Pharmacist-led Smoking-Cessation Services in the United States – A Multijurisdictional Legal Analysis

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Abstract

A challenge presents itself when pharmacy students and pharmacists have the knowledge, skills, and abilities to provide optimal patient care, which can prevent the healthcare industry from incurring expenditures reaching billions of dollars annually from chronic and acute disease state management, yet due to the lack of statutory or regulatory authority to independently prescribe and dispense smoking cessation products they are unable to tap into this potential.

Prescriptive authority of pharmacists is not a novel concept; however, State Legislatures and Boards of Pharmacy have been slow to expand upon the pharmacist's scope of practice to include this authority. As a consequence, this inaction hinders the opportunity of almost 21.5 million patients, who attempt to quit smoking annually, the ability to access a U.S. Food and Drug Administration approved, evidence-based medication-assisted or nicotine replacement therapy prescribed by a pharmacist.[2] Current legislative efforts, laws, and regulations regarding a pharmacist's prescriptive authority for tobacco cessation therapy vary greatly amongst the states and do not include reference to e-cigarettes or electronic nicotine delivery systems (e.g., e-cigs, vape pens, vapes, mods, etc.). Additionally, pharmacists are often required to practice under a statewide protocol or enter into a collaborative practice agreement ("CPA") with a designated physician, which are often complex and create significant barriers for the pharmacist to practice at the top of their license and for the benefit of the patient. This legal and regulatory study reveals the following: 1) Those States that have addressed or attempted to address the pharmacist's prescriptive authority for tobacco cessation therapy, 2) the authority to independently prescribe vs. practice under a statewide protocol, 3) the products able to be prescriber or dispensed under the pharmacist's prescriptive authority or statewide protocol, and 4) the guidelines and/or protocols referenced within their respective State laws and regulations. States and their residents would benefit greatly from amending their laws and regulations to expand upon the pharmacist's prescriptive authority, granting them the ability to help their communities by performing services they are highly trained to perform.

Keywords: Pharmacist; Pharmacy Student; Prescriptive Authority; Smoking Cessation; Tobacco Cessation Therapy; Regulations; Nicotine Replacement Therapy; Statewide Protocol

Background

Public Health Implications from Using Nicotine-based Products

The adverse health effects of tobacco-containing products (e.g., cigarettes, cigars, pipe tobacco, and chewing tobacco) and e-cigarette/vaping devices impose on public health is extensive and generational. These products have one common denominator that keeps approximately 34.1 million people in the United States using tobacco-containing products – a highly addictive chemical compound called nicotine.[80,84] All tobacco products currently available in the marketplace contains nicotine. The addictive properties of nicotine come about from changes to our brain chemistry, inducing cravings, thus leading to addiction. Of the 34.1 million people still smoking, statistical evidence tells us that smoking is prevalent within certain groups in the United States – men, adults 25-64 years old, adults with a lower-level of education, adults living below poverty level, adults living in the Midwest and South geographic regions, adults who are uninsured or only have Medicaid insurance coverage, adults who are living with a disability, adults with serious psychological distress, American Indians, Alaska Natives, multiracial adults, and adults who identify as part of the LGBTQIA community.[21]

The health implications of using these products are broad with substantial evidence correlating the consumption of nicotine, tobacco products, and vaping products to short-term health effects, long-term effects, withdrawal symptoms, and other health-related issues. Such effects include increased blood pressure, breathing, and heart rate, exposure of various chemicals to the lungs, significantly increased risk of cancer dependent on the type of product used, emphysema, cardiovascular disease, cataracts, pneumonia, and leukemia.[27] Use of these products while pregnant poses the risk of miscarriage, stillbirth, low birth weight, and developmental deficits. Vape products that also contain other chemicals, such as Vitamin E, have been linked to serious hospitalizations and deaths. These conditions only cover some of the possible short and long-term health implications affecting more than 16 million Americans living with smoking-related disease.[21,27]

To highlight a particular subset of patients, nicotine use by teenagers has the potential to impair the development of core brain circuits responsible for attention and learning. According

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to a 2020 "Monitoring the Future Study" performed by the National Institute on Drug Abuse (NIDA), an average of 34.5% of high school seniors vaped nicotine in the past year, with 24.0% having tried cigarettes of some kind.[21,83] The target audience of this survey showed trends amongst 8th graders, 10th graders, and 12th graders – all of which were substantial, yet still an unmentioned patient population in clinical practice guidelines and protocols across the board. The emphasis placed on the cessation of nicotine-containing products is imperative to public health as it is one of the most important preventable causes of premature disease, disability, and death in the United States, accounting for more than 480,000 deaths and $300 billion dollars in healthcare spending annually.[21,27,83] This means that nearly 1 in 5 deaths have a smoking-related cause. Tobacco-dependence is a chronic disease often requiring numerous interventions by clinicians and several attempts to quit by the user. Moreover, smoking cessation significantly reduces your risk of developing cardiovascular complications such as a heart attack or stroke.

