions Collaborative Practice Analysis -2019 DRAFT.

ROLES AND RESPONSIBILITIES OF PHARMACISTS

Accreditation Council for Pharmacy Education (ACPE) Requirements for a PharmD[1]

- **Basic Patient Assessment**: Collect, record, and assess subjective and objective patient data to define health and medication-related problems.
  Performance competencies include:
  - **Collect patient histories** in an organized fashion, appropriate to the situation and inclusive of cultural, social, educational, economic, and other patient-specific factors affecting self-care behaviors, medication use and adherence.
  - Obtain, record, and interpret a history from a patient to at minimum include **drug allergies and reactions, drugs (prescription, non-prescription, and herbal) being taken, doses being used, cultural, social, educational, economic, and other patient-specific factors affecting self-care.**
- **Obtain and interpret patient information** to:
  - determine the presence of a disease, medical condition, or drug-related problem(s), and **assess the need for treatment and/or referral.**
  - include a **basic medication history** from a patient to include drug allergies, a description of allergic reactions, drugs being taken, doses being used, over-the-counter medications being taken, and herbal/natural products being used.
- **Evaluate a patient's medication profile** to identify appropriate doses and patient instructions, duplicate medications, and clinically relevant drug interactions.

1. https://www.acpe-accredit.org/pdf/GuidanceforStandards2016FINAL.pdf

American Association of Colleges of Pharmacy - Core Entrustable Activities[1]

- Collect information to identify medication-related problems and health-related needs.
- Analyze information to determine the effects of medications, identify problems, prioritize health-related needs.
- Establish patient-centered goals and create a care plan that is evidence-based and cost-effective.
- Implement the care plan with the treatment team:
  - Follow-up and monitor the care plan.
  - Collaborate as a team member.
  - Identify patients at risk for prevalent diseases.
  - Minimize adverse drug events and errors.
  - Maximize the appropriate use of medications.
  - Ensure patients are appropriately immunized.

1. https://www.aacp.org/sites/default/files/2017-11/CoreEntrustableProfessionalActivitiesforNewPharmacyGraduates.pdf

Virginia Commonwealth University school of pharmacy prerequisites and curriculum

- **Prerequisites** - seventy-three credits hours including: biology, chemistry, physics, anatomy, physiology, microbiology, biochemistry, calculus, statistics, communications, biomedical science courses, such as genetics, molecular biology, immunology, and cell biology.
- **Curriculum** - 155.5 credit hours over 4 years including: Pharmacognosy, pharmaceutical calculations and biopharmaceutics, clinical therapeutics, pharmacokinetics, practice management, courses focused on body systems, such as cardiovascular, endocrinology, infectious diseases, psychiatry, hematology/oncology, etc.
- **Example of course description** - PHAR 541 Patient Assessment in Pharmacy Practice (30 hrs). Semester course; variable lecture and laboratory hours. Provides students with an introduction to patient assessment skills necessary in patient-centered pharmacy practice. Course topics include basic physical assessment techniques, interpretation of findings from laboratory tests or physical examinations and documenting findings from patient assessments. Laboratory time will be used to practice various assessment skills. The course will also build on communication and information skills presented in previous courses.

For full requirements see:
http://bulletin.vcu.edu/professional-studies/pharmacy/pharmacy-pharmd#degreerequirementstext.

CDC Guidance on Pharmacists' Roles under MTM and CPAs [1]

Medication Therapy Management

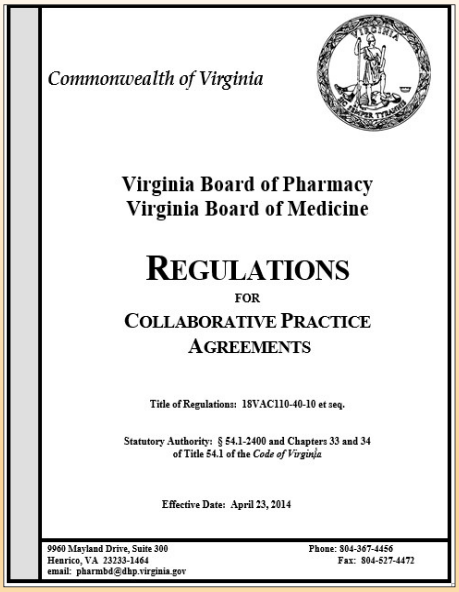
- Medication therapy review
- Personal medication record
- Medication-related action plan
- Intervention and/or referral
- Documentation and follow-up

