YOUR PHARMACIST WILL SEE YOU NOW: THE EXPANSION OF PRESCRIBING RIGHTS REACHES THE PHARMACIST

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I. INTRODUCTION

Historically, prescriptive authority has been reserved for physicians.[1] However, in light of the heightened responsibilities of health care providers, prescriptive authority has been expanded to include other groups such as nurses and physician's assistants.[2] Pharmacists are the next group seeking the right to prescribe medication through collaboration with other health care providers.[3] Most states provide some form of prescriptive authority to pharmacists, though the specific authority varies from state to state.[4]

The expansion of the pharmacist's role is not completely novel. The pharmacist's role expanded as early as the 1960s, when "[h]ospital pharmacists consulted with physicians about appropriate drug therapy and

1 Phyllis Coleman & Ronald A. Shellow, *Extending Physician's Standard of Care to Non-Physician Prescribers: The Rx For Protecting Patients*, 35 IDAHO L. REV. 37, 46 (1998).
2 *Id.* at 45.
3 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 8 (2017).
4 *Id.*

participating in initial prescription decisions."[5] Washington State pioneered expanding prescribing rights to pharmacists in 1979, when the state passed a law permitting pharmacists to prescribe under specific protocols with physician supervision.[6] Many states soon followed suit, imposing their own various limitations such as additional training, restrictions, and heightened physician supervision."[7] Although it was the first state to enact pharmacist prescribing legislation, Washington has made few changes to its law since then. Washington allows for broad "collaborative practice agreements," allowing limited prescriptive authority to pharmacists with physician supervision.[8] In California, the state Business & Professions Code describes a new type of pharmacist license—the advanced practice pharmacist license—which grants prescriptive authority to licensed pharmacists with additional training under certain conditions.[9] In this comment, I will examine the background of the legislative and regulatory frameworks governing prescriptive authority, as well as the underlying policies that these laws seek to promulgate. I will then compare the legislation in both Washington and California, arguing that there is a place for pharmacist prescribers, but that the legislation is overbroad and must be constricted to avoid unintended and potentially harmful consequences.

The health care community can avoid the aforementioned harmful consequences by eliminating broad and vague delegations of power from a physician to a pharmacist and increasing the legislation surrounding pharmacist prescribing. Pharmacists should be required to receive further advanced training in order to prescribe. However, this right to prescribe should not be extended to include the right to diagnose, and states and medical boards must legislate carefully in order to avoid this confusion of duties. Finally, there must be more physician oversight over pharmacists exercising their right to prescribe, including communication and review requirements.

II. BACKGROUND

For many years, there has been tension in the health care provider community over which groups should be granted the right to prescribe.[10] Many physicians believe that only a trained physician should have the right to prescribe medication to a patient.[11] Physicians undergo extensive training

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[5] Coleman, *supra* note 1, at 65.
[6] Coleman, *supra* note 1, at 65.
[7] Coleman, *supra* note 1, at 65.
[8] WASH. ADMIN. CODE § 246-863-100 (2018).
[9] CAL. BUS. & PROF. CODE § 4052.6 (2018).
[10] Coleman, *supra* note 1, at 58.
[11] *See, e.g.*, Anna Gorman, *Pharmacists Increasingly Take On Clinical Roles*, KAISER

on diagnosis and patient care, and many believe they are best positioned to decide what medication will help a sick patient.[12] As a result of their training, physicians are granted unrestricted prescriptive authority in all fifty states.[13] Two groups of secondary providers—nurses and physician's assistants—began seeking expansion of their scope of practice around 1965.[14] These providers argue that they are able to diagnose and treat patients with medication due to their extensive training.[15] Secondary providers argue that they provide the same quality of care as physicians, but at a lesser cost and higher patient satisfaction.[16] They also believe that allowing secondary providers to have prescribing rights will improve health care access in underserved populations.[17] These groups believe the objections coming from physicians are not based on concerns for patients but are rather manifestations of a "turf war" between physicians and other health care providers.[18]

Despite objections from physicians, legislators responded to these requests by amending state laws to include diagnosing and prescribing in the list of duties of nurse practitioners and physician's assistants.[19] As it currently stands, all fifty states provide nurses and physician's assistants with prescriptive authority in some capacity.[20] Some states limit prescriptions of controlled substances, while others require direct supervision by a physician.[21]

Many physicians have pushed back at the expansion of prescribing rights to these secondary health care providers.[22] Physicians argue that there

HEALTH NEWS (Feb. 11, 2014), https://khn.org/news/pharmacists-see-clinical-role-expand/; Katy Grimes, *Doctors Rip Idea of Nurses Playing Doctor*, CALWATCHDOG, (Aug. 8, 2013), https://calwatchdog.com/2013/08/08/doctors-rip-idea-of-nurses-playing-doctor/.

[12] Coleman, *supra* note 1, at 52.

[13] Coleman, *supra* note 1, at 46.

[14] Coleman, *supra* note 1, at 59.

[15] Coleman, *supra* note 1, at 48.

[16] Coleman, *supra* note 1, at 48.

[17] Coleman, *supra* note 1, at 48.

[18] Coleman, *supra* note 1, at 48. There is little evidence to back up either group of secondary practitioner's claims, as they are often opinions or inferences. For example, some secondary provider believe that physicians are "reacting to rising health care costs and severely restricted third-party payor reimbursement by attempting to protect tasks traditionally within their exclusive domain," such as prescribing. But physicians hold that these other providers lack the education and training necessary to safely prescribe. In fact, physicians contend a primary reason these secondary providers are seeking prescribing authority is to increase *their* income. Coleman, *supra* note 1, at 58.

[19] Coleman, *supra* note 1, at 59.