Pharmacists and their Role

Pharmacists are uniquely positioned to provide high quality patient care not just by their education and training in pharmacology, therapeutics, and counseling, but also by their proximity and direct access to millions of Americans nationwide. A survey conducted by the National Association of Chain Drug Stores (NACDS) in 2015, revealed that nearly 9-out-of-10 patients are located within five miles of a community pharmacy and 1.83 miles for those living in metropolitan areas. Respondents of this survey also stated that pharmacists ranked within the top three of all professionals in trust and integrity – falling just behind nurses and tying with medical doctors.[39]

The contributions of pharmacists to the overall health and wellbeing of Americans are vital as they are most often the last point of contact between a patient and their respective health care provider. Generally, pharmacists are known to provide vital medications to help patients manage their disease states, deliver medication and lifestyle counseling, provide over the counter (OTC) product recommendations, and offer various preventative care services – including administration of vaccinations. However, this is just the "tip of the iceberg" when detailing services pharmacists can provide to their patients. Their current scope of practice expands into clinical pharmacy services such as medication therapy management (MTM), health screenings, medication-use policy development, and drug therapy monitoring as just a few examples. The adaptability of pharmacists and the profession is undenounced, which has been exemplified through demonstrations of their utility on the frontlines serving our country's most vulnerable communities throughout the COVID-19 pandemic.

Time and time again, pharmacists are tasked with proving their value to medical professionals and/or local, state, and federal government officials despite not being recognized as a provider under the Medicare Part B provision of federal law, thus resulting in little-to-no reimbursement for their services – even for their significant successes in aiding their patient's smoking cessation path. As of April 22, 2021, flagship legislation entitled the *Pharmacy and Medically Underserved Areas Enhancement Act,* H.R. 2759/S. 1362, was introduced to the U.S. House of Representatives and U.S. Senate. This bill would grant pharmacists "provider status" and the ability to bill for patient care services, under Medicare Part B, in medically underserved communities. As quoted from a statement put forth by the American Pharmacists Association (APhA), "the legislation would ensure that pharmacists are fairly compensated for the valuable patient care they provide to beneficiaries who struggle to access basic health care services."[4] Given this statement, the strategic position pharmacists currently have, and the accessibility provided to our communities, the number of people who currently smoke could be drastically reduced with expansion of pharmacist reimbursement and smoking cessation services, namely pharmacist prescriptive authority for smoking cessation therapies.

Mechanisms Currently in Place

The commonality between current respective State and Federal law tells us that pharmacists are only able to provide counseling services with limited reimbursement ability and recommend Over the Counter ("OTC") nicotine replacement therapy ("NRT") to patients who ask for those services unless the pharmacist's respective State has tried to expand their scope already. See Table 1.1 for a list of States with coinciding laws or regulations pertaining to tobacco cessation therapy by pharmacists. Consequently, some senators and representatives have and/or are starting to acknowledge the value of pharmacists. Therefore, the starting points can be seen in several states where an effort is underway to expand upon the pharmacist's scope of practice through the introduction of legislative bills referencing clinical practice guidelines or state-specific protocols. See Table 1.2 for a list of States and respective legislative attempts expanding pharmacist prescriptive authority for smoking cessation products.

Clinical practice guidelines, incorporated by reference into various protocols, statutes and regulations, pertain to the *US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update*. This 2008 version updated a previous 2000 version through extensive literature searches and analysis of critical reviews by a panel of thirty-seven clinicians who provided an explicit, evidence-based methodology and their professional judgement. The current guidelines provide recommendations regarding screening and assessment, types of counseling and behavioral therapy modification, pharmacologic therapy use, and combination medication therapy, amongst other recommendations.[22] By incorporating this document by reference into protocols, statutes, and regulations, the States that do so essentially make these practice guidelines the law of the land in those States.

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Defining the Continuum of Pharmacist Prescriptive Authority

As states continue to recognize the added value of pharmacists to their communities, we see pharmacists shifting from the dispensing role into something more along the lines of a semi-autonomous or autonomous providers as outlined in each State's respective pharmacy act and corresponding administrative regulations, which greatly varies across the country. According to information provided by the National Alliance of State Pharmacy Associations ("NASPA") and an article entitled *The Continuum of Pharmacist Prescriptive Authority*, the type of authorization granting pharmacists prescriptive authority entails, thus increasing patients' access to smoking cessation therapies, can be categorized.[2] In a broad scope, the article breaks down pharmacist prescriptive authority into two categories – collaborative prescribing through a collaborative practice agreement with a practitioner ("CPA") and autonomous independent pharmacist prescribing. [2] Both can further categorized from the most restrictive to least restrictive respectively based on State statutory or regulatory mandates a pharmacist would need to comply with. [2] On this spectrum, the categories include Patient-Specific CPAs, Population-Specific CPAs, Statewide Protocols, and Unrestricted (Category-Specific) Prescriptive Authority. [2]