Collaborative Drug Therapy Management

- Within a defined protocol pharmacists are permitted to assume professional responsibility for performing:
  - Patient assessments
  - Counseling
  - Referrals
  - Order lab tests
  - Administer drugs
  - Selecting, initiating, monitoring, continuing and adjusting drug regimes

1. https://www.dhp.virginia.gov/pharmacy/ . Centers for Disease Control and Prevention. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. Atlanta, GA: US Dept. of Health and Human Services, Centers for Disease Control and Prevention; 2013.

LAWS AND REGULATIONS



Commonwealth of Virginia

Virginia Board of Pharmacy
Virginia Board of Medicine

REGULATIONS
FOR
COLLABORATIVE PRACTICE AGREEMENTS

Title of Regulations: 18VAC110-40-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Effective Date: April 23, 2014

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Henrico, VA 23233-1464
email: pharmbd@dhp.virginia.gov

Phone: 804-367-4456
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Virginia Administrative Code Chapter 18: Professional and Occupational Licensing

See Appendix II for details.

CPA Regulation Summary

- Oversight is performed by the Boards of Pharmacy and Medicine. CPA signatories include a ***'practitioner'*** and a ***'pharmacist'*** involved in direct patient care.
- **"Practitioner"** means a person authorized to have an agreement with a pharmacist...as prescribed in the definition of a collaborative agreement § 54.1-3300 of the *Code of Virginia:* (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.
- Alternative pharmacists may be designated by the pharmacist at a single location.
- There must be **documented informed consent from the patient**. Any of the parties, including the patient, may withdraw from the agreement at any time. Records, consents and orders must be kept on file at the primary places of practice.
- Contents of an agreement include: the treatment protocol, disease state or conditions, drugs or drug categories, laboratory tests, medical devices, and substitutions authorized by the practitioner, authorized activities of the pharmacist, procedures for pharmacist documentation and procedure for periodic review.

Boards of Pharmacy and Medicine Approval of Protocols Outside the Clinical Standard of Care

- If a practitioner and pharmacist intend to manage or treat a condition or disease state for which there is **not a protocol that is clinically accepted as the standard of care**, the practitioner and pharmacist shall apply for approval to an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members from the Board of Medicine who will receive and review the proposed treatment protocol and recommend approval or disapproval to the boards.
- **The JCHC may wish to amend 18VAC110-40-40 to allow the practitioner to determine all protocols and pharmacists' roles without the Boards' approval, in order to reduce unnecessary steps, reduce lag time to when a pharmacist may begin the protocol, and reduce the Boards' work loads.[1]**

1. The National Governors Association. The Expanding Role of Pharmacists in a Transformed Health Care System, updated in October 2014.

Liability

***Code of Virginia* Title 8.01. Civil Remedies and Procedure Chapter 21.1. Medical Malpractice**

- § 8.01-581.1. Definitions - "Health Care Provider" means (i) a person, corporation, facility or institution licensed by this Commonwealth to provide health care or professional services as a physician or hospital, dentist, **pharmacist**, registered nurse or licensed practical nurse or a person who holds a multistate privilege to practice such nursing under the Nurse Licensure Compact, nurse practitioner, optometrist, podiatrist, physician assistant, chiropractor, physical therapist, physical therapy assistant, clinical psychologist, clinical social worker, professional counselor, licensed marriage and family therapist, licensed dental hygienist, health maintenance organization, or emergency medical care attendant or technician who provides services on a fee basis.