[20] Mary Beck, *Improving America's Health Care: Authorizing Independent Prescriptive Privileges for Advanced Practice Nurses*, 29 U.S.F. L. REV. 951, 954 (1995).

[21] *Id.*

[22] *See* Gorman, *supra* note 11 ("some physicians, however, are wary of pharmacists doing too much on their own.").

is not enough collaboration and communication between secondary providers and physicians.[23] As a result of the lack of communication, important information can slip through the cracks. Additionally, they believe these groups do not receive enough training in diagnosing and prescribing.[24] Physician's assistants and nurses are generally required to receive more training before they can prescribe; in light of this training, they are typically deemed competent to diagnose basic and obvious diseases and conditions and treat accordingly.[25] However, more complicated, nuanced, or atypical ailments can cause concerns. Often, symptoms of a harmful disease may mimic those of a more mild ailment.[26] Diagnosis and subsequent prescribing is further complicated in instances where several ailments co-exist.[27] In these cases, the absence of a comprehensive medical background increases the probability that patients will be misdiagnosed.[28] Because of this, a non-physician prescriber may not know to refer a patient with a serious disease if the provider believes it to be a basic ailment.[29] There is also a standard of care issue when non-physicians prescribe. Physicians believe that if nurses and physician's assistants retain the right to prescribe, they should be held to the same standard in malpractice actions as a physician, but nurses and physician's assistants would prefer to be held to a lower standard.[30]

Pharmacists face many of the same challenges and objections to nurses and physician's assistants prescribing, but nevertheless they became the next group of health care providers to receive the coveted right to prescribe.[31] Most states allow pharmacists some form of limited prescriptive authority.[32] These states typically require a collaborative practice agreement or similar arrangement with a practicing physician.[33] A collaborative practice agreement ("CPA") is an agreement between a physician and a pharmacist, nurse, or other health care provider that delegates some form of authority from the physician to the aforementioned provider.[34] These agreements can go by other names as well, such as protocols, standing orders, collaborative

23 Gorman, *supra* note 11.
24 *See* Coleman, *supra* note 1, at 50.
25 Coleman, *supra* note 1, at 49–50.
26 Coleman, *supra* note 1, at 50.
27 Coleman, *supra* note 1, at 50.
28 Coleman, *supra* note 1, at 50.
29 Coleman, *supra* note 1, at 50.
30 Coleman, *supra* note 1, at 78–79.
31 *See* Gorman, *supra* note 11.
32 CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 8.
33 *Collaborative Practice Agreements: Resources and More*, NAT'L ALL. OF STATE PHARMACY ASS'NS., www.naspa.us/cpa (last visited Feb. 2, 2020).
34 *Id.*

care agreements, and others.[35] A CPA is just one of several pathways by which a pharmacist may gain prescriptive authority.[36] A physician can choose whether to enter into a CPA with a pharmacist and may delegate some form of authority to the pharmacist.[37] This authority can include the initiation of medication, otherwise known as prescribing, as well as modification or discontinuation of medication.[38] Other possibilities include the authority to substitute another drug in the same drug class for the medication originally prescribed.[39]

Moreover, the agreement may be limited in setting or may contain a requirement that the pharmacist prescribing a drug notifies the treating physician within a certain time frame after doing so.[40] The full range of pharmacist prescriptive powers allowed by CPAs varies from state to state and agreement to agreement.[41] Some states only allow modification of medication, but not initiation of a new drug therapy.[42] Some states specifically limit the classes of drugs that pharmacists may prescribe, while others remain silent on class restrictions.[43] Some of the most common medications that are allowed to be prescribed are those that treat asthma, hypertension, hyperlipidemia, and COPD.[44] Although these are typical examples of permitted pharmacist-prescribed medication, many states have no explicit restrictions on drug classes that a pharmacist may prescribe.[45]

The pharmacist prescribing laws of Washington and California represent two different eras of prescriptive law history. Washington's statute is vague, broad, and without a recent update.[46] It is a representation of an era

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35 CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 8.

36 *Pharmacist Prescribing: Statewide Protocols and More*, NAT'L ALL. OF STATE PHARMACY ASS'NS., www.naspa.us/swp (last visited Feb. 2, 2020).

37 *Collaborative Practice Agreements: Resources and More*, *supra* note 33.

38 *See, e.g.*, WASH. ADMIN. CODE § 246-863-100 (2)(c).

39 *See* N.D. ADMIN. CODE § 61-04-08-06(2) (2018).

40 *Compare* TEX. OCC. CODE § 157.101(b-1)(2) (2018) (limiting delegation authority to hospitals, hospital-based clinics, and academic health care institutions), *with* WASH. ADMIN. CODE § 246-863-100 (specifying no time limit in setting). *See* CAL. BUS. & PROF. CODE § 4052.2 (2018) (requiring notice within twenty-four hours).

41 *See Pharmacist Prescribing: Statewide Protocols and More*, *supra* note 36.

42 N.J. STAT. ANN. § 45:14-41 (2018) (allowing only for modification or discontinuation of drug therapy by a pharmacist).

43 *Compare* 243 MASS. CODE REGS. § 2.12(4)(e)(6)(b) (2018) (limiting the types of drugs that may be prescribed in community settings and disallowing controlled substance prescriptions), *with* WASH. ADMIN. CODE § 246-863-100 (no language to restrict the classes of drugs pharmacists may prescribe).

44 243 MASS. CODE REGS. § 2.12(4)(e)(6)(b).

45 *See, e.g.*, WASH. ADMIN. CODE § 246-863-100 (no language to restrict the classes of drugs pharmacists may prescribe); KY. REV. STAT. §§315.010 (no language regarding classes of drugs a pharmacist may prescribe).

