

**VERMONT SECRETARY OF STATE  
OFFICE OF PROFESSIONAL REGULATION**

**EVALUATION OF PHARMACIST PRESCRIBING AUTHORITY**

Page | 1

The Office of Professional Regulation (OPR) evaluated the costs and benefits of expanding pharmacists' scope of practice to include prescribing authority. In light of stakeholder input and the known effects of pharmacist-based prescribing models in other jurisdictions, we believe appropriately-limited prescribing by pharmacists could benefit Vermonters by broadening access to care while integrating the pharmacist clinician into healthcare teams and facilitating efficient collaboration with primary-care providers.

**Introduction and History of Clinical Pharmacy in Vermont**

**a. Background**

The legislature requested that OPR examine a proposal brought to it by the Vermont Pharmacists Association (VPA), the Vermont Retail Druggists (VRD), with assistance from the National Alliance of State Pharmacy Associations (NASPA). Beginning with a presentation to the Vermont Board of Pharmacy in December 2018, and continuing through the first half of the 2019-2020 legislative biennium, VPA, VRD, and NASPA requested that regulators and legislators modernize the statutory scope of pharmacy practice, with particular attention to the convenience and efficiency that may be unlocked by delivering models of clinical pharmacy care now prevailing in hospitals and larger clinical institutions at the level of the community pharmacy. As a result, the General Assembly has directed the Office of Professional Regulation (OPR) as follows:

*(a) The Office of Professional Regulation shall evaluate the costs and benefits of incorporating prescribing authority into the scope of practice of licensed pharmacists. This evaluation shall be conducted in consultation with relevant stakeholders and shall include consideration of:*

- (1) approaches to clinical pharmacy in jurisdictions outside Vermont;*
- (2) potential impacts on patient safety and on primary and preventive care delivered by other health care professionals;*
- (3) effects on patient access to care; and*
- (4) the appropriate extent, if any, of the prescribing authority.*

*(b) On or before January 15, 2020, the Office shall report its findings and any recommendations for legislative action to the House and Senate Committees on Government Operations, the House Committee on Health Care, and the Senate Committee on Health and Welfare.*

-2019 No. 30, § 15.

Hospital and clinic pharmacists generally work at the top of their licenses, deploying the full range of professional skills attained through education, training, experience, and testing. Retail pharmacists, who form a majority of working pharmacists, generally do not. Quintessentially, all pharmacists perform drug utilization reviews; assess pharmacotherapeutic appropriateness of prescribed medications,

checking for drug interactions, contraindications, and inappropriate dosing; provide patient counseling and drug information related to side-effects, lifestyle/disease-state warnings; and perform the final check for errant dispensing. However, many retail pharmacists' tasks are more mechanical and ministerial than clinical. Retail pharmacists play an important role in inventory, storage, packaging, dispensing, and sometimes compounding. Under current law, community pharmacists do not, however, engage in prescribing—the actual selection of a specific drug and dose. Unless actively paired with a third-party prescriber, the pharmacist under current law is constrained to work with the clinical judgments of others, executing the prescription drug orders of a physician, dentist, physician assistant, nurse practitioner, or naturopath, but powerless even in the simplest cases to make clinically prudent adjustments to the pharmacotherapy prescribed to a diagnosed patient.

To be sure, organized pharmacy, like every professional lobby, will tend to prefer and to seek ever broader discretion and more expansive practice privileges for its members, because those seem to come with enhanced professional importance and related commercial opportunities. We take these in-profession incentives for granted and look beyond them to the merits for the health, safety, and welfare of Vermonters.

Clinical pharmacy exists and functions very well in large institutions. Clinician-pharmacists already are found in most Vermont hospitals. The question becomes whether and how to embrace *community* clinical pharmacy: the idea of leveraging the clinical expertise of pharmacists at the local level, whether in a traditional retail setting or in a small provider's office, to provide convenient, basic care at points accessible to patients. The benefits of doing so could be considerable, as could the detriments. In a rural state perennially struggling to maximize access to care for its most vulnerable and least mobile citizens, proximity is a big deal, and a big deal too often ignored by regulators. By comparison to large clinics and physician offices, which generally cluster around cities, retail pharmacies are everywhere. Local pharmacies and the pharmacists they employ represent an untapped, built healthcare resource with exceptional geographic distribution. To expand the role of the pharmacist as a clinician is to expand the role of the pharmacy as a locus of clinical consultation.

*Done right*, community clinical pharmacy could improve medication compliance; enhance medication management of persons with chronic conditions; allow cost-saving therapeutic substitution; preserve scarce emergency-room beds and primary-care appointments for those who truly need them; provide underserved communities a critical entrée to the organized healthcare system; introduce a novel and badly-needed screening and referral system in rural localities; and save ordinary Vermonters as well as primary-care providers untold hours of unnecessary driving, waiting, calling, and paper-pushing. *Done wrong*, however, thoughtless expansion of access to prescription drugs could undermine the medical home centered around a designated primary-care provider; facilitate drug-seeking behavior; confuse primary-care providers as to the pharmacotherapies used by their patients; or divert patients who need the attention of a primary-care provider into dangerous efforts at self-management of conditions that may be more serious than they at first appear.

Fundamentally, the challenge confronting us in optimizing the scope of clinical pharmacy practice is how to make the pharmacy and clinical pharmacist an adjunct and extender of a primary-care home, without turning pharmacies into ersatz, self-help walk-in clinics without a diagnostician in sight. States are finding creative ways to meet that challenge, and we can learn from their experiences.

Forty-nine states have some type of pharmacist prescribing authority, most in the form of collaborative practice agreements (CPAs), statewide protocols or standing orders. Its naloxone protocol<sup>1</sup> and administrative rules allowing pharmacist immunization by way of CPA make Vermont one of them. Four States have more *generalized* pharmacist prescribing authority. Of particular note is the state of Idaho, which has introduced broad prescriptive authority.<sup>2</sup>

In addition to naloxone protocol-based prescribing and immunization, Vermont pharmacist prescribing activities have been in place for many years, most extensively in institutional pharmacy settings. Hospitals have Pharmacy and Therapeutics committees—interdisciplinary committees comprised of medical, nursing and pharmacy staff, hospital quality improvement representatives, and other health care professionals—that are charged with formulary management and oversight of medication-use processes, to include the approval of pharmacist clinical privileges and protocols including: therapeutic substitution to formulary medications; dose adjustments; “dose per pharmacy” protocols for weight-based medications requiring frequent titration to optimal pharmacotherapeutic effect; automatic switch of intravenous to oral dosage forms; and, pharmacist-ordered renal and coagulation labs. Additionally, pharmacists in Veteran’s Administration Medical Centers have enjoyed federal-level prescribing authority since 1995.<sup>3</sup>

In Vermont, pharmacist clinicians embedded within primary and ambulatory care practices and patient care programs, such as Vermont’s Support and Services at Home (SASH) program<sup>4</sup>, perform functions ranging from comprehensive medication review and patient assessments to CLIA-waived testing<sup>5</sup> and medication prescribing to manage chronic diseases.

Development of well-established patient-healthcare provider relationships, fostering trust, is not uncommon in community (retail) pharmacy. Resultant, in-depth knowledge of a patient’s personal- and family medical histories augment patient care. Community pharmacists routinely provide extensive pharmaceutical care for their patients with respect to over-the-counter (OTC) medications. This care includes: 1) drug-disease state interaction review, 2) product recommendations and warnings based on age, pregnancy or lactation, 3) assessment of the appropriateness for OTC self-care, 4) prescribed drug information counseling, and 5) referral to primary or emergency care.

The following table, from an article describing such services, illustrates the patient-care services repertoire of today’s community pharmacist.<sup>6</sup>

<sup>1</sup> The nearly universal decision by states to make naloxone—an opiate-overdose reversal agent—available liberally through pharmacies is less an example of clinical pharmacy in action than a collective state override of the FDA decision to make naloxone a legend drug. The states have effectively noted the fact and used protocols to make naloxone available over the counter regardless.