***Code of Virginia* §8.01.581.15.**

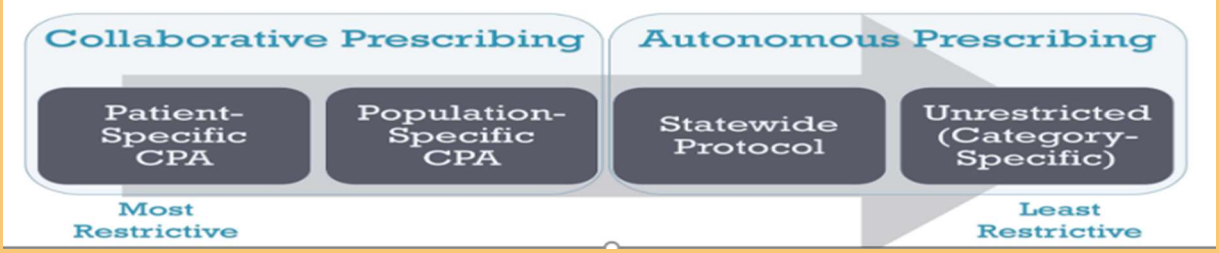
- For SFY 2019, the amount of required liability protection is $2.35M and increases by $5M each SFY through 2031.

The JCHC may wish to introduce language to add pharmacists to the list of DMAS providers and amend 38.2-3408 C.

- DMAS does not enroll pharmacists as providers due to federal regulations (pharmacists are not included in key sections of the Social Security Act which determine eligibility for payment by Medicare Part B[1] and under the Family Medical Leave Act); therefore, pharmacists are unable to bill DMAS for services provided to fee-for-service enrollees.[2]
- § 38.2-3408. (Effective October 1, 2019) 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 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.
- **C. This section shall not apply to Medicaid, or any state fund.**
- These sections do not apply to HMOs but Section 38.2-4312.E. prohibits discrimination against any class of providers listed in Section 38.2-4221.E (which includes pharmacists.) [4]

1. https://www.pharmacist.com/provider status-what-pharmacists-need-to-know-now.
2. Correspondence with DMAS Pharmacy Director, April 18, 2019.
3. Correspondence with BOI Deputy Commissioner, Life & Health Division, Sept. 20, 2019.
4. Correspondence with BOI Deputy Commissioner, Life & Health Division, Sept. 16, 2019.

Scope of Practice



Examples of Federal Programs and Policies Regarding the Provision of Services by Pharmacists

- The Indian Health Service has been engaged in an advanced pharmacy practice model whereby pharmacists deliver direct patient care services with physician collaboration since the early 1970s.
  - Clinical privileges are required for any position in which the clinical pharmacist has patient care activities and serves as a non-physician provider to initiate, modify, renew, or discontinue medication therapy. **The clinical privileges allow the clinical pharmacist to function with a high level of autonomy in collaboration with the health care team for the overall care of the patient. Prescriptive authority will be limited to practice areas for which the clinical pharmacist has experience and expertise, to include:**
  - addressing medication management needs of patients with defined diagnoses, management of medication-related adverse events, ongoing and acute medication monitoring, and collaboration with other health care providers for management of new diagnoses for patients. [1]
- The Veterans Health Administration implemented a similar program in 1995 that updated the granting of prescribing authority for clinical pharmacy specialists.
- The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Public Law 108-173, required Medicare Part D prescription drug plan sponsors to offer pharmacist MTM services to beneficiaries with multiple chronic diseases (e.g., diabetes, hypertension).
- Medicare Part D plan sponsors are required to reimburse pharmacies for MTM services separate and in addition to drug ingredient costs and dispensing fees.[2]

1 https://www.ihs.gov/ihm/pc/part-3/p3c7/

2 A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases, National Center for Chronic Disease Prevention and Health Promotion, 08/2012.

Standing orders and statewide protocols

- 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 (in 2011, CMS issued a transmittal which addressed standing orders [1]).
- A *standing order* is an order conditioned upon the occurrence of certain clinical events. The important characteristic of a standing order is that **all the patients who meet the criteria for the order receive the same treatment**. A common use of standing orders is in public health clinics that treat specific diseases.
- *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.
- *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[2].

1. https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r77soma.pdf
2. https://www.hcpro.com/HIM-315444-865/Patient-care-ordersprotocols-What-do-the-regulations-say.html

Example of Standing orders

Code of Virginia § 54.1-3408. Professional use by practitioners.