46 WASH. ADMIN. CODE § 246-863-100 (no agency filings affecting this section since 2003).

when pharmacist prescribing law was murky and actual pharmacist prescribers were uncommon. The law has remained unchanged despite the widening landscape of prescriptive authority and the expansion of the role of the pharmacist.[47] California, a state known for progressive legislation, represents the new era of expanded prescribing authority. In line with the modern trend, California's statute attempts to advance the rights and duties of pharmacists.[48] However, the statute recognizes that detailed parameters and legislation must surround pharmacist prescribing if it is to become the norm.[49]

III. ANALYSIS OF STATUTES

A. Washington

Washington's Administrative Code has allowed pharmacists to enter into CPAs, called Collaborative Drug Therapy Agreements (CDTAs), with physicians since 1980.[50] Pharmacists may exercise prescriptive authority in accordance with written guidelines or protocols previously established and approved by an authorized prescriber.[51] These protocols must include a statement of the types of diseases, drug categories involved, and the type of prescriptive activity (e.g., modification or initiation of drug therapy) authorized in each case.[52] There is no statutory authority to limit the classes or categories of drugs that physicians may allow pharmacists to prescribe.[53] Under a CPA, a pharmacist can prescribe controlled substances with a Drug Enforcement Administration number, and the pharmacist is not limited to any specific setting (i.e. institutional).[54] The protocol must include a statement of the activities that the pharmacist is to follow in the course of exercising prescriptive authority, including documentation of decisions made and a plan to provide feedback to the authorizing practitioner concerning specific decisions made.[55] However, there is no statutorily required time frame for communication between the primary provider and

[47] *Id.*; Gorman, *supra* note 11.

[48] CAL. BUS. & PROF. CODE § 4016.5 (2018); *see* Gorman, *supra* note 11.

[49] *See* Diana Yap, *The Saga of SB 493: Hernandez and California's New Provider Status Law*, PHARMACY TODAY (Mar. 1, 2014), https://www.pharmacist.com/article/saga-sb-493-hernandez-and-californias-new-provider-status-law.

[50] *See* WASH. ADMIN. CODE § 246-863-100.

[51] *Id*. at § 246-863-100(1).

[52] *Id*. at § 246-863-100(2)(c)(i)(ii).

[53] WASH. ADMIN. CODE § 246-863-100 (silent on limitations).

[54] *See* DRUG ENFORCEMENT AGENCY, U.S. DEP'T OF JUSTICE, PRAC.'S MANUAL § 5 (2006).

[55] WASH. ADMIN. CODE § 246-863-100(2)(d).

the pharmacist upon initiation of medication.[56] Additionally, there is no language in the statute pertaining to additional training or residency requirements.[57]

Currently, there are over 33,000 active CDTAs in the state of Washington.[58] Though CDTAs have been abundant in the state since 1979, inquiries into their scope are more recent and compelling.[59] In 2018, the Washington Medical Commission sought a formal opinion from the state Attorney General regarding the scope of pharmacists' authority.[60] The request sought, in part, to clarify whether a pharmacist's duties under a CDTA included diagnosis.[61] Additionally, the request inquired whether a physician could delegate diagnosis responsibilities to a pharmacist under a CDTA.[62] Finally, the request asked if a pharmacist diagnosing a patient pursuant to a CDTA constitutes an unlicensed practice of medicine.[63] The Commission took the position that the duty of a pharmacist does not include diagnosis, and therefore a physician cannot delegate this responsibility.[64] However, the response noted that the Commission does not acknowledge any statutes or rules that govern the responsibilities or limitations of physician delegation under a CDTA.[65]

In response to this request, the National Alliance of State Pharmacy Associations (NASPA) and the National Community Pharmacist's Association (NCPA) submitted a joint letter to the state Attorney General's office.[66] In the letter, NASPA and NCPA argued that Washington State pharmacists prescribing pursuant to a CDTA must do so in accordance with the terms agreed upon in the CDTA.[67] If a prescriber includes diagnosing or independent prescribing activities in the guidelines or protocols of the CDTA, then pharmacists may do so per the terms of the agreement.[68] NASPA and NCPA also asserted that Chapter 18.64 of the Washington Administrative Code (WAC) governs the practice of pharmacy and it cannot

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56 WASH. ADMIN. CODE § 246-863-100 (silent on communication time frame).

57 WASH. ADMIN. CODE § 246-863-100 (silent on additional training or education).

58 Letter from the Nat'l All. of State Pharmacy Ass'ns. & Nat'l Cmty. Pharmacists Ass'n. to Jeff Even, Deputy Solic. Gen. (Aug. 9, 2018) (on file with author).

59 *Id*. at 2–3.

60 Letter from the Wash. Med. Comm'n to Bob Ferguson, Attorney Gen. 10 (Jun. 8, 2018) (on file with author).

61 *Id.* at 5.

62 *Id*.

63 *Id*.

64 *Id*.

65 *Id*. at 10.

66 *See* Letter from the Nat'l All. of State Pharmacy Ass'ns. & Nat'l Cmty. Pharmacists Ass'n. to Jeff Even, Deputy Solic. Gen. 1 (Aug. 9, 2018) (on file with author).

67 *Id*. at 4.