<sup>2</sup> K. Weaver, A. Horton. Provider Status Implantation and Maryland Legislative Update. [https://cdn.ymaws.com/www.marylandpharmacist.org/resource/resmgr/2018\\_Mid-Year/2018\\_Presentations/Weaver.pdf](https://cdn.ymaws.com/www.marylandpharmacist.org/resource/resmgr/2018_Mid-Year/2018_Presentations/Weaver.pdf)

<sup>3</sup> S. Clause, J. Fudin, A. Mergener, J.L. Lutz, MM. Kavanaugh, K. Fessler, S. Chirumamilla. Prescribing Privileges Among Pharmacists in Veterans Affairs Medical Centers. *Am J Health-Syst Pharm.* 2001; 58:1143-5

<sup>4</sup> “SASH coordinates the resources of social-service agencies, community health providers and nonprofit housing organizations to support Vermonters who choose to live independently at home” <https://sashvt.org/learn/>

<sup>5</sup> CLIA is an initialism for Clinical Laboratory Improvement Amendments. CLIA waived tests are generally simple and non-technical. CLIA regulations address test complexity, proficiency testing, quality assurance, and other clinical laboratory processes establishing quality standards for clinical laboratory testing for patient diagnosis and treatment. Over 1,400 test systems have been waived. See <https://www.acponline.org/practice-resources/business-resources/laboratory-proficiency-testing-program/cli-waived-testing>.

<sup>6</sup> J. Goode, J. Owen, A. Page, S. Gatewood. Community-Based Pharmacy Practice Innovation and the Role of the Community-Based Pharmacist Practitioner in the United States. *Pharmacy* 2019, 7, 106

Medication Optimization	Wellness and Prevention	Chronic Care Management	Acute Care Management	Patient Education	Other Patient Care Services
	<b>Screenings</b>				
	Blood pressure				
	Diabetes				
	Cholesterol				
	Osteoporosis				
	Body Fat				
	HIV				
	Hepatitis C				
Medication Packing	Allergy				
	Lead poisoning				
Home Delivery	<b>Risk Assessment</b>				
	Falls	Diabetes			
Medication Reconciliation	Depression	HTN			
	Asthma	Cholesterol		Store	
	Cardiovascular risk	Asthma		• Brochures	
Appointment-Based Medication Synchronization	Weight management	Anticoagulation		• Videos	
	Tobacco cessation	Heart failure	Test and treat (rapid diagnostics)	• Shelf-talkers	
		Hepatitis C		• Posters	Tuberculosis testing
Medication Adherence Programs	Contraception	Menopause		Individual	Telehealth
		Monitoring through laboratory testing	• Influenza	Group	Durable medical equipment
Comprehensive Medication Management Services	Bioidentical hormone replacement	• BHRT	• Strep	Exercise classes	Care transitions
	Fluoride treatments	• saliva testing	Urgent care (minor ailments)	Diabetes prevention program	Population health
	Naloxone	• Anticoagulation	• <i>H. pylori</i>		Emergency preparedness
Targeted Medication Review	Needle exchange	• A1c	• TSH		
	Drug take back	• Pharmacogenetics	• Triage and referral	Diabetes education program	
Medication Administration	Nutraceuticals	• Liver function			
Deprescribing	Annual wellness				
	• In physician office				
	Pharmacogenomics				
	Sleep assessment				
	Falls prevention				
	Immunizations				
	Pre-travel health services				

Reproduced from: Pharmacy 2019, 7, 106

## b. The Safety of Contemporary Pharmacist Training and Testing:

States have felt comfortable expanding the scope of pharmacist prescribing, in part because rigorous national accrediting standards establish consistent curricular standards. Since 2000, the mandatory degree for pharmacists is the Doctor of Pharmacy, or PharmD. The evolution to doctoral training began in 1948 when the American Council on Education declared that the pharmacy degree should be a 6-year program, provoking colleges of pharmacy throughout the United States to begin implementing PharmD programs.<sup>7</sup> In addition to foundational coursework in jurisprudence and biological and pharmaceutical sciences, the current PharmD curriculum provides extensive training in clinical sciences and pharmacy

<sup>7</sup> DH. Kreling, PhD, WR. Doucette, PhD, EH. Chang, PharmD, CA. Gaither, PhD, DA. Mott, PhD, JC. Schommer, PhD. Practice Characteristics of Bachelor of Science and Doctor of Pharmacy Degreed Pharmacists Based on the 2009 National Workforce Survey. *American Journal of Pharmaceutical Education* 2010; 74 (9) Article 159

practice. Clinical modules focus on the pathophysiology, therapeutics, pharmacology and medicinal chemistry related to infectious diseases, GI/nutrition, neurology/psychology, rheumatology/oncology, nephrology/toxicology, as well as, the cardiovascular, respiratory, endocrine and genitourinary systems. Pharmacy skills labs provide hands-on training in physical assessment, laboratory testing, patient counseling and pharmacy practice integrated problem-solving activities include case studies, instruction in pharmacist patient care processes, drug information, biostatistics and scientific literature evaluation.<sup>8</sup>

Approximately one-third of graduating pharmacy students elect to pursue post-graduate residencies,<sup>9</sup> typically two years in duration, providing enhanced competency and focused expertise in a variety of specialties, from ambulatory and critical care to cardiology, infectious diseases, internal medicine, solid organ transplant, psychiatric and emergency medicine.<sup>10</sup>

The Bachelor's-trained pharmacist is in no way an inferior pharmacy clinician. Nine years after the PharmD became mandatory, a 2009 pharmacist survey showed that pharmacists in community pharmacy settings (vs. hospitals) spent the same amount of time in patient-care activities regardless of degree type.<sup>11</sup> A 2015 Vermont Department of Health (VDH) pharmacy workforce survey found that 99.0% of VT pharmacists who graduated since 2005 earned PharmD degrees.<sup>12</sup> A 2017 VDH pharmacy workforce survey showed that 51.6% of Vermont's pharmacists hold PharmD vs. BS degrees.<sup>13</sup>

It is professionally required that all pharmacy graduates, whether BS- or PharmD-trained, stay current with advancements in pharmacotherapeutics and healthcare. As a result, in lock-step with requirements for Vermont physicians, all pharmacists holding a Vermont license must engage in 30 hours of continuing education (CE) per 2-year licensing period. Vermont Administrative Rules for the Board of Pharmacy, at Rule 3.7, require that pharmacist's CE programs, "...shall include subject matter designed to maintain the professional competence of pharmacists licensed to practice and to improve their professional skills in order to protect the public health and safety."<sup>14</sup> Furthermore, only CE approved by the Accreditation Council for Pharmacy Education (ACPE) is acceptable.<sup>15</sup> The ACPE is the organization responsible for the accreditation of pharmacy schools, including enforcement of standards for the PharmD curriculum, so pharmacy continuing education closely matches evolving curricular standards.

### c. Office of Professional Regulation's Approach to this Report and Stakeholder Outreach

At its core, this report assesses other states' and nations' models for pharmacist prescribing. Extensive research into those models is elaborated upon below. The Office of Professional Regulation (OPR) also made every effort to examine empirical studies and data to assess risks to patient safety when pharmacists prescribe.

To gather stakeholder input, OPR noticed and convened two stakeholder meetings in Montpelier, one November 14<sup>th</sup>, the other November 20<sup>th</sup>, and both available by webcast to participants who could not travel to the capital. There were more than twenty participants, including prescribers from a variety of specialties including family practice, pediatrics and psychiatry, and type, including physicians, a

<sup>8</sup> Current Curriculum for PharmD at Albany College of Pharmacy and Health Sciences, sent to me from S. Rosa, Director of Pharmacy Practice Experiences, ACPHS

<sup>9</sup> G. Kalinoski. Residency Programs: Not Enough to Go Around. *Drug Topics* August 14, 2017.

<sup>10</sup> What is a Residency and How Do I Get One? *American College of Clinical Pharmacy*.