- X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued **by a prescriber or a standing order issued by the Commissioner of Health** or his designee authorizing the **dispensing of naloxone** or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Several state allow pharmacists to dispense tobacco cessation and hormonal birth control products without a CPA

- As of August 2019, several states have statutes or regulations addressing pharmacist prescribing of tobacco cessation aids (without a CPA or local standing order). [1]
  - Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Maine, New Mexico and West Virginia.
- As of May 2019, ten U.S. states have statutes or regulations that allow pharmacists to prescribe contraceptives without a CPA:
  - California, Colorado, District of Columbia, Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, and West Virginia.[2]

1. https://www.drugtopics.com/latest/six-new-clinical-services-pharmacists/page/0/4
2. https://naspa.us/tag/pharmacist-prescriging/

The jchc may consider expanding statewide standing orders to include smoking cessation products

Through expanded authority and national efforts to advance the tobacco cessation knowledge and skills of pharmacy students and licensed pharmacists, the profession's role in tobacco cessation has evolved substantially in recent years. Eight states have created, or are in the process of creating, pathways for autonomous pharmacist prescriptive authority.[1]

MYTH

Tobacco cessation aids are **too dangerous** for pharmacists to prescribe. In 2016, FDA removed the Boxed Warning from Chantix (varenicline) and Zyban (bupropion).

FACT

Pharmacists have been safely prescribing these medications in New Mexico since 2004. [2]

1. https://www.japha.org/article/S1544-3191(18)30001-3/fulltext
2. https://naspa.us/resource/tobacco-cessation/

The jchc may consider expanding statewide standing orders to include hormonal contraceptives for some women

- The American College of Obstetricians and Gynecologists (ACOG) supports access to comprehensive contraceptive care and methods ..and is committed to encouraging and upholding policies and actions that ensure the availability of affordable and accessible contraceptive care and contraceptive methods. In order to accomplish this goal, ACOG recommends and supports over-the-counter access to oral contraceptives with accompanying full insurance coverage or cost supports.[1]
- Women at higher risk for unintended pregnancy, such as younger women, women who had previous unintended pregnancy, women belonging to a minority group, and women without insurance are likely to utilize the pharmacy to procure hormonal contraception.
- **As May 2019, several states had legislation in place allowing pharmacists to furnish or prescribe FDA-approved self-administered hormonal contraception; California, Colorado, New Mexico, Oregon, Hawaii, Maryland, Utah, Tennessee, New Mexico, Washington State and Washington D. C.,** and several other states are considering legislation to promote or advance pharmacist-prescribed hormonal contraception.
- All states require **an educational or training component** that pharmacists must undergo prior to prescribing.
- Congressional Democrats introduced legislation in both chambers on June 113, 2019 to require insurance to cover any birth control pills and to make them available over-the-counter without a prescription.[2]

1. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception
2. Tak CR, Kessler LT, Scott MA, Gunning KM, Pharmacist-Prescribed Hormonal Contraception: A Review of the Current Landscape, Journal of the American Pharmacists Association (2019), doi: https://doi.org/10.1016/j.japh.2019.05.015.

The jchc may wish to mandate the creation of an expert workgroup to develop a list of drugs or drug categories for which the commissioner of health can issue statewide standing orders

- A workgroup may consist of representatives from the Boards of Pharmacy and Medicine, the Department of Health, DMAS, the Secretary of Health and Human Services, the VCU School of Pharmacy and other expert stakeholders, in order to develop a list of drugs or drug classes that can be included in statewide standing orders.
- Diseases for which CLIA-waivered tests exist may be used as a resource.
- The JCHC also may consider creating a permanent workgroup, or determining a sunset clause which can be periodically updated, in order to be able to respond to a changing environment.

Clinical Laboratory Improvement Amendments (CLIA) Waived Tests

- Waived testing is laboratory testing that employs test methods designated under CLIA of the Food and Drug Administration (FDA) as "waived."
- To be "waived" means that certain tests can be performed without the need for the conduct of more stringent standards imposed by CLIA.[1]
- The FDA classifies as "waived" tests that employ relatively simple methodologies when performed properly **are least likely 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.**
- One example of a CLIA waived test is influenza. A list of CLIA waived tests may be accessed at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

1. https://www.labce.com/spg1376052_definitions_point_of_care_testing_and_waived_testi.aspx

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The jchc may consider expanding statewide standing orders to include influenza testing and dispensing of antiviral products