CPAs are formal agreements between a licensed provider and a designated pharmacist in which the provider delegates agreed upon patient care activities to a pharmacist, within their scope of practice who oversees the care of the patient. Pursuant to the CPA, a pharmacist is then delegated the authority to perform specific patient care activities outlined in a protocol, which is either patient-specific or population specific. There is a high amount of variability between each State's respective CPA laws and regulations; however, for the purpose of this research we will not delve into much more than a brief introduction to each protocol's definition but rather focus on specific State allowances for the pharmacist's ability to independently prescribe smoking cessation products. Patient-specific CPAs limit a pharmacist to providing designated services to patients that (1) have been seen previously and/or referred by the collaborating health care provider; (2) the patient is identified in the agreement; and/or (3) requires further disease management post-diagnosis. Patient-specific CPAs are most often associated with pharmacists who manage chronic conditions in close collaboration with the patient's provider. This differs from population-specific CPAs as there is no delineation of patients in the agreement, ultimately giving the pharmacist some autonomy to provide services to patients that fit the inclusion criteria. Population-specific CPAs are generally used for services dealing with acute care, preventative measures, or public health where a collaborating provider and pharmacist may provide expanded services to any patient, regardless of whether there is a pre-existing collaborating provider-patient relationship .[2,12]

Statewide protocols are like population-specific CPAs, but there are a few specific differences that allow a pharmacist to practice more autonomously. "In this model, there are specific circumstances under which a pharmacist can prescribe related to populations; however, the agreement is not between pharmacists and providers. Instead, this agreement is between the pharmacist and an authorized body of state government (e.g., Board of Pharmacy, Department of Health, and Board of Nursing). Benefits to statewide protocols include fewer liability concerns than a CPA that is negotiated; reduced barriers to implementing a covered service, as the pharmacist does not need to identify a collaborating provider and negotiate the terms of a CPA; and greater consistency across the State."[12] Lastly, the least restrictive type of authority is unrestricted prescriptive authority given certain criteria. This type grants pharmacists the ability to freely prescribe medications that are explicitly outlined within a framework set forth by the legislature, board of pharmacy, or both.

Research Results and Discussion

After a 50-state legal and regulatory analysis of current and proposed laws/regulations allowing pharmacists to provide smoking cessation services, there are a total of 22 states that have taken the necessary actions granting pharmacists this ability. These states include Arizona, Arkansas, California, Colorado, Florida, Idaho, Indiana, Iowa, Kentucky, Maine, Minnesota, Missouri, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Utah, Vermont, Virginia, and West Virginia. Of those 22 states, fourteen states allow pharmacists to practice independently having full prescriptive authority of smoking cessation medications (see Table 2). To note, almost all these states have minimum education requirements regarding tobacco cessation education for those pharmacists wishing to participate in having prescriptive privileges, in addition to regulatory mandates that require: (1) a patient screening, (2) documentation requirements, and (3) specific intervention related information. A comprehensive list of the language pertaining directly to the pharmacist's authority to partake in smoking cessation services can be seen in Table 1.1 below.

Additionally, 13 states have taken initiative since January 2017 by addressing expansion of the pharmacist's role in treating nicotine addiction through the introduction of legislative bills that are currently in process or have been left pending in committee as most recently as November 2021 with the last update. Of those thirteen states, eight had legislative bills in process. These states include Alaska, Iowa, Kansas, Louisiana, Massachusetts, North Carolina, and Rhode Island. To aid in the potential passing of these bills, one can use the bill number and proposed language provided in Table 1.2 to contact their local Senator and House Representatives to advocate for each respective bill.

On the contrary, further exploration into the preambles of why some bills have not passed leads us in the direction of cost-benefit analyses, financial impact reports, and feasibility of implementing pharmacist-led smoking cessation services under

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restrictive legislative language requiring amendments to a State's respective pharmacy practice act. A key State exemplifying the "why" behind a bill failing is Maryland. The proposed bill, introduced in January 2019, added almost $700,000 to annual Medicaid and Maryland Children's Health Program (MCHP) expenditures the way it was written after financial analysis. This is due to coverage for tobacco cessation being included under both Medicaid and MCHP when the counseling and cessation aids are provided by a licensed health care practitioner. Therefore, the expansion of Maryland pharmacist's scope of practice to include tobacco cessation counseling and prescribing of related cessation aids will increase utilization of services, as well as the number of prescriptions issued.[13] However, this does not justify the hinderance of the expansion of pharmacist services in this State.