<sup>11</sup> DH. Kreling, PhD, WR. Doucette, PhD, EH. Chang, PharmD, CA. Gaither, PhD, DA. Mott, PhD, JC. Schommer, PhD. Practice Characteristics of Bachelor of Science and Doctor of Pharmacy Degreed Pharmacists Based on the 2009 National Workforce Survey. *American Journal of Pharmaceutical Education* 2010; 74 (9) Article 159

<sup>12</sup> [https://www.healthvermont.gov/sites/default/files/documents/pdf/HS\\_Pharm-2015.pdf](https://www.healthvermont.gov/sites/default/files/documents/pdf/HS_Pharm-2015.pdf)

<sup>13</sup> <https://www.healthvermont.gov/sites/default/files/documents/pdf/Pharm2017.pdf>

<sup>14</sup> <https://www.sec.state.vt.us/media/702345/5-RX-Rules-2015-Final-Adopted-August-24-2015.pdf>

<sup>15</sup> <https://www.acpe-accredit.org/about/>

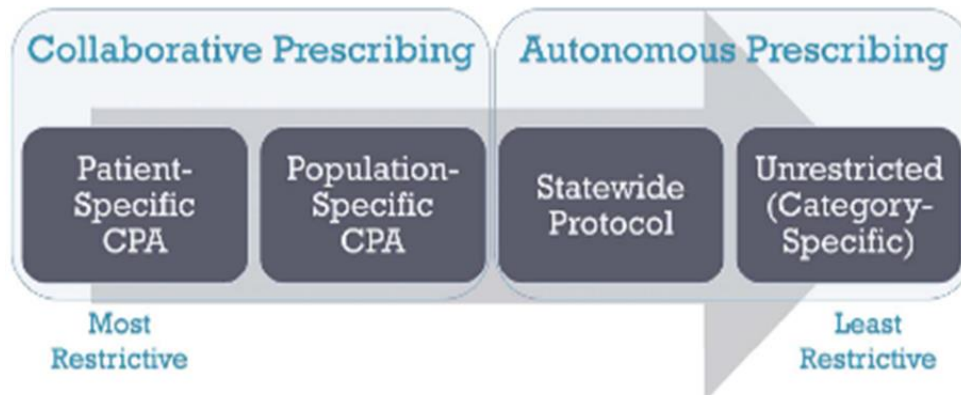
physician's assistant and advanced practice registered nurses (APRN); assistant professors from Vermont's nursing and pharmacy universities and colleges; retail and clinical pharmacists; representatives from Blue Cross Blue Shield of Vermont and the Department of Vermont Health Access; members of the Vermont Boards of Nursing, Pharmacy and Medical Practice, including their Chairs; and members of Vermont's Pharmacist and Druggist's Associations. Several of the references within this report were shared before the meeting or within the meetings.

The stakeholders held wide and diverse beliefs. Many supported a broad expansion of pharmacists' prescriptive authority; some opposed scope amendment; and many fell cautiously between.

Related topics were raised and deliberated upon during the meetings; these included: primary care access in Vermont; issues with access to electronic medical records; untoward influence of commercial incentives upon pharmacist prescribing; pharmacy prescribers replacing primary care and disruption of the patient-centered medical home; timely and thorough documentation and communication to primary care providers of pharmacist prescribing interventions; development of pharmacist prescribing protocols; preparation of pharmacists engaging in prescribing activities. Dominant policy considerations are discussed more fully below.

### The Continuum of Prescriptive Authority

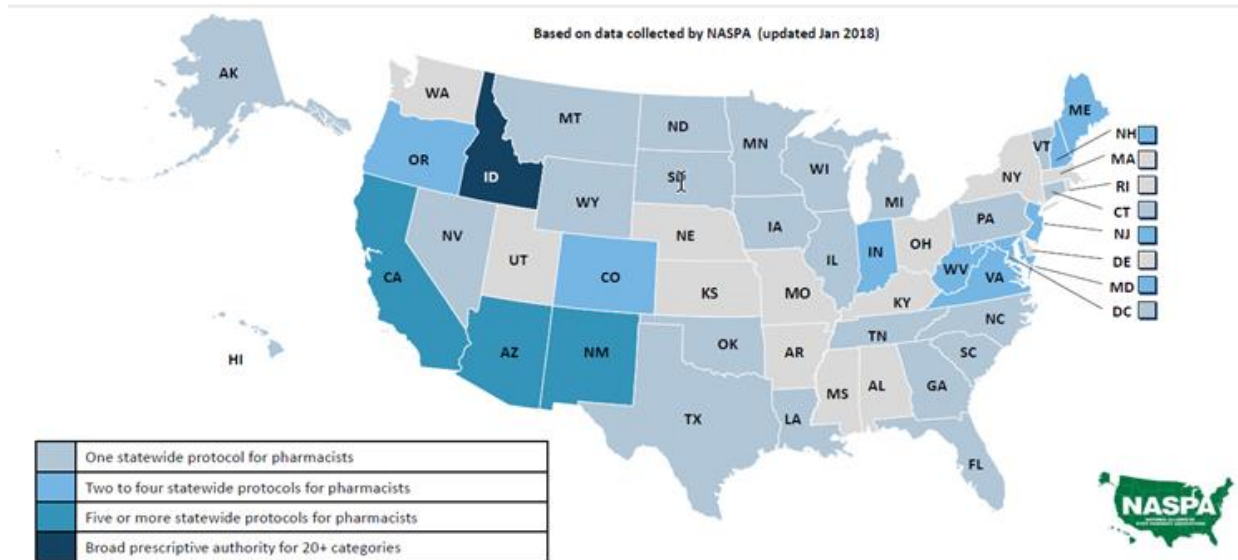
Pharmacist prescribing occurs along a spectrum of clinical independence, from collaborative prescribing paradigms involving collaborative practice agreements (CPAs) to more autonomous platforms.<sup>16</sup>



Reproduced from: *Annals of Pharmacotherapy* 2016, Vol. 50(9) 778 – 784

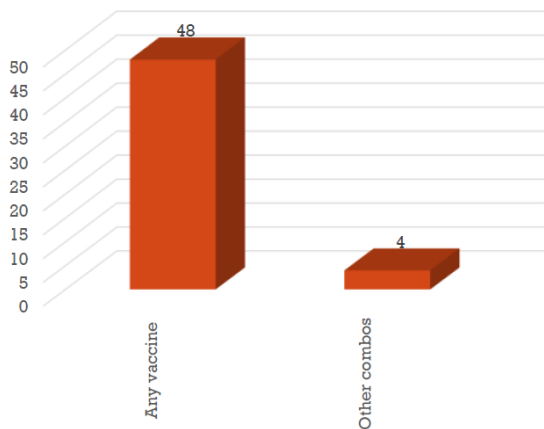
Within the more restrictive collaborative end of the spectrum, CPAs can be specific to certain patients or apply more broadly to specific patient populations. Vermont's pharmacist immunization authority is an example of the latter. Less restrictive forms of pharmacist prescribing authority include statewide protocols (such as Vermont's naloxone protocol) and unrestricted category-specific or general prescribing authority.

<sup>16</sup> Alex J. Adams, PharmD, MPH, and Krystalyn K. Weaver, PharmD. The Continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy* 2016, Vol. 50(9) 778 – 784



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Today, almost every state in the nation has decided that it is to the public benefit for pharmacists to provide immunizations. States have approached the immunization need in a variety of models.<sup>17</sup>



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

\* Via Rx for some

Reproduced from NASPA, publicly available data, used with permission.

The following information and data on pharmacist prescribing models were compiled by NASPA, and accessed from their website<sup>18</sup>, the most up-to-date available source of cross-state legislative surveys on clinical prescribing by pharmacists. Some states employ combinations of the models below.

<sup>17</sup> <https://nasma.us/wp-content/uploads/2019/04/IZ-Authority-012019.pdf>  
<sup>18</sup> <https://nasma.us/restopic/scope/> publicly available data, used with their permission.

### a. United States: Collaborative Pharmacist prescribing models, patient-specific and population-specific CPAs

In 1979, Washington State broke pharmacy regulatory ground by becoming the first state to authorize collaborative drug therapy agreements, a CPA by another name. As of March 2018, Washington has 9,000 pharmacists utilizing 34,000 collaborative drug therapy agreements.<sup>19</sup>

A CPA can be patient-specific or population-specific. A patient-specific CPA is an individual plan between a pharmacist and a specific primary-care provider, for a specific patient. A population-specific CPA is an agreement between a pharmacist and a provider or providers for a group of patients.

Recognizing community pharmacists are, “an underutilized public health resource” and “well positioned to help fill the chronic disease management gap,” the Centers for Disease Control and Prevention teamed with the American Association of Nurse Practitioners, the American Medical Association, American Pharmacists Association, and NASPA in to create a resource for using collaborative-practice agreements to incorporate the pharmacy clinician into team-based care for chronic diseases, particularly cardiovascular disease<sup>20</sup>

The Centers for Medicaid and CHIP Services issued an Informational Bulletin in January 2017 urging States’ regulatory bodies to allow independent or CPA-related prescribing by pharmacists, noting that, “(t)he time required for individuals or pharmacists to contact prescribing providers for prescriptions could undermine access to, and the efficacy of, certain medications that require timely administration in order to be effective.”<sup>21</sup> Per the National Association of Boards of Pharmacy (NABP) 2019 Survey of Pharmacy Law, of 49 States reporting, only three do not allow pharmacists to initiate, modify, and/or discontinue drug therapy pursuant to a CPA or protocol. Those states are Delaware, Oklahoma and South Carolina. Of 50 states supplying information, thirteen lack some type of CPA allowance for administering diagnostic tests by pharmacists, and just under half (23) permit pharmacist prescribing pursuant to test results.<sup>22</sup>

### b. United States: Autonomous Pharmacist Prescribing Through Statewide Protocols Model

Autonomous pharmacist prescribing through statewide protocols means authorizing a pharmacist to prescribe to any individual if the drug(s) regimen falls under a “statewide protocol.” The authorizing agent for a statewide protocol differs from state to state. In Vermont, the authorizing agent for the Naloxone statewide protocol is the Department of Health, with a standing order from the Commissioner of Health. The Naloxone protocol is Vermont’s only statewide protocol. Comparatively, other states have employed protocols more broadly to address common healthcare needs.