- Respiratory tract infections are a common cause of visits to emergency departments and outpatient settings.
- Evidence published in the Journal of American Pharmacists Association showed that pharmacist influenza testing an be effective.
  - The purpose of this study was to demonstrate the feasibility of implementing a CLIA-waived, real time testing into a community pharmacy setting as part of an influenza and group A *Streptococcus*(GAS) disease management program.
  - Two hundred and two patients received care at 2 pharmacies Sixty (38%) tested positive for influenza with 51 receiving an antiviral prescription and 16 (18%) testing positive and treated for GAS. No patient testing negative for either or positive for influenza was dispensed an antibiotic. For patients consenting to a follow up culture, all GAS cultures sent for confirmatory testing were negative.
- **Conclusions: A protocol driven community pharmacy-based disease management program utilizing real time testing for influenza and GAS was able to offer appropriate treatment to patients without overuse of antibiotics.**
- Feedback from VDH included concern that Influenza presents with non-specific "flu-like" symptoms. Pharmacists do not have the training to assess/differentiate influenza from pneumonia and other conditions with similar symptoms. Pharmacists providing testing without examining the patient could result in a missed or delayed diagnosis.

1. https://www.japha.org/article/S1544-3191(19)30349-8/pdf

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Policy Options
1. Take no action
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).
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.**
4. Introduce legislation to add independent nurse practitioners and physician assistants as the practitioner (as defined in CPA regulations) in a CPA.
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.

PUBLIC COMMENTS

Written public comments on the proposed options should be submitted to JCHC by close of business on October 25, 2019.

Comments may be submitted via:

- E-mail: jchcpubliccomments@jchc.virginia.gov
- Fax:804-786-5538
- Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 14th decision matrix meeting.

(All public comments are subject to FOIA release of records)

APPENDIX I: STUDY MANDATE – HOUSE JOINT RESOLUTION NO. 662

Patrons: Delegate Christopher P. Stolle, M.D.

And Delegate Alfonso H. Lopez

"WHEREAS a pharmacist practicing in the Commonwealth may only dispense drugs or devices pursuant to a valid prescription issued by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine…; a physician assistant licensed by the Board of Medicine who has entered into a practice agreement with a licensed physician…; a nurse practitioner (NP)…who has entered into a practice agreement with a patient care team physician; or a TPA-certified optometrist, or pursuant to a standing order or protocol in accordance with a collaborative practice agreement;

And WHEREAS the roles and responsibilities of pharmacists vary depending on the authority pursuant to which they dispense drugs or devices; now, therefore, be it RESOLVED

…that the JCHC be directed to study the dispensing of drugs and devices pursuant to prescriptions, pharmacy collaborative practice agreements (CPAs), standing orders, and statewide protocols in the Commonwealth."

- **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;
- **Review the roles and responsibilities** of pharmacists and other health care prescribing providers including the evaluation of the roles and responsibilities of pharmacists authorized to practice pursuant to pharmacy collaborative practice agreements, conducting patient assessments and identifying appropriate drugs or devices for dispensing or administration;
- **Determine the legal liability** of pharmacists and other health care providers pursuant to CPAs;
- **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.
- **Develop specific proposals** to implement changes identified, including amendments to laws and regulations necessary to implement such changes;
- **Provide for stakeholder input** from the Department of Health, the Department of Health Professions, the Medical Society of Virginia, the Virginia pharmacists Association.

Appendix II. CPA Regulations

18VAC110-40-10. 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.

§ 54.1-3300

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and

(i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry;

(ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement;

(iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or

(iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes.

§ 32.1-276.3 "Physician's office" means a place (i) owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever or by a corporation, partnership, limited liability company or other entity that employs or engages physicians, and (ii) designed and equipped solely for the provision of fundamental medical care, whether diagnostic, therapeutic, rehabilitative, preventive or palliative, to ambulatory patients.

§ 54.1-2957 C. A nurse practitioner who meets the requirements of subsection I may practice without a written or electronic practice agreement.

§ 54.1-2957 I. A nurse practitioner, other than...in the category of certified nurse midwife or certified registered nurse anesthetist, who has completed the equivalent of at least five years of full-time clinical experience as a licensed nurse practitioner, as determined by the Boards, may practice in the practice category in which he is certified and licensed without a written or electronic practice agreement upon receipt by the nurse practitioner of an attestation from the patient care team physician...