Table 1.1. States with Coinciding Laws or Regulations Pertaining to Tobacco Cessation Therapy by Pharmacists

State	*Respective Law(s)/Regulation(s) Language
Arizona[5]	"A. A pharmacist who is licensed pursuant to this chapter and who meets the requirements of this section may prescribe and dispense tobacco cessation drug therapies to a qualified patient. Prescriptive authority is limited to nicotine-replacement tobacco cessation drug therapies, including prescription and nonprescription therapies."
Arkansas[7]	"… Under a statewide protocol, a pharmacist may initiate therapy and administer or dispense, or both, drugs that include Naloxone and nicotine replacement therapy products;"
California[10,11]	"(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met … "
Colorado[14]	"… b. A statewide protocol shall, at minimum, contain the following information: 1. The nature and scope of evidence-based healthcare services appropriate for certain conditions or diagnoses and include specific directions for the patient information to be obtained, the drug therapies to be dispensed, the specified dosage regimen, and dosage forms and route of administration which are authorized … " *Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products:* "This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to dispense safe and effective tobacco cessation products according to and in compliance with all applicable state and federal laws and rules."
**Florida[23,24]	"Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to Section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement: (1) Hyperlipidemia: (2) Hypertension; (3) Anti-coagulation management; (4) Nicotine Dependence; (5) Opioid use disorder; (6) Those chronic health conditions enumerated in Section 465.1865(1)(b), F.S."
Idaho[29]	"Practice of pharmacy" means: … … (5) The prescribing of drugs, drug categories, or devices that are limited to conditions that: (a) Do not require a new diagnosis; (b) Are minor and generally self-limiting; (c) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or (d) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider. The board shall not adopt any rules authorizing a pharmacist to prescribe a controlled drug."
Indiana[32]	… "Sec. 11. (a) The state health commissioner or the commissioner's designated public health authority who is a licensed prescriber may, as part of the individual's official capacity, issue a standing order, prescription, or protocol that allows a pharmacist to administer or dispense any of the following: (1) An immunization that is recommended by the federal Centers for Disease Control and Prevention Advisory Committee on Immunization Practices for individuals who are not less than eleven (11) years of age. (2) A smoking cessation product. However, the pharmacist must inform the patient that the patient must have a follow-up consultation with the patient's licensed prescriber …"
Iowa[33,34,35]	"A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and available on the board's website at pharmacy.iowa.gov, order and dispense medications pursuant to rules 657-39.8 (155A), 657-39.9 (155A), and 657-39.11(155A). For the purpose of this rule, the order shall constitute a prescription."

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Kentucky[38]	… "Section 2. Procedures. A pharmacist may initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services under the following conditions: …" … "Section 5. Authorized Conditions. Board-authorized protocols may be established for the following conditions: … (14) Tobacco use disorder; …"
Maine[41]	… "28. Practice of Pharmacy. "Practice of pharmacy" means the interpretation and evaluation of prescription drug orders; …" … "the ordering and dispensing of over-the-counter nicotine replacement products approved by the United States Food and Drug Administration; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy."
Minnesota[46,47,48]	"Subd. 2.Prescribing and filing. (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a licensed dietitian or licensed nutritionist, pursuant to section 148.634; a nurse, pursuant to section 148.235, subdivisions 8 and 9; physician assistant; medical student or resident; or pharmacist according to section 151.01, subdivision 27, to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of sections 147A.02 and 147A.09.
Missouri[51,53,54]	… "1. For the purposes of this chapter, "nicotine replacement therapy product" means any drug or product, regardless of whether it is available over the counter, that delivers small doses of nicotine to a person and that is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation. 2. The board of pharmacy and the board of healing arts shall jointly promulgate rules governing a pharmacist's authority to prescribe and dispense nicotine replacement therapy products. Neither board shall separately promulgate rules governing a pharmacist's authority to prescribe and dispense nicotine replacement therapy products under this subsection …"
New Hampshire[59]	… "I. In this section, "standing order" means a written and signed protocol authored by a physician licensed under RSA 329:12, a physician assistant licensed under RSA 328-D:2, or an advanced practice registered nurse licensed under RSA 326-B:18. The agreement shall specify a protocol allowing a licensed pharmacist to provide nicotine cessation therapy under the delegated prescriptive authority of the physician, physician assistant, or APRN, a mechanism to document screening performed and the prescription in the patient's medical record, and include a plan for evaluating and treating adverse events. The prescriptions shall be considered a legitimate medical purpose in the usual course of professional practice. II. Licensed pharmacists following standing orders may provide nicotine cessation therapy to persons in this state without a prior prescription …"
New Mexico[60]	… "A. Protocol: (1) Prescriptive authority for tobacco cessation drug therapy shall be exercised solely in accordance with the written protocol for tobacco cessation drug therapy approved by the board. (2) Any pharmacist exercising prescriptive authority for tobacco cessation drug therapy must maintain a current copy of the written protocol for tobacco cessation drug therapy approved by the board …"
**North Carolina[64,65]	… "(b) Clinical pharmacist practitioners are authorized to implement predetermined drug therapy, which includes diagnosis and product selection by the patient's physician, modify prescribed drug dosages, dosage forms, and dosage schedules, and to order laboratory tests pursuant to a drug therapy management agreement that is physician, pharmacist, patient, and disease specific under the following conditions: (1) The North Carolina Medical Board and the North Carolina Board of Pharmacy have adopted rules developed by a joint subcommittee governing the approval of individual clinical pharmacist practitioners to practice drug therapy management with such limitations that the Boards determine to be in the best interest of patient health and safety. (2) The clinical pharmacist practitioner has current approval from both Boards. (3) The North Carolina Medical Board has assigned an identification number to the clinical pharmacist practitioner which is shown on written prescriptions written by the clinical pharmacist practitioner …"
North Dakota[68]	… "1. Statewide Protocol a. Prescriptive authority for tobacco cessation therapy shall be exercised solely in accordance with the statewide protocol approved by the Board b. An authorized pharmacist exercising prescriptive authority must maintain and have readily available a current copy of the statewide protocol approved by the Board …"