Tobacco Cessation: As of August 2019, twelve (12) states<sup>23</sup> allow pharmacist prescribing of tobacco cessation aids—some restricted to only nicotine-replacement therapies, others extending to any tobacco cessation products approved by the FDA. An additional 7 states recently proposed legislation related to tobacco cessation.<sup>24</sup>

<sup>19</sup> Krystalyn K. Weaver, PharmD. Collaborative practice agreements: Explaining the basics. Vol. 24, Issue 3, p55, 2018

<sup>20</sup> Centers for Disease Control and Prevention. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017

<sup>21</sup> Vikki Wachino, Director Center for Medicaid and CHIP Services. CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf>

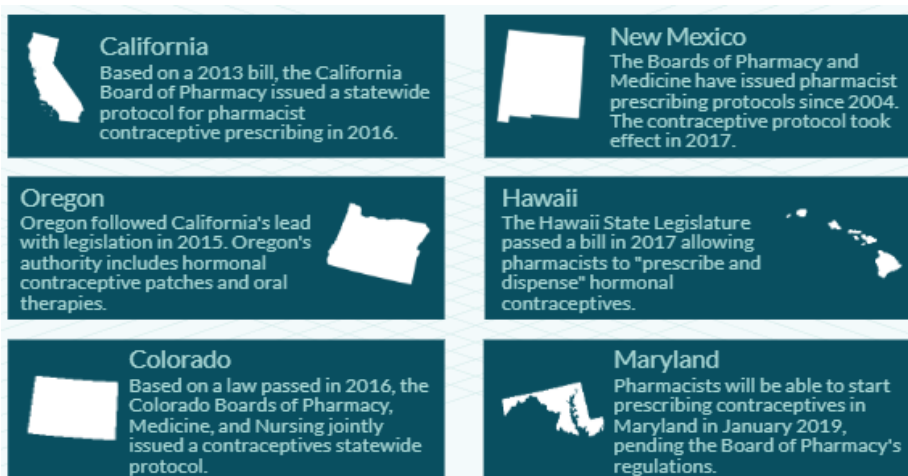
<sup>22</sup> The 2019 Survey of Pharmacy Law®. Editor and Publisher National Association of Boards of Pharmacy 1600 Feehanville Drive Mount Prospect, IL 60056

<sup>23</sup> Idaho, Colorado, New Mexico, Illinois, Iowa, Arkansas, Maine, West Virginia, California, Arizona, Missouri and Oregon

<sup>24</sup> Minnesota, Michigan, Maryland, Delaware, Connecticut, Massachusetts, Hawaii



Birth Control: In 2016, pharmacists' prescribing of hormonal contraception/birth control began in California and Oregon. By February 2018, New Mexico, Hawaii, Colorado and Maryland followed suit:



Reproduced from NASPA, publicly available data, used with permission.

As of May 2019, a total of ten states have statewide protocols for hormonal contraception.<sup>25</sup> In August 2019, New Hampshire's Board of Pharmacy reviewed final-proposed rules authorizing pharmacists to, "...perform...pertinent physical assessments and initiate hormonal contraceptives ... under a statewide protocol."<sup>26</sup> If these rules should be adopted, New Hampshire will be the eleventh state to have a statewide protocol related to hormonal birth control.

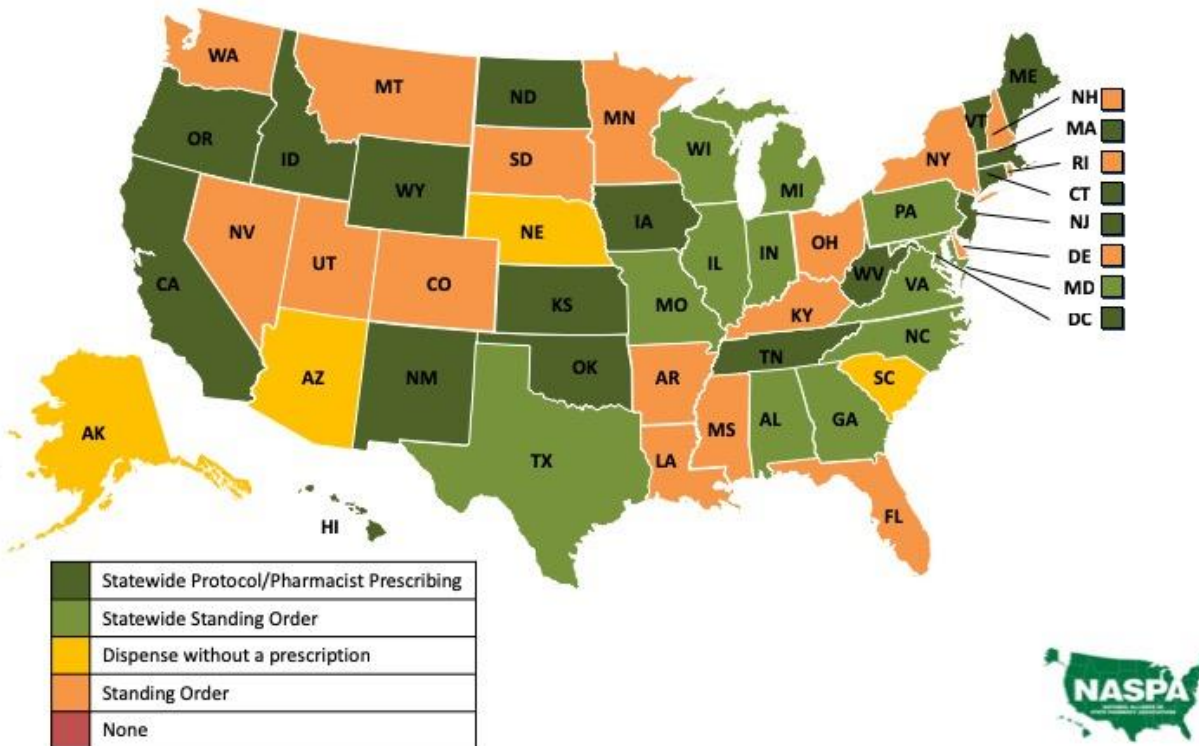
By far, the most widespread example of autonomous pharmacist prescribing is that of naloxone, an opiate antagonist that functions as an overdose rescue drug, in response to the opioid epidemic. All 50 states have authorized pharmacists independently to dispense prescription naloxone in some manner. However, the majority of states use statewide protocols:

<sup>25</sup> Idaho, the District of Columbia, Utah and West Virginia

<sup>26</sup> Chapter Ph 2400. Pharmacist Initiation and Dispensing of Hormonal Contraceptives. <https://www.oplc.nh.gov/pharmacy/documents/ph2400-20190821.pdf>

# Naloxone Access in Community Pharmacies

Based on data collected by NASPA (updated January 2019)



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### c. United States – Unrestricted Category-Specific Autonomous Pharmacist Prescribing model

The autonomous pharmacist prescribing unrestricted model allows a pharmacist to use her clinical judgment to prescribe within specific categories of condition and/or medication class.