68 *Id*. at 5.

impose any limitations on non-pharmacists—including duties non-pharmacist prescribers are authorized to delegate to pharmacists.[69] NASPA and NCPA contended that pharmacists are limited in their scope of authority by threat of litigation and ethical duty alone.[70] The letter states that "Pharmacists have an ethical duty to self-restrain from accepting any delegation of patient care services beyond their individual competency."[71] The letter points out that since the establishment of the CDTA in Washington, there have been no lawsuits questioning CDTA's legal authority or asserting patient harm caused by their use.[72] As a result, the two groups contend that there is no need for further regulatory restriction on the use of CDTAs.[73]

The conflicting opinions between the Washington Medical Commission, NASPA, and NCPA are further evidence of the need for state restriction on the practice of pharmacy. The Washington Medical Commission recognizes the vagueness of the statutes governing pharmacists' scope of practice.[74] The Commission seeks to clarify the overbroad statutory language that leaves patients at risk of receiving subpar care. The NASPA and NCPA wrongfully rely on the lack of lawsuits as evidence that the current system is working.[75] However, as the patient population and patient needs increase, physicians will be forced to look to secondary providers to ease their burdens.[76] The State must protect pharmacists from broad delegations of duty that cannot be adequately discharged. Further, allowing the pharmacy profession to regulate itself on ethics alone is irresponsible. Such a regulatory scheme will pressure pharmacists to accept more responsibility than qualifications can justify so the needs of their supervising physicians are satisfied. Pharmacists will be caught in an ethical conundrum between whether to help patients who need care, or to acknowledge certain limitations and reject a physician's delegated duties.

[69] *Id*.

[70] *Id*. at 6.

[71] *Id.* at 6.

[72] Letter from the Nat'l All. of State Pharmacy Ass'ns. & Nat'l Cmty. Pharmacists Ass'n. to Jeff Even, Deputy Solic. Gen. 3 (Aug. 9, 2018) (on file with author).

[73] *Id*.

[74] *See* Letter from the Wash. Med. Comm'n, *supra* note 60, at 3.

[75] *See* Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

[76] Gorman, *supra* note 11 ("[H]ealth officials are looking for ways to ease the strain on overloaded doctors, improve care and contain costs. With millions of people gaining coverage under the nation's health law, experts say pharmacists can fill gaps in primary care and help avoid unnecessary hospital admissions.").

B. California

Before the introduction of the Advanced Practice Pharmacist license, California pharmacists could only prescribe in accordance with a CPA alongside a physician in an institutional setting.[77] Institutional settings include hospitals, nursing homes, and long-term care facilities—places where interaction between all members of a patient's health care team are frequent.[78] A pharmacist was required to complete clinical residency training, or demonstrate clinical experience in direct patient care delivery, prior to entering into a CPA.[79] In 2014, California introduced the Advanced Practice Pharmacist license.[80] President of the California Chapter of the American College of Emergency Physicians, Tom Sugarman, M.D., stated that "[t]o ensure patient safety and quality of care, it's critical to have the physician as the point of contact for care."[81] Sugarman also noted his particular concerns about the license's creation of a new pharmacist class of opioid prescribers in a time where over prescribing of such drugs is already a highly volatile issue.[82]

C. Comparison

Because California's Advanced Practice Pharmacist initiative faced such opposition when it was first introduced, it was consequently amended several times to ensure that it was limited and specific in its prescriptive authority.[83] These amendments ensured that while pharmacists could still benefit from an expansion in their prescriptive authority, they could only do so with specific and explicit limitations.[84] California community pharmacists seeking to enter into CPAs as Advanced Practice Pharmacists are required to complete extra training on patient care and drug therapy management.[85] The law also requires communication between the

77 CAL. BUS. & PROF. CODE § 4052.2(a).
78 *See id.*
79 CAL. BUS. & PROF. CODE § 4052.2(d).
80 CAL. BUS. & PROF. CODE § 4016.5 (2018).
81 Grimes, *supra* note 11.
82 Grimes, *supra* note 11.
83 Yap, *supra* note 49.
84 *See* Yap, *supra* note 49.
85 CAL. BUS. & PROF. CODE § 4210 (2018). This further training requires the pharmacist to satisfy two out of three of the following criteria: (1) earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board; (2) complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams; (3) have provided clinical services to patients for at least one year

pharmacist and physician within 24 hours of initiating new medication.[86] This is especially important in a community pharmacy setting, such as a Walgreens or Rite Aid, where interactions with the primary physician and pharmacist may be less frequent. Additionally, all CPAs require approval from the state's pharmacy board.[87]

Washington State's Administrative Code allows for much broader pharmacist authority and relies greatly on deference to the physician and pharmacist.[88] Though the Washington Medical Commission argues that the law should not allow a pharmacist to prescribe, this is not clear from the statute.[89] NASPA and NCPA argue that the law allows for total delegation by a physician of prescribing and diagnosing authority to a pharmacist in any setting, if desired.[90] Regardless of the true meaning behind the statute, it is clear that further regulation and clarification are needed.[91]

The only requirement for specificity of the CDTA is a mandatory list of the types of diseases, drugs, or drug categories covered by the agreement.[92] This leaves much of the decision making up to the pharmacists if they choose not to consult with their supervising physicians prior to writing a prescription. The law includes no discussion of limitation in setting, granting community pharmacists the same level of authority as institutional setting pharmacists without any additional training or communication requirement. Furthermore, there is no requirement for additional training for a pharmacist seeking to enter into a CDTA, regardless of setting.

In regards to communication, the law states that the CDTA must include "a plan for communication or feedback to the authorizing practitioner concerning specific decisions made," but does not include a time frame for the pharmacist to report diagnoses or initiation of new medications to the physician.[93] Frequency of communication is left up to the pharmacist and physician, which could result in delayed communication after initiation of medication leading to patient harm. Unlike California's law, the

under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

86 CAL. BUS. & PROF. CODE § 4052.

87 CAL. BUS. & PROF. CODE § 4210.

88 *See* WASH. ADMIN. CODE § 246-863-100.