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Ohio[70,71]	… "(A) As used in this section, "nicotine replacement therapy" means a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation. (B) Subject to division (C) of this section, if use of a protocol that has been developed under this section has been authorized under section 4731.90 of the Revised Code, a pharmacist may dispense nicotine replacement therapy in accordance with that protocol to individuals who are eighteen years old or older and seeking to quit using tobacco-containing products …"
Oregon[73,74,75]	… "(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist shall only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations …"
Utah[85]	(1) Beginning January 1, 2022, a pharmacist may prescribe a prescription drug or device if: (a)prescribing the prescription drug or device is within the scope of the pharmacist's training and experience; (b)the prescription drug or device is designated by the division by rule under Subsection (3)(a); and (c)the prescription drug or device is not a controlled substance that is included in Schedules I, II, III, or IV of: (i)Section 58-37-4; or (ii)the federal Controlled Substances Act, Title II, P.L. 91-513. (2) Nothing in this section requires a pharmacist to issue a prescription for a prescription drug or device. (3) The division shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to: (a)designate the prescription drugs or devices that may be prescribed by a pharmacist under this section, beginning with prescription drugs or devices that address a public health concern that is designated by the Department of Health, including: …" … "(iv)smoking cessation; and …"
Vermont[88]	… "(2) State protocol. (A) A pharmacist may prescribe, order, or administer in a manner consistent with valid State protocols that are approved by the Commissioner of Health after consultation with the Director of Professional Regulation and the Board and the ability for public comment: (i) opioid antagonists; (ii) epinephrine auto-injectors; (iii) tobacco cessation products; …"
Virginia[90]	… "A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may prescribe, dispense, and administer the following controlled substances and devices in accordance with a statewide protocol developed by the Board in consultation with the Board of Medicine and set forth in regulations of the Board: 1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; 2. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; 3. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist; 4. Epinephrine; 5. Drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; …"
West Virginia[93]	… "A pharmacist licensed under §30-5-1 et seq. of this code may initiate and dispense a noncontrolled prescription medication, over-the-counter medication, or other professional service to a patient who is 18 years old or older; pursuant to a standing prescription drug order made in accordance with §16-56-4 of this code without any other prescription drug order from a person licensed to prescribe a tobacco cessation therapy; and in accordance with the dispensing guidelines in §16-56-6 of this code …"

*Please note, the language listed below only pertains to granting a pharmacist the authority to perform smoking cessation services. For the full statutory and regulatory language, please see the State's respective citation provided at the end of this document.

**Additionally, being as though pharmacists practice under a collaborative practice agreement in Florida and under a drug therapy management agreement with the title of "Clinical Pharmacist Practitioner" in North Carolina, the language was included as it specifically mentions "nicotine dependence" or "tobacco use disorder" in the statute, regulation, or respective protocol.

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Table 1.2. States and Respective Legislative Attempts Expanding Pharmacist's Prescriptive Authority

State	Legislative Bill	Status Last Known Update	*Language
Alaska[3]	House Bill No. 145	In-Process April 2021	"(a) A pharmacist may, under a collaborative practice agreement with a written protocol approved by a practitioner, 1. provide patient care services for a disease or condition with an existing diagnosis and for a condition that does not require a new diagnosis. b) A pharmacist may independently provide patient care services for (1) general health and wellness; (2) disease prevention; and (3) optimization of medication therapy for a condition that …"
Connecticut[20]	House Bill No. 6543	Left Pending in Committee January 2019	"Be it enacted by the Senate and House of Representatives in General Assembly convened: 1. That the general statutes be amended to permit pharmacists to 2. Prescribe tobacco cessation products…"
Hawaii[26]	House Bill No. 153	Left Pending in Committee January 2019	"(1) Allowing a pharmacist to prescribe vaccines, provide patient care services, and submit protocol concepts to the public health and pharmacy formulary advisory committee; (2) Establishing a formulary of drugs and devices, as recommended by the public health and pharmacy formulary advisory committee, that a pharmacist may prescribe and dispense to a patent pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis; provided that the formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine autoinjectors, *smoking cessation aids*, discharge medications for transitions of care, rapid strep tests, and spacers;"
Illinois[30]	Senate Bill No. 3147	Session Sine Die January 2021	"Amends the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois. Provides that the Director of Public Health shall establish a standing order complete with the issuance of a prescription for a smoking cessation product. Prescribes minimum requirements for the standing order …" "Amends the Pharmacy Practice Act. Provides that the "practice of pharmacy" includes the assessment and consultation of patients and dispensing of tobacco and nicotine cessation drugs and products. Amends the Illinois Public Aid Code. Provides that, subject to approval by the federal Centers for Medicare and Medicaid Services, the medical assistance program shall cover patient care services provided by a pharmacist for smoking cessation assessments and consultations …"
Iowa[36]	Senate Bill No. 296	In-Progress May 2021	"A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and consistent with subsection 2 3, order and administer the following to patients ages eighteen years and older: a. Naloxone b. tobacco cessation products"
Kansas[37]	House Bill No. 2385	In-Progress January 2021	"(I) the initiation of drugs, drug categories or devices that are initiated in accordance with the product's federal food and drug administration-approved labeling and limited to conditions listed below 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."