Within the United States, Idaho has moved fastest to expand the scope of pharmacy practice with respect to prescribing authority. Idaho implemented unrestricted category-specific models in 2017, when Idaho pharmacists were granted the authority to prescribe independently from the following categories: all over-the-counter medications; medications to treat minor ailments such as flu, strep throat, uncomplicated UTIs, lice, cold sores; medications to prevent motion sickness, Lyme disease; travel medications; immunizations; fluoride supplements; medications to address gaps in care, such as statins for patients with diabetes; tobacco cessation medications; tuberculin skin tests; opioid antagonists: inhaler spacers, nebulizers, diabetes testing supplies, pen needles, syringes; emergency meds for anaphylaxis like epinephrine autoinjectors and short-acting beta-agonist bronchodilators.<sup>27</sup>

<sup>27</sup> N. Chopski PharmD, BCGP, ANP. "One State's Innovative Transition to Standards of Care Regulation", – National Association of Boards of Pharmacy District meeting presentation, Fall 2019

Only two years later, in 2019, Idaho’s legislature went further after there were no adverse events related to the prescribing authority granted in 2017, expressly including general or independent pharmacist prescribing within the statutory scope of practice:

*Practice of pharmacy means...the prescribing of...drugs, drug categories...that are prescribed in accordance with the product’s federal food and drug administration-approved labeling and that are limited to conditions that:*

- (i) Do not require a new diagnosis;*
- (ii) Are minor and generally self-limiting;*
- (iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or*
- (iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.<sup>28</sup>*

The Idaho legislature adopted the 2019 approach so an annual legislative process to add eligible medications would no longer be necessary. Broadening Idaho pharmacists’ prescriptive authority further in 2019, mild acne, mild cough, and allergic rhinitis were added as “minor ailments” for pharmacists may prescribe. Finally, a new “dose per pharmacy” provision enables a pharmacist to choose the medication and dose most appropriate for an individual patient.<sup>29</sup>

#### **d. Other Countries**

Pharmacists in other countries have broader prescribing authority than do those in the U.S. Expanded pharmacist scope of practice, to include prescribing, has been occurring since the early part of the century, most prevalently in the United Kingdom (UK) and Canada. Pharmacist and other non-physician prescribing in the UK began with “supplementary prescribing” in 2003 and broadened to “independent prescribing” in 2006.<sup>30</sup>

<sup>28</sup> Idaho Code Ann. § 54-1704. See <https://legislature.idaho.gov/statutesrules/idstat/Title54/T54CH17/SECT54-1704/>

<sup>29</sup> N. Chopski PharmD, BCGP, ANP. “One State’s Innovative Transition to Standards of Care Regulation”, – National Association of Boards of Pharmacy District meeting presentation, Fall 2019

<sup>30</sup> T. Jebara, S. Cunningham, K. MacLure, A. Awaisu, A. Pallivalapila, D. Stewart. Stakeholders’ views and experiences of pharmacist prescribing: a systematic review. *Br J Clin Pharmacol* (2018), 84: 1883 – 1095

Year of introduction in the UK	Supplementary prescribing 2003	Independent prescribing 2006
<b>Definition</b>	"A voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific CMP with the patient's agreement" [5]	"The prescribing by a practitioner (e.g. doctor, dentist, nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing" [6]
<b>Eligible health professionals</b>	Dieticians, nurses, optometrists, pharmacists, physiotherapists, podiatrists, radiographers	Nurses, optometrists, pharmacists, physiotherapists, podiatrists, therapeutic radiographers
<b>Clinical conditions managed</b>	Any, within their clinical competence	Any, within their clinical competence
<b>Diagnosis responsibilities</b>	A doctor (or dentist) must diagnose the condition before prescribing can commence	The independent prescriber can assess and manage patients with diagnosed or undiagnosed conditions
<b>Need for a CMP</b>	A written or electronic patient-specific CMP must be in place before prescribing can commence	No need for a CMP
<b>Need for formal agreement</b>	The CMP must be agreed with the doctor (or dentist) and patient before prescribing can commence	No need for any formal agreement
<b>Drugs prescribed</b>	Any, within their clinical competence	Any licensed medicines within their clinical competence. Nurse- and pharmacist-independent prescribers in particular can prescribe unlicensed medicines and controlled drugs

CMP, clinical management plan

Reproduced from: Br J Clin Pharmacol (2018), 84: 1883 – 1095

In July 2013, the National Health Service (NHS) put forth a national campaign, "NHS England. Pharmacy call to action<sup>31</sup>" meant to encourage the entry of community pharmacists into the independent prescribing pool and general practitioner (GP) practice settings, in part, to ease the overload on physician GPs in the UK. Scotland set a goal that by 2023 all pharmacists will be NHS accredited clinical pharmacist independent prescribers, especially those in GP settings. By 2017, 40% had become or were in the process of being registered with the General Pharmaceutical Council.<sup>32</sup>

Since 2007, pharmacists in the Canadian province of Alberta have been permitted to prescribe, including emergency prescribing, adaptation of an existing prescription, and independent prescribing in a "collaborative environment" under advanced prescribing authorization. In the past 12 years, prescribing authority has been extended to pharmacists, to varying degrees, in all 10 provinces.<sup>33</sup>

<sup>31</sup> <https://www.pharmaceutical-journal.com/news-and-analysis/news/nhs-issues-call-to-action-over-community-pharmacys-place-in-primary-care/11131709.article?firstPass=false>




<sup>32</sup> <https://www2.gov.scot/Resource/0043/00434053.pdf>

<sup>33</sup> S. Bhatia, SH Simpson, and T. Bungard. Provincial Comparison of Pharmacist Prescribing in Canada Using Alberta's Model as the Reference Point. *Can J Hosp Pharm.* 2017;70(5):349-57

## Pharmacists' Scope of Practice in Canada

Scope of Practice <sup>1</sup>		Province/Territory													
		BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	NWT	YT	NU	
Prescriptive Authority (Schedule 1 Drugs) <sup>1</sup>	Independently, for any Schedule 1 drug	X	✓ <sup>5</sup>	X	X	X	X	X	X	X	X	X	X	X	
	In a collaborative practice setting/agreement	X	✓ <sup>5</sup>	✓ <sup>5</sup>	✓ <sup>5</sup>	X	X	✓	✓	X	X	X	X	X	
	Initiate <sup>2</sup>	For minor ailments/conditions	X	✓	✓	✓ <sup>5</sup>	P	✓	✓	✓	✓ <sup>5</sup>	✓	X	X	X
		For smoking/tobacco cessation	X	✓	✓	✓ <sup>5</sup>	✓	✓	✓	✓	✓ <sup>5</sup>	✓	X	X	X
		In an emergency	✓	✓	✓	✓	X	X	✓	✓	✓	X	X	X	X
Adapt <sup>3</sup> / Manage	Independently, for any Schedule 1 drug <sup>4</sup>	X	✓ <sup>5</sup>	X	X	X	X	X	X	X	X	X	X	X	
	Independently, in a collaborative practice <sup>4</sup>	X	✓ <sup>5</sup>	✓ <sup>5</sup>	✓ <sup>5</sup>	X	X	✓	✓	X	X	X	X	X	
	Make therapeutic substitution	✓	✓	✓ <sup>7</sup>	X	X	P	✓	✓	✓	✓	X	P	X	
	Change drug dosage, formulation, regimen, etc.	✓	✓	✓ <sup>7</sup>	✓	✓	✓	✓	✓	✓	✓	X	P	X	
	Renew/extend prescription for continuity of care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	P	X	
Injection Authority (SC or IM) <sup>1,5</sup>	Any drug or vaccine	P	✓	✓	✓	X <sup>8</sup>	P <sup>9</sup>	✓	X	✓	✓	X	X	X	
	Vaccines <sup>6</sup>	✓	✓	✓	✓	✓	P	✓	✓	✓	✓	X	P	X	
	Influenza vaccine	✓	✓	✓	✓	✓	P	✓	✓	✓	✓	X	X	X	
Labs	Order and interpret lab tests	X	✓	P <sup>10</sup>	✓ <sup>11</sup>	X	✓	P	P <sup>10</sup>	✓ <sup>13</sup>	X	X	X	X	

Reproduced from: © Canadian Pharmacists Association. Current as of July 2019<sup>34</sup>

 Implemented in jurisdiction
  Pending legislation, regulation or policy for implementation
  Not implemented

A review of 558 Canadian pharmacist disciplinary cases, spanning the years 2010 through mid-2017, showed that 24 were related to pharmacists performing “full scope activities.” None was due to adverse events, but rather, actions outside regulations. Eight were clerical or documentary in nature, such as failing to obtain proper authorization for renewing or adding refills to a prescription, or incomplete documentation for adapting prescriptions. Seventeen arose from pharmacists’ failure to satisfy specific training requirements related to clinical service provision, like first aid/CPR, injection training, and acquiring authorization to prescribe medications outside pharmacist’s scope of practice.<sup>35</sup>

### Potential Impacts on Patient Safety and on Delivery of Primary and Preventive Care in Vermont

#### a. Health Care Access

Pharmacist prescribing authority could ease issues Vermont patients face in accessing primary care. The Vermont Department of Health’s (VDH) 2018 physician census summary report, published in October 2019, illustrates the challenges confronting the State in the provision of primary care. Vermont physicians in *primary care* comprised only 25 % of all Vermont physicians. In the 2018 census, 15% of those 615 primary care physicians reported plans to decrease hours or retire within 12 months.<sup>36</sup> In fact, the Area Health Education Centers’ 2018 Vermont Primary Care Practitioner Workforce Report,<sup>37</sup>

<sup>34</sup> [https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Scope%20of%20Practice%20in%20Canada\\_July2019.pdf](https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Scope%20of%20Practice%20in%20Canada_July2019.pdf)

<sup>35</sup> E. Ai-Leng Foong, BSc; KA Grindrod, BScPharm, PharmD, MSc; SK D. Houle, BSP, PhD. Will I lose my license for that? A closer look at Canadian disciplinary hearings and what it means for pharmacists’ practice to full scope. *Can Pharm J (Ott)* 151:332-344, 2018

<sup>36</sup> Vermont Department of Health. *2018 Physician Census Summary Report*. October 2019.