§ 54.1-2957.01 A. In accordance with the provisions of this section…a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1.3400 et seq.).

18VAC110-40-20. 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, 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.

18VAC110-40-30. 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 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*, (Informal fact finding proceedings) 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.

18VAC110-40-40. Content of an agreement and treatment protocol

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

A. The treatment protocol shall describe the disease state or condition, drugs or drug categories, drug therapies, laboratory tests, medical devices, and substitutions authorized by the practitioner.

B. 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.

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

D. 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.

18VAC110-40-50. 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.

18VAC110-40-60. 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.

18VAC110-40-70. 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.

Appendix III: Other Related Regulations

***Code of Virginia* Title 54.1. Professions and Occupations Subtitle III. Professions and Occupations Regulated by Boards within the Department of Health Professions Chapter 33. Pharmacy - Article 1. General Provisions**

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with

(i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry;

(ii) a physician's office as defined in § 34.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement;

(iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or

(iv) Any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

Title 54.1. Professions and Occupations Subtitle III. Professions and Occupations Regulated by Boards within the Department of Health Professions Chapter 33. Pharmacy - Article 1. General Provisions, Continued

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

Title 54.1. Professions and Occupations Subtitle III. Professions and Occupations Regulated by Boards within the Department of Health Professions Chapter 33. Pharmacy - Article I. General Provisions, Continued

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

Virginia Administrative Code 18VAC110-40-10 through 70 - Professional and Occupational Licensing Agency 110 Board of Pharmacy

- The signatories to an agreement shall be a practitioner and a pharmacist involved directly with patient care. The pharmacist may designate alternate pharmacists, provided they are involved directly in patient care and at a single physical location.
- An agreement shall only be implemented for an individual patient pursuant to an **order from the practitioner**. Documented informed **consent from the patient** shall be obtained by the practitioner or the pharmacist who are party to the agreement.
- If a practitioner and pharmacist intend to manage or treat a condition or disease state for which there is **not a protocol that is clinically accepted as the standard of care, the practitioner and pharmacist shall apply for approval to an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members from the Board of Medicine** who will receive and review the proposed treatment protocol and recommend approval or disapproval to the boards.
  - There is an application fee of $750.

Virginia Administrative Code 18VAC110-40-10 through 70 - Professional and Occupational Licensing Agency 110 Board of Pharmacy

- **An agreement shall contain treatment protocols that are clinically accepted as the standard of care** within the medical and pharmaceutical professions.
- The treatment protocol shall:
  - Describe the disease state, drug(s) or drug categories, drug therapies, lab tests, medical devices and substitutions authorized by the practitioner.
  - Contain **a statement by the practitioner that describes the activities the pharmacist is authorized to engage** in, including;
    - The procedures, decision criteria, or plan the pharmacist shall follow,
    - The procedures the pharmacist shall follow for documentation, and reporting activities and results to the practitioner.
    - **A procedure for periodic review and revision** of procedures and protocols of the agreement.
    - **An order for a specific patient** from the prescribing practitioner authorizing the implementation of the drug therapy management shall be noted in the patient's medical record and kept on file by the pharmacist.
    - The patient's document informed consent shall be retained by the practitioner in the patient record.
    - A signatory may rescind or a patient may withdraw from an agreement at any time.
    - A practitioner may override the agreement whenever he deems necessary or appropriate for the patient.

§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted

A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless

(i) the prescriber indicates such substitution is not authorized by specifying on the prescription,

"brand medically necessary" or

(i) the patient insists on the dispensing of the brand-name drug product.

§ 54.1-3408.04. Dispensing of interchangeable biosimilars permitted

A pharmacist may dispense a biosimilar that has been licensed by the U.S. Food and Drug Administration as interchangeable with the prescribed product unless

(i) the prescriber indicates such substitute is not authorized by specifying on the prescription "brand medically necessary" or

(ii) the patient insists on the dispensing of the prescribed biological product. In the case of an oral prescription, the prescriber's oral dispensing instructions regarding dispensing of an interchangeable biosimilar shall be followed.