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Louisiana[40]	Senate Resolution 39 of 2nd Extraordinary Session of 2020 Legislature	In-Progress March 2021	"Section 1. R.S. 37:1220 is hereby enacted to read as follows: §1220. Collaborative practice; limited prescriptive authority by protocol or formulary for pharmacists B. A pharmacist may, pursuant to a statewide drug therapy management protocol developed by the Pharmacy Formulary and Protocol Advisory Committee convened pursuant to R.S. 37:1220.1 and adopted by administrative rule, provide approved patient care services including, but not limited to, smoking cessation therapy and travel health services."
Maryland[13,42,43]	House Bill 1217 Senate Bill 0497	Withdrawn by Sponsor – Added $700K to annual Medicaid Expenditures April 2019	"This bill expands the scope of practice for a licensed pharmacist, who meets specified requirements, to include prescribing and dispensing medications approved by the U.S. Food and Drug Administration (FDA) as an aid for the cessation of tobacco products (tobacco cessation aids). By September 1, 2020, the State Board of Pharmacy must adopt specified regulations. Medicaid and the Maryland Children's Health Program (MCHP) must provide coverage for services provided by a licensed pharmacist for screening an enrollee and prescribing tobacco cessation aids to the same extent as services rendered by any other licensed health care practitioner."
Massachusetts[44]	Senate Bill No. 1490	In-Progress November 2021	" … Section 19E. (a) Notwithstanding any other law, a licensed pharmacist may dispense Smoking Cessation Agents in accordance with written, standardized procedures or protocols developed by an actively practicing physician registered with the commissioner to distribute or dispense a controlled substance in the course of professional practice pursuant to section 7 if such procedures or protocols are filed at the pharmacist's place of practice and with the board of registration in pharmacy before implementation … "
Mississippi[50]	House Bill 1220	Left Pending in Committee January 2017	"… 73-21-131. In accordance with rules adopted by the State Board of Pharmacy and pursuant to a protocol, a pharmacist may provide approved patient care services including, but not limited to, smoking cessation and travel health services."
North Carolina[66]	Senate Bill No. 575	In-Progress May 2021	"An immunizing pharmacist may prescribe and dispense the following medications: (1) Tobacco cessation medications that are approved by the United States Food and Drug Administration"
Rhode Island[78,79]	Senate Bill No. 0589 House Bill No. 6047	In-Progress May 2021	"5-19.1-34.1. Tobacco cessation therapy prescriptive authority. (a) A pharmacist who is licensed pursuant to this chapter and who meets the requirements of this section may prescribe and dispense first line tobacco cessation drug therapies to a qualified patient pursuant to rules adopted by the board of pharmacy."
Texas[81]	House Bill No. 4285	Left Pending in Committee May 2019	"Authorizes pharmacists to furnish certain medications under protocol: (5) tobacco cessation drugs,"

*Please note, the language listed below only pertains to granting a pharmacist the authority to perform smoking cessation services. For the legislative language, please see the State's respective citation provided at the end of this document.

Continuum of Pharmacist Prescriptive Authority

Of the preceding 22 States in Table 2, 14 States have prescriptive authority without having restrictions and/or exceptions based on statutory authority and regulations. The States deemed as exceptions are Maine and North Carolina. In each of these cases, pharmacists have prescriptive authority but only for OTC products and through advanced licensure respectively. Being as though pharmacists practice under a collaborative practice agreement in Florida and North Carolina, the language was only included as it specifically mentions "nicotine dependence" or "tobacco use disorder" in the statute or regulation. The statewide protocols for both Vermont and Virginia are currently under review by their respective Boards of Pharmacy and have not yet been made available to the public as of the date of this writing.

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Table 2. States and Continuum of Pharmacist Prescriptive Authority for Smoking Cessation Services