<sup>37</sup> Area Health Education Centers Program, University of Vermont Larner College of Medicine. *The Vermont Primary Care Practitioner Workforce 2018 Snapshot*. January 2019.

published in January 2019, shows a Statewide shortage in *all types* of practitioners (MDs/ODs, APRNs and PAs) specializing in internal medicine/adult primary care.

It is important to recognize that primary care “access” issues go beyond a patient’s inability to find a designated primary care provider (PCP) for routine medical care and prescribing needs. Primary care access issues occur when:

- A patient, under a PCP’s care, arrives at the pharmacy after typical PCP office hours (nights, weekends, holidays) to learn that their long-standing maintenance medication, already prescribed by their PCP, is no longer the preferred therapy covered by their insurance’s pharmacy benefits manager (PBM), requiring the pharmacist or patient to contact the PCP to get a new prescription for the PBM’s preferred formulary medication;
- A patient has exhausted refills of long-standing maintenance medications, for which abrupt discontinuation can cause serious adverse events;
- A busy PCP office appropriately prioritizes the needs of patients requiring acute, urgent care over those with minor ailments:
  - A chronic disease patient’s routine follow-up
  - A patient with a bothersome but minor ailment, such as cold sores
  - A patient who has finally decided to quit smoking; or
  - A healthy woman seeking contraception

An expanded scope of pharmacist prescribing authority offers opportunities to fill gaps in patient care, represented by these latter types of access issues, that may otherwise result in the exacerbation of an already-diagnosed chronic or recurrent condition and hinder medication compliance or healthy-living choices.

### **b. Improved Pharmacotherapeutic Care: Disease State Management, Prescription Adaptation, Substitution, Titration**

Disease state management: In 2016, 63 studies examining pharmacist-led chronic disease-state management, 53 of which involved pharmacist prescribing interventions, underwent systematic review as part of a Department of Veterans Affairs Evidence-based Synthesis review program. Most of these studies involved pharmacists in primary care settings, caring for patients with hypertension, diabetes, chronic kidney disease, hyperlipidemia, depression and chronic obstructive pulmonary disease. Results from pharmacist-led disease management did not differ significantly from, and, “increased the proportion of patients achieving target goals for blood pressure, cholesterol, and blood glucose compared with usual care.”<sup>38</sup>

Prescription adaptation services by pharmacists fall into two general categories: renewals and changes. Adaptation services relative to existing prescriptions include the following:

<sup>38</sup> N. Greer, PhD; J. Bolduc, PharmD; E. Geurkink, PharmD; T. Rector, PhD, PharmD; K. Olson, MD; E. Koeller, BA; R. MacDonald, MS; and T.J. Wilt, MD, MPH. Pharmacist-Led Chronic Disease Management: A Systematic Review of Effectiveness and Harms Compared With Usual Care. *Ann Intern Med.* 2016; 165:30-40. doi:10.7326/M15-3058

Category	Subcategory
Renewals	Emergency renewals Continuation-of-therapy renewals
Changes	Therapeutic substitution Dispensing quantity Formulation or route Dose/Interval Complete missing information

Reproduced from: *Annals of Pharmacotherapy* 2018, Vol. 52(7) 700 – 703

Adaptation services are offered broadly in Canada. US pharmacist adaptation services are limited primarily to emergency renewals, though some states have authorized therapeutic substitution on a prescriber opt-in basis.<sup>39</sup> Pharmacist emergency renewals, for minimal quantities, can ensure continuity of therapy and improve compliance when a patient has exhausted supply and refills of long-term maintenance medications. Emergency renewal can also help mitigate effects associated with abrupt discontinuation of certain medications.

A pharmacist's ability to independently substitute medications within a drug category not only eases access issues related to prescription-benefit formularies and facilitates cost-containment efforts, but also adds problem-solving capacity in the event of drug shortages and recalls. For example, numerous angiotensin receptor blockers (ARBs), used for blood pressure control, were pulled from the market during 2019 due to carcinogen contamination in the manufacturing processes.<sup>40</sup> This situation required prescribers to issue new prescriptions for different ARBs, quite suddenly. Without a doubt, prescribers were inundated with phone calls from pharmacies seeking new scripts for patients, and some number of patients went without for periods as a result. If pharmacists, who are drug experts and aware of equivalent dosages within drug classes, had the authority to independently substitute a new ARB, these burdens would have been greatly diminished.

Finally, certain disease states require frequent titration of doses for adequate control and/or side-effect relief. Examples include heart failure<sup>41</sup>, diabetes<sup>42</sup>, gout<sup>43</sup>, and thromboembolic disorders<sup>44</sup> (i.e. blood clot in a limb or lung). Pharmacists in clinics, health-systems, and community settings are uniquely poised to assist with, and even manage, such titration strategies.

### c. Concerns Related to Records Integrity and Inter-Provider Communication

Accessibility of patients' electronic medical records is a significant challenge throughout the American healthcare system. Prescriber stakeholders broached this issue and its impact on pharmacists' access to pertinent patient health information for the documentation and communication of pharmacotherapeutic interventions. Primary-care providers expressed concern that lack of unfettered access to records, including electronic communication and documentation within the patient medical record, may complicate efforts to safely integrate pharmacist prescribing.

<sup>39</sup> A.I. Adams. Prescription Adaptation Services: A Regulatory and Practice Perspective. *Annals of Pharmacotherapy* 2018, Vol. 52(7) 700 – 703

<sup>40</sup> <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan>

<sup>41</sup> AS. Martinez, J. Saef, A. Paszczuk, H. Bhatt-Chugan. Implementation of a pharmacist-managed heart failure medication titration clinic. *Am J Health-Syst Phar* Vol 70 Jun 15, 2013

<sup>42</sup> AW. Benedict, et al. Evaluation of a Pharmacist-Managed Diabetes Program in a Primary Care Setting Within an Integrated Health Care System. *J Manag Care Spec Pharm.* 2018;24(2):114-22

<sup>43</sup> Huang, I.J., Liew, J.W., Morcos, M.B. et al. Pharmacist-managed titration of urate-lowering therapy to streamline gout management. *Rheumatol Int* (2019) 39: 1637

<sup>44</sup> VM. Wong, T. Tock. Efficacy and safety of a pharmacist-managed inpatient anticoagulation service for warfarin initiation and titration. *J Clin Pharm Ther.* 2011 Oct;36(5):585-91

Pharmacists are accustomed to jumping through the myriad technological hoops required to obtain, complete, and thoroughly document and communicate, vital patient health information in the provision of pharmaceutical care. Electronic pharmacy systems differ between community pharmacies not under common management; but electronic records also differ between, and even *within*, individual hospital/health systems and primary care office and clinic sites. Pharmacists play an essential role in Vermont's Prescription Monitoring Program. A pharmacist also has the most complete picture from the patient's insurance profile of all prescriptions a patient has obtained. Consequently, pharmacists often are the first to detect duplicate prescriptions or contra-indications.

Compared to other healthcare providers, pharmacists are often early "team-player" adopters of the frequently aggravating, but absolutely essential, workarounds required to access and document necessary information in electronic medical records.<sup>45</sup> Pending the development of universal electronic medical records, information sharing will complicate all inter-provider management of patient care.

A glimmer of hope appears in this area. Vermont Information Technology Leaders (VITL), BlueCross/BlueShield VT, and other Vermont health care entities, are pursuing a relationship with a real-time care collaboration network whose technology would comb pharmacy claims, identify changes in patients' prescriptions, and send electronic messages to the patients' PCPs to make them aware of the change.<sup>46</sup>

Access to medical records is a worthy concern. Every U.S. and international pharmacist prescribing model makes provisions of one or another kind for the collection of patient medical records and thorough, timely communication of any pharmacist prescribing interventions made. A responsible plan for pharmacist prescribing in Vermont must contain appropriate measures to ensure accurate pharmacotherapeutic information is communicated to primary care providers.