89 Letter from the Washington Medical Comm'n, *supra* note 60.

90 Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

91 The Washington State Attorney General's Office has yet to release a response to either party.

92 WASH. ADMIN. CODE § 246-863-100(2)(c)(i)(ii). This is not an inclusive list. A physician may, but is not required to, include specific drugs or drug categories, such as amoxicillin, or antibiotics generally. If the physician chooses, he or she may authorize a pharmacist to prescribe for a disease state, such as high blood pressure or asthma, with no mention of drug classes or categories.

93 WASH. ADMIN. CODE § 246-863-100(2)(d).

Washington law, allowing pharmacist prescribing through a CDTA, has not been updated in recent years.[94] As it stands, it seems the legislature is content to rely on feedback from the medical field to initiate changes to the CDTA law.[95]

IV. IMPLICATIONS OF EXPANDED AUTHORITY

A. Benefits of Expansion

Though some argue that pharmacists and other second level health care providers should not have the right to prescribe, with the proper legislative guidance, pharmacists can exercise their limited prescriptive authority safely and effectively to the great benefit of the medical community.[96] One of the driving factors behind expanding prescribing rights has always been the need to serve the growing patient population.[97] Physicians alone cannot keep up with the masses of patients who need medical care, and other groups of health care providers can alleviate this burden.[98] In medically underserved populations, it may be too expensive or burdensome for patients to visit a physician every time they need a prescription.[99] Examples of these underserved populations include both poor rural and inner-city Americans, as well as the elderly.[100] These populations might see their doctor once a year but may see their community pharmacist weekly, allowing them to form a close relationship with their local pharmacist. Due to the ease of access, they may be more comfortable asking questions and more likely to make an in-person visit in case of a problem.[101]

Additionally, many pharmacists believe they are practicing below their degrees.[102] Pharmacists practicing in retail drug stores spend the majority of their time on activities that do not require a pharmacist license.[103] A survey

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[94] WASH. ADMIN. CODE § 246-863-100.

[95] *See WSMA Weighs in as State Attorney General Considers Pharmacists' Scope of Practice,* WASH. STATE MED. ASS'N, (Aug. 8, 2018), https://wsma.org/Shared_Content/News/Membership_Memo/20180808/wsma_weighs_in_as_state_attorney_general_considers_pharmacists_scope_of_practice. Without the inquiry by Washington Medical Commission, it is unlikely that the Attorney General would have addressed the issue raised. As of this article, the Attorney General has yet to issue an opinion on the matter.

[96] *See, e.g.*, Coleman, *supra* note 1, at 67.

[97] Gorman, *supra* note 11.

[98] *See* Gorman, *supra* note 11.

[99] *See* Coleman, *supra* note 1, at 55-58.

[100] Coleman, *supra* note 1, at 55-58.

[101] *See* Gorman, *supra* note 11.

[102] *See* Jannet M. Carmichael & Janice A. Cichowlas, *The Changing Role of Pharmacy Practice - A Clinical Perspective*, 10 ANN. HEALTH L. 179, 186 (2001).

[103] *Id.* at 185.

conducted by the National Association of Chain Drug Stores Education Foundation showed that pharmacists were spending sixty-eight percent of their time on processing orders and prescriptions, managing inventory, and other miscellaneous activities that do not require a licensed pharmacist.[104] The survey determined that pharmacists were spending only thirty-one percent of their time on activities that actually require a licensed pharmacist, including reviewing and interpreting prescriptions, assessing patients' drug therapy, and counseling patients.[105]

Although they may not attend medical school, pharmacists receive highly technical training in drug therapy management.[106] Pharm.D. programs usually include four years of professional study, followed by two to four years of preprofessional education.[107] In their six to eight years of study, Pharm.D. students take courses in biology, chemistry, pharmacology, pharmacotherapy, patient assessment, and medical ethics.[108] The students also receive experience-based education to gain experience providing care to patients through services such as immunizations, medication management, chronic disease management, patient assessment, and many others.[109] Though pharmacists may not receive training specifically on diagnosis and medication selection, by working with a physician, pharmacists are more than capable of making decisions regarding patient care and prescribing.

B. Hazards of Expansion

Many of the potential issues with pharmacist prescribing come from a lack of communication between physician and pharmacist.[110] It is unclear how involved a physician needs to be in a CPA, as there are not always specific requirements for meaningful communication and collaboration beyond a notification when a pharmacist initiates a medication.[111] This lack of specificity creates a high risk of miscommunication or lack of communication, especially in a community pharmacy where a pharmacist is not working alongside a physician in the same hospital as nurses and

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[104] *Id.*

[105] *Id.*

[106] *See* Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

[107] Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

[108] Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

[109] Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

[110] *See* Keri D. Hager, Donald Uden & Daniel M. Tomaszewski, *Bridging the Location Gap: Physician Perspectives of Physician-Pharmacist Collaboration in Patient Care (BRIDGE Phase II)*, 5.2 J. OF RES. IN INTERPROFESSIONAL PRAC. AND EDUC. 1 (2015).