Title 54.1 Professions and occupations; Chapter 34: Drug Control Act. § 54.1-3401. Definitions.

- "Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

Title 38.2 Insurance. § 38.2-602. Definitions.

- "Medical professional" means any person licensed or certified to provide health care services to natural persons, including but not limited to, a physician, dentist, nurse, chiropractor, optometrist, physical or occupational therapist, social worker, clinical dietitian, clinical psychologist, licensed professional counselor, licensed marriage and family therapist, pharmacist, or speech therapist.

Title 38.2 Insurance Chapter 28. Medical Malpractice Joint Underwriting Association § 38.2-2800. Definitions.

"Provider of health care" means any of the following deemed by the Commission to be necessary for the delivery of health care: (i) a physician and any other individual licensed or certified pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1; (ii) a nurse, dentist, or pharmacist licensed pursuant to Title 54.1; (iii) any health facility licensed or eligible for licensure pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 or Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2; and (iv) any other group, type, or category of individual or health-related facility that the Commission finds to be necessary for the continued delivery of health care after providing notice and opportunity to be heard.

Appendix IV: Examples of State Laws Regarding Scope of Practice and Pharmacist Status

State	Description
Wash.	48.43.094 Pharmacist provided services—Health plan requirements. (1) For health plans issued or renewed on or after January 1, 2017: (a) Benefits shall not be denied for any health care service performed by a pharmacist licensed if: (i) The service performed was within the lawful scope of such person's license; (ii) The plan would have provided benefits if the service had been performed by a physician..., an advanced registered nurse practitioner..., or a physician's assistant; and (iii) The pharmacist is included in the plan's network of participating providers; and (b) The health plan must include an adequate number of pharmacists in its network of participating medical providers. (2) The participation of pharmacies in the plan network's drug benefit does not satisfy the requirement that plans include pharmacists in their networks of participating medical providers. (3) For health benefit plans issued or renewed on or after January 1, 2016, but before January 1, 2017, health plans that delegate credentialing agreements to contracted health care facilities must accept credentialing for pharmacists employed or contracted by those facilities. Health plans must reimburse facilities for covered services provided by network pharmacists within the pharmacists' scope of practice per negotiations with the facility.

State	Description
CO	The legislature approved legislation that would require insurers to reimburse pharmacists for services delivered in an area with a health professional shortage, if the plans cover the same services when delivered by a physician or advanced practice nurse. The legislation provides an opportunity for pharmacists to bill and get reimbursed for non-dispensing services and expands access for patients in rural communities.
Idaho	• HB 3 includes prescribing, administering, and interpreting tuberculosis tests. • HB 4 includes prescribing all tobacco cessation therapies. • HB 191 allows the state Board of Pharmacy to determine drugs or devices that pharmacists may prescribe for certain conditions.
WVA	• A bill that passed in the state legislature offering West Virginians birth control pills, rings, and patches to women aged 18 and over took effect in June, 2019. • The screening process will be similar to that of vaccines, ruling out issues such as high blood pressure and other factors that could put their health at risk.
AZ	• SB 1269 Allows pharmacists to authorize emergency refills for maintenance medications, prescribe OTC and prescription nicotine replacement products, and administer oral fluoride varnish.
TN	• SB 461 includes pharmacists in private insurance plans as providers. • HB 628 covers MTM by pharmacists in Medicaid.

PharmacyToday, March 2018

Appendix V: Pharmacists' roles in medication therapy management

PHARMACIST SERVICE	DEFINITION & ASSOCIATED SERVICES	EXAMPLES OF CURRENT PRACTICE
Medication Management	• Medication management, in the form of MTM, has been defined by the pharmacy profession as: *a distinct service or group of services that optimize therapeutic outcomes for individual patients that are independent of, but can occur in conjunction with, the provision of a drug product.*[117] • Components of medication management typically include collecting medical and drug histories from patients, patient education, comprehensive medication review, medication monitoring, and provider outreach to relay recommendations for adjustments to drug therapy when necessary.	• Since 2006, MTM has been a required part of the Medicare Part D benefit. Although requirements have evolved over the years, this program has generally targeted patients with multiple chronic conditions utilizing multiple Part D-covered drugs. • Pharmacist-provided medication management is also provided through Medicaid and commercial payers, and can vary from Part D MTM in scope of services and patients targeted. • Pharmacist-provided medication management has been implemented in private sector patient-centered medical homes (PCMHs) with pharmacists receiving payment for services rendered.[118]