#### **d. Strengthening the Coordinated Medical Home with Prescribing Pharmacists**

It is Vermont's public health policy that every Vermonter should have access to primary care and a coordinated medical home. Vermont's Blueprint for Health initiative began in 2003, developing programs to address Vermont's healthcare quality concerns and expenditures. Its programs include patient-centered medical home (PCMH) models of primary care delivery, community health teams, the Women's Health Initiative and Support and Services at Home (SASH), among others.<sup>47</sup> In 2018, the Blueprint for Health expressly involved pharmacy in its efforts, when its SASH program piloted enhanced diabetes/pre-diabetes management service for its participants by adding a community pharmacist to the team. This pharmacist reviewed medications and lab results; but also met one-on-one with SASH participants. Results were positive: hemoglobin A1C<sup>48</sup>, weight and LDL<sup>49</sup> cholesterol values were all reduced for the SASH participants.<sup>50</sup> The benefit of the PCMH in Vermont is obvious and significant, but the community and health-system pharmacist remains a substantially untapped resource in this model. The results from the SASH pilot program demonstrate to OPR the clear value of adding pharmacists to the delivery of primary care.

<sup>45</sup> SD. Nelson, J. Poikonen, T. Reese, D. El Halta, C. Weir. The pharmacist and the EHR. *Journal of the American Medical Informatics Association*, 2017, Vol. 24, No. 1

<sup>46</sup> Personal email communication with Brian Murphy, Director of Pharmacy & Vendor Management, Blue Cross Blue Shield of VT, received 12-27-19 to the Executive Director of Pharmacy

<sup>47</sup> <https://blueprintforhealth.vermont.gov/>

<sup>48</sup> Hemoglobin A1C lab tests measure the average blood glucose levels over 3 months and is used to diagnose and manage diabetes therapies.

<https://www.cdc.gov/diabetes/managing/managing-blood-sugar/a1c.html>

<sup>49</sup> LDL cholesterol is low-density lipoprotein or "bad" cholesterol [https://www.cdc.gov/cholesterol/dl\\_hdl.htm](https://www.cdc.gov/cholesterol/dl_hdl.htm)

<sup>50</sup> [https://blueprintforhealth.vermont.gov/sites/bfh/files/2018 Blueprint for Health Annual Report final.pdf](https://blueprintforhealth.vermont.gov/sites/bfh/files/2018%20Blueprint%20for%20Health%20Annual%20Report%20final.pdf)



Many Vermont prescribers expressed concern that adding a pharmacist to the prescribing community would destabilize the PCMH by fragmenting primary care in many of the same ways that urgent-care clinics and emergency departments (EDs) currently do: With each avenue to care or medication adjustment comes a new opportunity for health-relevant events that are not immediately known or supervised by a patient's primary-care provider. Any State pharmacist prescribing model should provide for mandatory documentation and communication of any prescribing interventions made—protective measures that are notably absent from regulatory requirements pertaining to urgent-care clinics and EDs. If we can ensure timely recording and communication of pharmacist-initiated measures, we can build a system in which the clinical expertise of pharmacists supplements and supports PCMHs without undermining coordination of care by a designated primary-care provider.

Outside Vermont, it is not uncommon to find pharmacists incorporated within PCMH sites. At two PCMH clinics in Ann Arbor, Michigan pharmacists have been ordering and discontinuing medications, ordering lab tests and adjusting doses via CPA-based prescribing for diabetes, hypertension and hyperlipidemia patients since about 2012. To expand the reach of the medical home, and its valuable pharmacist clinical services, community pharmacists at nearby CVS pharmacies were trained by the clinic-based pharmacists to follow evidence-based clinical guidelines to perform disease-state management and comprehensive medication reviews in face-to-face patient care visits at the pharmacy. They performed blood pressure and medication adherence/effectiveness assessments, discussed diet and exercise modifications to recommend and implement medication changes. Compared to a control group of patients who did not meet with a pharmacist, those doing so had improvements in A1C values and outcomes that were not statistically significantly different than patients seen at the PCMH clinic. Additionally, "...leadership in both clinics agreed...they were satisfied with the care provided...and that the community pharmacist made appropriate clinical recommendations for patients."<sup>51</sup>

With proper coordination, prescribing pharmacists may stabilize patient-centered medical homes, extend their reach, and improve clinical outcomes.

#### **e. Commercial Incentives & Clinical Judgment**

Some prescriber stakeholders expressed the concern that pharmacists with prescribing privileges may be tempted to prescribe unnecessarily to increase outlet sales, assuming the patient would continue to fill the prescription at the site of pharmacist prescribing. Like concern about records access, this worry is valid, but also endemic to every corner of the healthcare system and susceptible to mitigation. A pharmacist's education includes instruction in both pharmaceutical drug industry practices and medical ethics, creating a properly-skeptical, highly-principled healthcare professional. Furthermore, pharmacists follow a code of ethics commensurate to those in the related health-science professions. Were a pharmacist to prescribe for commercial benefit in a manner inconsistent with sound clinical judgment, the practice quickly should become apparent to patients' primary providers, and an enforcement action could be taken to restrict or remove that pharmacist from practice. The risk of commercially-motivated misconduct is not trivial, but neither is it appreciably different from the risk that a dentist might over diagnose caries. The State regulates health-science providers specifically because they are in advantaged positions relative to their patients, and those who exploit that position can be disciplined.

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<sup>51</sup> KB. Farris, BM Mitrzyk, P. Batra, J. Peters, HL. Diez, A. Yoo, K. McKay, K. Friend, L. Danko, R. Waber, VD., Marshall, HM. Choe. Linking the patient-centered medical home to community pharmacy via an innovative pharmacist care model. *Journal of the American Pharmacists Association* 59 (2019) 70e78

Currently, there are prescribing practitioners that are employed in Vermont's eleven Federally Qualified Healthcare Centers (FQHCs). Such centers are "covered entities," eligible to purchase medications via the Federal 340B Drug Pricing Program operated by the Health Resources and Services Administration (HRSA) that, "...requires drug manufacturers...to provide covered outpatient drugs to enrolled "covered entities" at or below the statutorily-defined ceiling price."<sup>52</sup> Five of Vermont's FQHCs own, and purchase drugs for, Community Health Pharmacy in Colchester. At least 2 other Vermont FQHCs have onsite pharmacies for which they do the same. Drugs filled at these pharmacies for Medicare and privately insured patients are reimbursed at the full rate, making the difference between the 340B purchase price, and its reimbursement, revenue for the covered entities.<sup>53</sup> Prescribers at FQHCs abide by the HRSA requirement to inform patients of the option to fill their prescriptions at any pharmacy of their choosing.<sup>54</sup> An analogous requirement would be a sensible component of any pharmacist prescribing paradigm. OPR is not aware of any allegation that FQHC prescribers have been inappropriately influenced in their prescribing practices. It is reasonable to expect the same ethical behavior for pharmacists with the ability to prescribe.

#### **f. Credible Research on Safety and Effects of Various Scope Models**

A literature database and internet search for adverse events related to pharmacist prescribing in the U.S. and elsewhere was performed contemporaneously to this report.

No issues to date have been reported with respect to U.S. efforts, particularly in Idaho. However, in June 2019, there were some serious events, to include patient deaths, reported in the UK. As described previously, in the UK, pharmacist independent prescribers' activities do not have to be predicated upon a doctor's diagnosis, and many of these events centered around pharmacists with independent prescribing authorization in general practice office environments undertaking triage and diagnoses remote from the patients (by phone or online), without full medical record review, and without appropriate training. Additionally, several involved opiates.<sup>55</sup>

A final compendium of pharmacist prescribing information bears particular attention. The Cochrane Library, "is a collection of databases that contain different types of high-quality, independent evidence to inform healthcare decision-making," and its database of systematic reviews is, "the leading resource for systematic reviews in health care."<sup>56</sup> One of its 2016 reviews, titled Non-medical Prescribing Versus Medical Prescribing for Acute and Chronic Disease Management in Primary and Secondary Care, included 46 studies involving 37,337 participants, 26 of which evaluated nurse-prescribing and 20, pharmacist-prescribing—all but one involved comparison to "usual care" medical prescribing.