State	Continuum of Pharmacist Prescriptive Authority
Arizona [5-6]	Prescriptive Authority
Arkansas [7-8]	Prescriptive Authority
California [10-11]	Prescriptive Authority
Colorado [14-17]	Prescriptive Authority
Florida [23-25]	Collaborative Practice Agreement (CPA) *only*
Idaho [28-29]	Prescriptive Authority
Indiana [31-32]	Statewide Protocol/Standing Order
Iowa [33-36]	Prescriptive Authority
Kentucky [38]	Statewide Protocol/Standing Order (Functions like a population-specific CPA)
Maine [41]	Prescriptive Authority (*only* for OTC products)
Minnesota [45-49]	Prescriptive Authority
Missouri [51-55]	Prescriptive Authority
New Hampshire [58-59]	Statewide Protocol/Standing Order (Functions like a population-specific CPA)
New Mexico [60-61]	Prescriptive Authority
North Carolina [64-66]	Prescriptive Authority (*only* if practicing as a Clinical Pharmacist Practitioner)
North Dakota [67-68]	Prescriptive Authority
Ohio [69-71]	Statewide Protocol/Standing Order
Oregon [72-75]	Prescriptive Authority
Utah [85-86]	Prescriptive Authority
Vermont [87-88]	Prescriptive Authority
Virginia [89-90]	Prescriptive Authority
West Virginia [92-93]	Statewide Protocol/Standing Order

Variability within State Laws

Of the preceding 21 States allowing for pharmacist-provided tobacco cessation services, only 9 States allow for pharmacists to utilize all FDA-approved products without statutory or regulatory exceptions. The remaining 12 States only allow for the use of OTC or prescription nicotine replacement therapy ("NRT"). Pharmacists located within Maine, New Hampshire, North Dakota, Ohio, and Virginia are allowed to dispense OTC NRT without a prior prescription pursuant to statutory authority. However, it is interesting to compare Tables 3.1 and 3.2 as it relates to the use of approved products with coinciding protocols and evidence-based guidelines (*Treating Tobacco Use and Dependence: 2008 Update*). The variability of treatments provided across each State is uniquely noted within specific regulatory language and an important consideration to keep in mind when developing patient-centered care plans, since some therapies may or may not work for all individuals attempting to partake in nicotine cessation.

Table 3.1 States and Respective Pharmacologic Therapy Options

State	Pharmacologic Therapy
Arizona [5-6]	*Nicotine Replacement Therapy (NRT)
Arkansas[62]	*Nicotine Replacement Therapy (NRT) *alone or in combination*
California[10]	*Nicotine Replacement Therapy (NRT) *alone or in combination*
Colorado[17]	**All FDA-approved products
Idaho[1]	**All FDA-approved products
Indiana[9]	**All FDA-approved products
Iowa[63]	*Nicotine Replacement Therapy (NRT)
Kentucky[82]	**All FDA-approved products
Maine [41]	*Nicotine Replacement Therapy (NRT) *(only allows for OTC products)*
Minnesota[76]	*Nicotine Replacement Therapy (NRT) *+ Nicotine Inhaler and Nicotine Nasal Spray*
Missouri[56]	*Nicotine Replacement Therapy (NRT) *+ Nicotine Inhaler and Nicotine Nasal Spray*
New Hampshire [58-59]	*Nicotine Replacement Therapy (NRT) *(only allows for OTC products currently)*
New Mexico [60-61]	**All FDA-approved products
North Carolina [64-66]	**All FDA-approved products
North Dakota[68]	*Nicotine Replacement Therapy (NRT) *(only allows for OTC products currently)*

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Ohio [69-71]	*Nicotine Replacement Therapy (NRT) *(only allows for OTC products currently)*
Oregon[77]	**All FDA-approved products
Utah[86]	**All FDA-approved products
Vermont [87-88]	*Nicotine Replacement Therapy (NRT) *(only allows for OTC products)*
Virginia [89-90]	*Nicotine Replacement Therapy (NRT) *(only allows for OTC products currently)*
West Virginia [92-93]	**All FDA-approved products

*Nicotine Replacement Therapy (NRT) = Nicotine Patch, Nicotine Lozenge, and Nicotine Gum *only*

**All FDA-approved products = Nicotine Patch, Nicotine Lozenge, Nicotine Gum, Nicotine Inhaler, Nicotine Nasal Spray, Varenicline (Chantix), Bupropion (Xyban), and/or an Evidence-Based Combination + any other FDA-approved medications listed in the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: *Treating Tobacco Use and Dependence: 2008 Update*[15]

***Items that are *italicized* are taken directly from the respective State's regulatory language

Based on what was addressed specifically in the legislative bills, protocols, and regulatory language, it was unequivocally mentioned for pharmacists to follow some form of a protocol or evidence-based clinical practice guideline in all but 6 States as shown in Table 3.2 below. Pharmacists located in Arizona, New Hampshire, Ohio, Vermont, Virginia, and West Virginia must have their respective Board of Pharmacy, among the State Board of Medicine, State Board of Nursing, and State Department of Health, etc., promulgate rules pursuant to the statute and develop their respective statewide protocols. The *Treating Tobacco Use and Dependence* guideline is incorporated by reference within State-specific protocols and/or used solely (e.g., Idaho and Maine), whereas several States do not have a reference to specific guidelines or protocols. For those States where a protocol is not available, it was found that one is currently in process of being developed but not yet made available to the public as of the date of this writing.