[111] *See, e.g.*, WASH. ADMIN. CODE § 246-863-100 (silent on further communication requirements).

physician's assistants typically do.[112] Even for higher level secondary prescribers, such as nurse practitioners, lack of communication is still a pertinent issue that becomes more troublesome as prescribing rights are expanded to more groups.[113] In *Collip v. Ratts*, a physician entered into a CPA with a nurse practitioner.[114] The CPA required the physician to review at least five percent of the nurse's charts on a weekly basis and to document her prescribing practices.[115] The physician had entered into eleven other CPAs and also maintained a ninety-hour-per-week medical practice; he admitted that he only engaged in a limited review of the nurse's notes.[116] He became concerned about the amount of narcotics that the nurse was prescribing to her patients but never followed up.[117] Ultimately, one of the nurse's patients, who had never been treated, seen, or heard of by the physician, died as a result of multiple drug interactions.[118] This tragedy occurred in a situation where the nurse and physician were working in close proximity – a practice that is much less common in a pharmacist-physician relationship.[119] Even more concerning is that nurse practitioners, despite the advanced training they are required to have in order to prescribe, are still at risk to make catastrophic mistakes without sufficient physician supervision.[120] Pharmacists are subject to this same risk, but without the requirement of advanced training or sufficient physician communication.[121]

Pharmacists should be allowed to utilize some form of prescriptive power. The current legislative landscape, however, leaves too much room for over-delegation by the physician and too much discretion to the pharmacist. As previously stated, pharmacists are not trained in diagnosis.[122] The NASPA and NCPA are comfortable with a pharmacist in Washington making a diagnosis and subsequently prescribing a medication if this is what the physician has delegated under a CDTA.[123] This is troubling, especially in light of the fact that a pharmacist in that state is not required to receive extra training in diagnosis, prescribing, or patient care in order to enter into

[112] *See* Collip v. Ratts, 49 N.E.3d 607 (Ind. Ct. App. 2015).
[113] *See id.*
[114] *Id*. at 609.
[115] *Id.*
[116] *Id.* at 610.
[117] *Id.*
[118] Collip v. Ratts, 49 N.E.3d 607, 611 (Ind. Ct. App. 2015).
[119] *Compare Collip*, 49 N.E.3d at 607, *with Hager*, *supra* note 110 at 2.
[120] Coleman, *supra* note, at 60; *see Collip*, 49 N.E.3d at 611.
[121] *See, e.g.*, WASH. ADMIN. CODE § 246-863-100 (no mention of extra training or communication requirements).
[122] Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.
[123] Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

a CDTA.[124] The only limitation to the pharmacist's authority is the physician's discretion in delegating and the pharmacist's ethical code.[125] This is a recipe for overprescribing and mis-prescribing of medication. Extending prescribing rights to any secondary health care provider carries these same risks.[126]

In *Evans v. Griswold*, an optometrist prescribed an antibiotic for a patient that he diagnosed as suffering from a bacterial eye infection.[127] The patient's condition did not improve, and the optometrist sent her for tests and stopped treatment.[128] The patient returned almost two weeks later because her eye was worse, and the optometrist recommended she take the same antibiotic for another ten days.[129] Two days later, the patient consulted an ophthalmologist who concluded that the patient was experiencing a toxic reaction to the medication that had not been recognized by the optometrist.[130]

Similar to pharmacists, optometrists receive an advanced degree and are able to prescribe some medication in a limited capacity but are not considered medical doctors.[131] An ophthalmologist is a medical doctor who has completed college and at least eight years of additional medical training and is licensed to practice medicine and surgery.[132] It is not difficult to see how a similar situation could easily arise between a pharmacist prescribing for a simple infection in accordance with a CPA, only to find that the patient experiences an unforeseen reaction. Even ordinarily benign drugs like antibiotics or hormonal birth control have side effects which may affect individuals in unusual ways.[133] Pharmacists may not always have sufficient knowledge to respond to these unexpected problems arising from their prescriptions.[134]

A similar example is pharmacist-prescribed hormonal birth control. Hormonal birth control is generally seen as innocuous, and many believe it could someday be granted over-the-counter status by the FDA.[135] Oregon

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[124] WASH. ADMIN. CODE § 246-863-100 (no mention of extra training or education).

[125] Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.

[126] *See* Evans v. Griswold, 935 P.2d 165 (Idaho 1997); *Collip*, 49 N.E.3d at 607.

[127] *Evans*, 935 P.2d at 166.

[128] *Id.* at 166-67.

[129] *Id.* at 167.

[130] *Id.*

[131] *Difference Between an Ophthalmologist, Optometrist and Optician,* AMERICAN ASS'N. FOR PEDIATRIC OPHTHALMOLOGY AND STRABISMUS, https://aapos.org/glossary/difference-between-an-ophthalmologist-optometrist-and-optician (last visited Jan. 17, 2020).

[132] *Id.*

[133] *See*, *e.g.*, *Evans*, 935 P.2d at 165.

[134] *See* Coleman, *supra* note, at 57-58.

[135] Maria I. Rodriguez, K. John McConnell, Jonas Swartz & Alison B. Edelman, *Pharmacist Prescription of Hormonal Contraception in Oregon: Baseline Knowledge and*

and California have both passed laws allowing pharmacists to prescribe short acting hormonal contraception to women without a visit to a physician.[136] The pharmacist must first complete a five hour training module covering information on contraception mechanisms of action and patient counseling on issues such as pill adherence, side effects, and potential interactions.[137] However, a statewide survey conducted in Oregon revealed that only thirty-nine percent of pharmacists were interested in prescribing birth control.[138] Most of the pharmacists in this minority group cited the need for further training in general contraception information and identifying contraindications before they would feel comfortable independently prescribing.[139] It seems that even a number of pharmacists are uncomfortable with the level of authority they have been given by the legislature.[140]

Not all drugs in the same class or category are created equal, and not all diseases can be treated by just one type of drug. A disease state or drug class listed in a CPA may not give pharmacists enough direction on what to prescribe, with the differences leading to small but potentially significant effects for the patient.[141] Additionally, granting pharmacists this discretion will allow them to make choices between brands of drugs, which will introduce them to the issues facing physician prescribers and pharmaceutical companies. Pharmaceutical companies may decide to target their marketing to pharmacists, who do not receive training on transparency and anti-kickback laws. As it stands, the Sunshine Act only requires that pharmaceutical companies report their spending on primary health care providers.[142] Companies are not required to report spending on secondary health care providers, including pharmacists, even if those pharmacists are prescribers.[143] This exemption creates a huge loophole that could be used by

Interest in Provision, 56.5 J. AM. PHARMACISTS ASS'N 521, 522 (2016).