A meta-analysis of the studies evaluated surrogate markers for certain chronic diseases, diabetes (glycated hemoglobin<sup>57</sup>) and cardiovascular disease (systolic blood pressure and low-density lipoprotein). The conclusions reached, from the findings of the analysis are that, "...non-medical prescribers, practicing with varying but high levels of prescribing autonomy...were as effective as usual care medical prescribers" and that, "With appropriate training and support, nurses and pharmacists are

<sup>52</sup> <https://www.340bpvp.com/resource-center/faqs/340b-pricing/-covered-outpatient-drugs/>

<sup>53</sup> State of Vermont Agency of Human Services, Department of Vermont Health Access. Act 165, Sec. 5 340B Drug Reimbursement Report <http://legislature.vermont.gov/assets/Legislative-Reports/340B-Report-DVHA-FINAL-5.2.17.pdf>

<sup>54</sup> <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

<sup>55</sup> Personal email communication with the Head of Policy for The Pharmacists' Defence Association

<sup>56</sup> <https://www.cochranelibrary.com/about/about-cochrane-library>

<sup>57</sup> Hemoglobin with linked glucose, a marker for elevated blood glucose. <https://www.sciencedirect.com/topics/medicine-and-dentistry/glycated-hemoglobin>

able to prescribe medicines as part of managing a range of conditions to achieve comparable health management outcomes to doctors.”<sup>58</sup>

## Report Findings and Recommendations

Positions taken on pharmacist prescribing opportunities discussed at the stakeholder meetings are summarized as:

Concerns Related to Pharmacist Prescribing	Stakeholder Position	Comments
Pediatric patients	NO	Reasonable exception discussed by all stake holders – <i>influenza vaccination</i>
Mental/behavioral health patients	NO	Possible exception – emergency refill of minimal quantity for drugs prone to cause abrupt-discontinuation adverse effects
Controlled Substances	NO	Full consensus that controlled substances (i.e. narcotics, opiates) would not be an option for pharmacist prescribing
Initial prescribing of antibiotics	NO	Some prescriber stakeholders raised concerns about exacerbation in overuse of, and microbial resistance to, antibiotics. Lengthy discussions ultimately led to initial prescribing of antibiotics as being “off the table”
Pharmacist Prescribing Opportunities	Stakeholder Position	Comments
Statewide Protocols for “self-diagnosed” conditions (i.e. not requiring a physical assessment and diagnosis)		
Tobacco cessation	MIXED	Supported by pharmacy stakeholders and some of the prescriber stakeholders. Concerns were raised by some prescriber stakeholders with respect to Zyban (due to its dual indication for depressive disorders) and Chantix (due to risks in patients with major depressive disorders)
Hormonal Contraception (Birth Control)	MIXED	Supported by pharmacy stakeholders and some of the prescriber stakeholders. Some prescriber stakeholders raised concerns regarding privacy for patients and whether pharmacists know to ask about certain contraindicated disease states and need to provide counseling on safe-sex practices
Statewide Protocols for conditions benefitting patients by broadening access to care (that are either previously diagnosed or may be diagnosed via Point-of-Care CLIA-waived test or by standardized clinical guideline algorithm)		
Mild Acne	NO	see “Initial prescribing of antibiotics” above
Uncomplicated urinary tract infections (UTIs)	NO	see “Initial prescribing of antibiotics” above

<sup>58</sup> Weeks G, George J, Maclure K, Stewart D. Non-medical prescribing versus medical prescribing for acute and chronic disease management in primary and secondary care. *Cochrane Database of Systematic Reviews* 2016, Issue 11. Art. No.: CD011227

Acute streptococcal pharyngitis (Group A Strep)	NO	see “Initial prescribing of antibiotics” above
Cold Sores (previously diagnosed, recurrent)	MIXED	Supported by pharmacy stakeholders and some of the prescriber stakeholders. Some prescriber stakeholders raised concerns whether pharmacists know when to refer a patient to PCP for differential diagnosis of more serious condition
<b>Autonomous, category-specific prescribing that stream-lines continuity of patient care and eases primary-care provider workload</b>		
Therapeutic substitution within drug category (due to insurance changes in covered brand)	YES	Consensus that since a new prescription for a known medication is required anyway, pharmacist prescribing the new covered brand ensures uninterrupted therapy
Prescribing of OTC medications, for patient utilization of their FSA/HSA insurance benefits	YES	Pharmacists routinely provide OTC pharmaceutical care. This reduces patient’s out-of-pocket expenses for meds that they are already using which do not require a prescription
Prescribing “devices” (diabetic testing supplies; pen needles for injectable drugs; spacers with inhalers)	YES	none
Continuation of therapy (i.e. extending long-term maintenance medication prescriptions with exhausted supply and refills, typically occurring after typical PCP office hours)	MIXED	Pharmacy stakeholders supported it, as did some prescriber stakeholders. Consensus that extending such prescriptions by providing minimal quantities (i.e. 72-hour supply) was sensible. Concerns were that a larger extension (1 to 3 months supply) would interfere with the patient returning to the PCP for care associated with the condition that the exhausted medication treats
Gap-in-care prescribing (statin for diabetes patients; SABA in asthma patients)	MIXED	Pharmacy stakeholders supported it; prescriber stakeholders did not - discomfort with pharmacist practice inappropriately approaching diagnosis

Based upon information gathered from thoughtful stakeholder discussions; consideration of approaches to pharmacist prescribing authority in other States and countries, and their lessons learned; review of the considerable body of evidence-based literature from peer-reviewed journals, clinical guidelines, and professional health care research organizations and associations on the subject, to include development and implementation of prescribing parameters, guidelines, and protocols to guard-rail such authority; OPR’s recommends that the General Assembly include prescribing within the lawful scope of pharmacy practice, with appropriate limitations.

OPR recommends that the Legislature pursue a hybrid, two-tiered prescribing model that employs: (1) the more structured CPA/protocol-based models for addressing common, lower-risk items to affect immediate benefits and address health access issues that face Vermonters, and (2) the more “hands-off”

approach of unrestricted prescribing models, in which not every last thing is legislated, but pharmacists may exercise clinical prescribing judgment in specified circumstances.

This approach facilitates collaboration yet preserves accountability, with clear roles to produce coordinated, improved patient care that ensures patient safety by featuring requirements for development of pharmacist prescribing protocols including input from other prescribing clinicians; training for pharmacists engaging in prescribing activities; addressing logistical issues in community pharmacy environments affecting the privacy of, and 24/7 follow-up for, pharmacist prescribing.

The State could make better use of community pharmacists through implementation of the following pharmacist prescribing opportunities:

1. Minimal emergency extension of long-term maintenance medications; intra-therapeutic category substitution
2. OTC products when self-care appropriateness is assessed for utilization of HSA/FSA benefits
3. Diabetes testing supplies, pen needles, spacers
4. Docosanol (Abreva®) for recurrent, diagnosed cold sores
5. Hormonal contraception for adult women
6. Tobacco cessation products

### **VIII. Conclusions**


The contemporary pharmacist holds a doctor-of-Pharmacy degree and very likely has more training in pharmacotherapeutics than the median prescriber. And yet she stands in the retail pharmacy as a gatekeeper without a key to her own gate, unable under existing Vermont law to exercise very basic forms of discretion in the service of patients—for example, titrating dosages of low-risk drugs based on side-effects actually experienced by the patient; providing hormonal birth control to an adult woman with a known medical history and an unavailable primary-care provider; supplying prescription docosanol to address a cold sore; working with an already-diagnosed patient to try comparable drugs in the same class, either to save out-of-pocket costs or to manage the balance of side effects and therapeutic effect.


Vermont's current prescribing practitioners include allopathic and osteopathic physicians, dentists, physician's assistants, advanced practice registered nurses, optometrists and naturopaths. Pharmacists interact with these providers on a daily basis and carry their own, substantially untapped expertise in monitoring, calibrating, and improving the quality of pharmacotherapeutic interventions. The generally positive experiences of jurisdictions that have extended pharmacist prescribing authority tend to illustrate that pharmacist prescribing can be safely integrated into a coordinated healthcare system in a manner consistent with accepted standards of care and patient-centered primary care overseen through a patient-centered medical home.

Respectfully submitted to the House and Senate Committees on Government Operations, the House Committee on Health Care, and the Senate Committee on Health and Welfare.

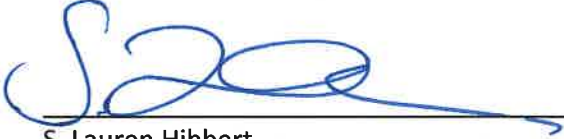
STATE OF VERMONT  
SECRETARY OF STATE  
OFFICE OF PROFESSIONAL REGULATION

BY:

  
\_\_\_\_\_  
Carrie C. Phillips, Executive Officer, Board of Pharmacy, January 15, 2020  
Date

  
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Gabriel M. Gilman, General Counsel OPR January 15, 2020

APPROVED:

  
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S. Lauren Hibbert, Director OPR January 15, 2020  
Date