https://avalere.com/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment

Medication Reconciliation	• Medication reconciliation can be defined as: *the comprehensive evaluation of a patient's medication regimen any time there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions, as well as to observe compliance and adherence patterns. This process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten or adjusted, or if the patient has added nonprescription medications to [his or her] self care.*[119]	• The focus on reducing medication discrepancies during transitions of care has been growing. Medication reconciliation is a particularly important part of ensuring continuity of care during transitions across different settings. • Pharmacists in some care transition programs increasingly deploy more robust medication management in addition to obtaining accurate medication lists. • Medication reconciliation is a component of medication management, but also can be a stand-alone service. This practice may be evolving from solely reconciliation to more robust medication management. • Medication reconciliation can be provided by a number of healthcare practitioners, including pharmacists.

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PHARMACIST SERVICE	DEFINITION & ASSOCIATED SERVICES	EXAMPLES OF CURRENT PRACTICE
Preventive Services (Screening and Immunization)	• Screening includes tests waived under the Clinical Laboratory Improvement Amendments, such as cholesterol and glycated hemoglobin measurements, and screening for infectious disease (e.g., *Streptococcus pneumoniae*, hepatitis C, HIV), among others. • Immunizations include pharmacist-administered vaccinations, as allowed by each state's scope of practice.	• Pharmacists have recently taken more visible roles in preventive care, primarily as front line advocates for screening for major diseases and through the promotion and administration of vaccines.[19,22] • Screening and vaccination by pharmacists are regulated by state law, and requirements and circumstances vary by state.
Education and Behavioral Counseling	• Some literature evaluates stand-alone counseling related to "health and wellness," such as tobacco cessation, or related to a patient's medication therapy with targeted goals of improving measures of medication use. • Pharmacist-provided education and behavioral counseling can occur as one component of other interventions.	• Pharmacist-provided education and behavioral counseling can be implemented in a variety of settings. For instance, pharmacists have provided targeted counseling in ambulatory/outpatient settings, post-hospital discharge, and community pharmacy settings.[24,26,120] • Pharmacy coaching programs have been used by private health plans in value-based insurance designs.[29]

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COLLABORATIVE CARE MODELS	DEFINITION & ASSOCIATED SERVICES	EXAMPLES OF CURRENT PRACTICE
Collaborative Drug Therapy Management	• Although the above services can be performed individually in collaboration with physicians or other providers, more formal collaborative care models have been defined in state practice guidelines to provide a mechanism for facilitating these services, in addition to enabling a broader scope of practice for pharmacists in close collaboration with physicians. • The principal type of arrangement is formally known as "collaborative drug therapy management" (CDTM), and is defined as *a collaborative practice agreement between one or more physicians and pharmacists wherein qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens.*[121]	• Although the scope of CDTM can vary by state, 47 states allowed pharmacists to practice collaboratively with physicians through CDTM as of 2013.[122] • CDTM models have been implemented in a variety of settings, spanning physician offices,[46,123] Veterans Affairs Medical Centers,[40,124] hospital outpatient clinics,[45] inpatient settings,[125] community pharmacies,[126] and pharmacy clinics.[127] • CDTM models have been deployed across a number of therapeutic areas, including diabetes,[41,128] hypertension,[36,129] dyslipidemia,[40,42] heart failure,[130] and anticoagulation,[45,125] among others.

Appendix VI: Stakeholder Input

Commonwealth Strategy & Virginia Commonwealth Health System

The National Alliance of State Pharmacy Associations

Virginia Department of Health

Virginia Department of Health Professions (Boards of Pharmacy and Medicine)

Virginia Pharmacy Association

Virginia Department of Medical Assistance Services

Virginia Commonwealth University School of Pharmacy

Bremo Pharmacy

The Medical Society of Virginia

The Virginia Society of Health System Pharmacists

The Center for Health Hearts Free Clinic

- **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.

- **VCU 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).
- 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**
  - 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.

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