[136] *Id.* at 521.

[137] *Id.* at 522.

[138] *Id.* at 524.

[139] *Id.*

[140] *See id.*

[141] Patricia A. Marken & J. Stuart Munro, *Selecting a Selective Serotonin Reuptake Inhibitor: Clinically Important Distinguishing Features*, 2 PRIMARY CARE COMPANION J. CLINICAL PSYCHIATRY 205 (Dec. 2000).

For example, a physician may authorize a pharmacist to prescribe a selective serotonin reuptake inhibitor (SSRI) to a patient with a diagnosis of depression. All SSRIs have the same mechanism of action and are similarly efficacious for the treatment of depression. However, individual patients may respond differently to the same SSRIs, and.individual pharmacologic differences may make one SSRI more or less suited for a given patient.

[142] 42 CFR § 403.902. The Sunshine Act requires that manufacturers of drugs and medical devices that are reimbursable by federal health care programs to track and report to the Centers for Medicare and Medicaid Services (CMS) all financial relationships with physicians. The law aims to increase transparency and uncover potential conflicts of interest.

[143] *Id.*; Thomas Sullivan, *Physician Payment Sunshine Act Final Rule: Definitions*, POL'Y

pharmaceutical companies to avoid the system put in place to discourage bribery of heath care providers.

This loophole is particularly significant in the context of the opioid epidemic. There is great danger in introducing a new class of opioid prescribers in a market already rampant with overprescribing.[144] The Department of Justice has increased scrutiny on offenders from every level of the system in the opioid-saturated market.[145] Physicians, pharmaceutical companies and their representatives, and even pharmacists have been targeted by lawsuits from both private citizens and the government.[146] A pharmacist able to prescribe opioids pursuant to a CPA or CDTA is now a new target for opioid users, abusers, and eventually prosecutors. Opioid users may use these new pharmacist prescribers to skip the trip to the physician, leaving one less barrier to the addictive drugs.

There is also a question of liability and standard of care in expanding prescribing rights. If a pharmacist makes a mistake while acting in accordance with a CPA, the law is not always clear on whether it is the pharmacist or the physician who will be held liable.[147] The Court of Appeals of Indiana addressed this issue in a case concerning a CPA between a nurse practitioner and a physician.[148] The court stated, "[i]f a doctor complied with his or her review and oversight obligations . . . and sees nothing troubling, and one of the patients is harmed by the negligence of the nurse practitioner, the doctor has not breached the duty to that patient."[149] This suggests that so long as the physician complies with the CPA he or she drafted, the physician will not be liable.[150] The liability will instead fall to the secondary health care provider.[151]

There are differing opinions as to the standard of care that is expected

& MED. (May 6, 2018), https://www.policymed.com/2013/02/physician-payment-sunshine-act-final-rule-definitions.html.

[144] Grimes, *supra* note 11.

[145] *See* Nate Raymond & Jonathan Stempel, *U.S. Joins Whistleblower Case Against Insys Over Kickbacks*, REUTERS (May 14, 2018), https://www.reuters.com/article/us-insys-opioids/u-s-joins-whistleblower-case-against-insys-over-kickbacks-idUSKCN1IF31M.

[146] *See* David Armstrong, *Lawsuit Blames Improper Marketing of Potent Opioid for Woman's Death*, STAT NEWS (Mar. 24, 2017), https://www.statnews.com/2017/03/24/opioid-insys-improper-marketing-lawsuit/; Raymond, *supra* note 145.

[147] *See Collip*, 49 N.E.3d at 607.

[148] *Id.* at 609.

[149] *Id.* at 615.

[150] *See Collip*, 49 N.E.3d at 615.

[151] *See id.*

from a prescribing pharmacist.[152] Currently, two different standards are applied to secondary health care providers performing tasks traditionally reserved to medical doctors, such as prescribing.[153] Under the first and more stringent standard, prescribing pharmacists are considered to be acting as doctors, and are held to that same high standard of care.[154] Courts generally shy away from applying this higher standard to secondary providers.[155] The second lower standard provides that because of their limited education, secondary providers should be held to the standard of care of a "reasonably prudent professional of similar experience and training."[156] The standard asks whether the health care provider exercised the specific knowledge and skill of similar professionals.[157] This allows each profession to set its own standards on how it will be judged.[158] However, if secondary health care providers believe they are able to prescribe just as well as physicians without sacrificing patient safety, their argument against holding them to a physician's standard of care is illogical.[159] This "similar professional" rule lowers the bar for prescription errors and other functions traditionally within the exclusive domain of a physician.[160]

C. Suggestions for Legislative Reform

It is clear that this area of the law needs further regulation and clarification. It is not sufficient that the legislature defers to the medical community to initiate change. The medical community is not able to agree on the best path for pharmacist prescribing, or if it should even exist at all. With so much discord between physicians and secondary prescribers, the legislature needs to act as a neutral third party to determine what is truly in the best interest of the people. Collaboration between different healthcare providers can reduce healthcare costs and improve patient outcomes.[161] However, pharmacists in community settings find this collaboration to be