Table 3.2 States and Respective Guidelines and/or Protocols Referenced

State	Guideline(s) and/or Protocol(s)
Arizona [5-6]	***N/A*
Arkansas[62]	"Nicotine Replacement Therapy Statewide Protocol – Arkansas State Board of Pharmacy"
California[10]	"16 CCR § 1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
Colorado[17]	"Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
Idaho [28-29]	**Treating Tobacco Use and Dependence* Guideline *only*
Indiana[9]	"Indiana State Department of Health Protocol for Dispensing Tobacco Cessation Products under Statewide Standing Order" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
Iowa[63]	"Nicotine Replacement Tobacco Cessation Statewide Protocol – Iowa Board of Pharmacy" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
Kentucky[82]	"Tobacco Cessation Therapy Protocol v2 – Approved 12/11/2019" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
Maine [41]	**Treating Tobacco Use and Dependence* Guideline *only*
Minnesota[76]	"Pharmacist Prescribing Protocol Nicotine Replacement Medication – Minnesota Board of Pharmacy" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
Missouri[56]	"The Board has not approved or adopted a standard screening procedure. Instead, pharmacists should use their professional judgment to select screening procedures/criteria appropriate for your practice setting. The following resources may be helpful and include clinical screening guidelines from other state/federal entities: ● Clinical Practice Guideline – Treating Tobacco Use and Dependence (U.S. Dept. of Health and Human Services, Public Health Services) ● Indian Health Services Pharmacist Tobacco Cessation Clinic Protocol ● APhA Guidance for Expanding Pharmacy-Based Tobacco Cessation Services Within the Appointment-Based Model"
New Hampshire [58-59]	***N/A*
New Mexico [60-61]	"Protocol for Pharmacist Prescribing for Tobacco Cessation – New Mexico Pharmacist prescribing of tobacco cessation, as intended to support and pursuant to, New Mexico Board of Pharmacy Regulation (16.19.26)" which incorporates reference to the **Treating Tobacco Use and Dependence* Guideline
North Carolina [64-66]	"Clinical Pharmacist Practitioner Protocol granted by individual physician-pharmacist relationships"
North Dakota[68]	"Chapter 61-04-15. Limited Prescriptive Authority for Tobacco Cessation Therapies"

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Ohio [69-71]	**N/A
Oregon[77]	"Preventive Care – Tobacco Cessation-NRT (Nicotine Replacement Therapy) and Non-NRT Statewide Drug Therapy Management Protocol for the Oregon Pharmacist"
Utah[86]	"Utah Guidance for Tobacco Cessation Products" which incorporates reference to the *_Treating Tobacco Use and Dependence_ Guideline
Vermont [87-88]	**N/A
Virginia [89-90]	**N/A
West Virginia [92-93]	**N/A

*_Treating Tobacco Use and Dependence_ Guideline = US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: _Treating Tobacco Use and Dependence: 2008 Update_

Recommendations and Conclusions

When looking at possible directions to expand the prescriptive authority of pharmacists, we can explore several avenues. First, we can begin by suggesting an update to the current clinical practice guidelines - US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: *Treating Tobacco Use and Dependence: 2008 Update*. This guideline has not been updated since 2008, and only provides recommendations for tobacco-related products in adults ages 18 and up. Additionally, the guideline fails to incorporate e-cigarettes or vaping-products as a contributor to nicotine addiction. A more applicable model to approach tobacco use, e-cigarette, and vape use would be to apply a more generalizable umbrella term, such as "nicotine addiction," in the guideline. By having an encompassing term, we can benefit by expanding the therapies limited to tobacco-cessation in the guideline and apply them to other forms of nicotine-use in the United States. The guideline goes on to highlight several key recommendations to provide effective medication treatments and tobacco-dependence counseling to patients, thus significantly increasing long-term rates of abstinence. Pharmacists are specifically mentioned as a targeted clinician type yet are not studied directly and are listed as a "future research" topic. It is our belief that inclusion of pharmacists to a higher degree in the clinical practice guideline on smoking cessation services could potentially prompt State associations, boards of pharmacy, and State legislatures to promulgate language grants pharmacists more authority than what is currently made available across the country.

Secondly, we can look at the research, provided above, to suggest State associations, boards of pharmacy, and State legislatures take a positive stance in expanding the current authorities of pharmacists in their respective States. In this fashion, we can look at the current protocols/authority in place and slowly begin to transition them to a more independent practice by pharmacists. Not only would this take some burden off physicians, physician assistants, and advanced practice nurses, but this also gives pharmacists more freedom to help their communities in ways they are trained to do. For example, we can take a patient-specific protocol and apply that to a population-specific collaborative practice agreement protocol. This provides pharmacists the ability to impact more patients; however, we can still expand the CPA protocols further into limited prescriptive authority with statewide protocols and even fully unrestricted pharmacist-provided services.

Lastly, to States looking to further expand into a fully expanded pharmacist-run smoking cessation service, we would recommend that they use New Mexico as a model State. New Mexico currently has the longest pharmacist-run smoking cessation service in the country with approximately twenty years of success from implementation of legislation in 2001 until present day.

Disclaimer: The views expressed in this manuscript are those of the authors alone, and do not necessarily reflect those of their respective employers or universities.

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