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[152] *See* Coleman, *supra* note, at 78.
[153] *See* Coleman, *supra* note 1, at 72.
[154] *See* Coleman, *supra* note 1, at 72.
[155] *See* Coleman, *supra* note 1, at 73.
[156] *See* Coleman, *supra* note 1, at 72.
[157] Coleman, *supra* note 1, at 75; *see, e.g.*, N.C. GEN. STAT. § 90-21.12 (2018) (stating that, in determining damages for malpractice, the trier of facts must consider whether the care was "in accordance with the standards of practice among members of the same health care profession with similar training and experience . . ."); IDAHO CODE § 6-1012 (2018) ("individual providers of health care shall be judged in such cases in comparison with similarly trained and qualified providers of the same class in the same community, taking into account his or her training, experience, and fields of medical specialization, if any.").
[158] Coleman, *supra* note, at 75-76.
[159] Coleman, *supra* note 1, at 78-79.
[160] Coleman, *supra* note 1, at 78.
[161] Hager, *supra* note 110, at 2.

particularly challenging as they have great difficulty communicating with the delegating physician.[162] Some physicians report a lack of trust between themselves and community pharmacists as compared to institutional pharmacists.[163] Other physicians report that their limited communications with pharmacists outside their own practice are impersonal and often unclear.[164] This lack of trust and clarity can be combatted by frequent, meaningful, and mandatory communications between physicians and pharmacists entering into a CPA.

There must be a guarantee that pharmacists and physicians will communicate about the patients being treated. It seems many physicians and pharmacists want this level of effective communication, but simply need assistance from the legislature or state boards in order to achieve it.[165] At the very least, state pharmacy boards should implement communication requirements for CPAs. In addition, state legislators could set statewide minimum standards for communication between physicians and pharmacists entering a CPA. This will ensure actual collaboration between the physician and pharmacists, as the legislature intended, and not just pharmacists prescribing independently under the "oversight" of an absentee physician.

There also should be limitations, either implemented by state boards of pharmacy or statute, on the types of medications pharmacists may prescribe. Any substance with a high potential for abuse, including opioids and other Schedule II controlled substances, should be excluded from a pharmacist's prescriptive authority.[166] These drugs can cause severe psychological or physical dependence, especially when over or mis-prescribed.[167] Therefore, patients should be required to visit a physician to obtain a prescription. At the very least, if the state is not comfortable creating a banned drugs list, the legislature should require that a CPA list the specific drugs a pharmacist can prescribe for a specific diagnosis. The pharmacist should not have the discretion to choose between different drugs in the same class or category. If the pharmacist wishes to make a change or is unsure of a diagnosis, he or she should be required to either contact the physician prior to making a change or refer the patient back to the physician. Additionally, a pharmacist should not have the authority to diagnose a patient simply because a physician has delegated said authority. In order to create any truly effective regulations surrounding pharmacist prescribing, clarification to the law

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[162] Hager, *supra* note 110, at 2.

[163] Hager, *supra* note 110, at 4, 9.

[164] *See* Hager, *supra* note 110, at 4, 7.

[165] *See* Hager, *supra* note 110, at 4, 7.

[166] For a list of such controlled substances, *see Controlled Substance Schedules*, DRUG ENFORCEMENT ADMIN., https://www.deadiversion.usdoj.gov/schedules/ (last visited Jan. 14, 2019).

[167] *Id.*

regarding physician delegation under a CDTA is required. Specifically, the ability to diagnose patients should be unassignable to a pharmacist and should remain solely with the supervising physician.

Finally, further training should be required for pharmacists seeking prescribing rights under a CPA. Unlike nurses and physician's assistants, pharmacists do not receive training in patient assessment and diagnoses in their education. A short, one-day training course or an entirely online course are both insufficient methods in preparing a pharmacist for prescribing medication. If pharmacists wish to prescribe under a CPA, they should be required to undergo an extensive and meaningful training program. California's Advanced Practice Pharmacist license, which requires extensive training in patient care and clinical services, can serve as a model to other states looking to expand prescribing rights.[168]

V. CONCLUSION

Pharmacists are on the front lines of patient care and are positioned to effectively prescribe medications if regulated properly. Most states, including Washington and California, are on board with granting this group of providers broader authority to implement patient care regimens.[169] These states recognize the potential pharmacists have to increase patient satisfaction and promote positive health outcomes.[170]

Washington was one of the first states to allow for pharmacist prescribing under a CDTA, and the practice has become immensely popular throughout the state.[171] California recently introduced a new advanced pharmacist license that allows for pharmacist prescribing under a CPA so long as the pharmacist meets the heightened license requirements.[172] However, granting pharmacists broad and undefined prescriptive authority could result in disaster. The profession cannot be allowed to regulate itself entirely. With physicians busier than ever, it is too easy for communication to fall to the wayside and for pharmacists to be saddled with more than they are qualified to accomplish. The state legislature must regulate prescriptive authority to ensure adequate communication about patients and initiation of medication. The state must also ensure that physician delegation is limited to correspond with a pharmacist's training and education level. Physicians should be prevented from assigning diagnosing duties to a pharmacist, and pharmacists should be prevented from accepting such duties. Additionally, all Collaborative Practice Agreements need to have specific requirements,

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168 *See* CAL. BUS. & PROF. CODE § 4052.6.
169 *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 28–33.
170 *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 3.
171 Letter from the Nat'l All. of State Pharmacy Ass'ns., *supra* note 58.
172 CAL. BUS. & PROF. CODE § 4052.6.

set by the state legislature, limiting the discretion of the pharmacist to an appropriate level. Pharmacists seeking prescribing rights in any regard should be required by the state to undergo further advanced training in patient interaction, diagnosis, and prescribing in order to reduce the risk of patient harm. Without these changes, problems of overprescribing and mis-prescribing will continue to rise, pharmacists will hesitate to utilize their prescriptive power, and underserved populations will continue to suffer from a lack of care.