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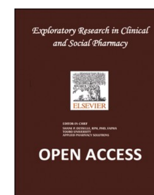

Implementation of the California advanced practice pharmacist and the continued disappointment of tiered licensure

Alex J. Adams[a,*], Tim P. Frost[b]

[a] Idaho Division of Financial Management, Eagle, ID 83616, USA
[b] Idaho Division of Occupational and Professional Licenses, Boise, ID, USA

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ABSTRACT

The Advanced Practice Pharmacist (APh) designation in California was created via legislation 10 years ago. California pharmacists who meet certain criteria can be designated as an APh and unlock additional practice authority. Just 1065 pharmacists, or 2% of licensed California pharmacists, have obtained the APh designation through 2022. APhs did not report benefiting from the designation as it relates to expanded scope of practice. This experience of low uptake and minimal benefit mirrors the tiered licenses created by three other states. More recent legislation broadened the independent prescriptive authority of APhs, but this increased value proposition aligns with the practice authority adopted by other states who have imposed fewer barriers to entry. Given the track record observed to date, we doubt that tiered licensure will ever prove successful in the pharmacy profession. Instead, state policymakers and pharmacy advocates should consider adopting a "standard of care" regulatory approach to improve patient access to safe and beneficial pharmacist services.

It has been more than 10 years since California Governor Jerry Brown signed Senate Bill 493 on October 1, 2013.[1] Hailed as a "landmark" law for the pharmacy profession, optimism was high that its many provisions would become a "bellwether" for other states to follow.[2,3]

One specific provision of the bill was the creation of the Advanced Practice Pharmacist (APh) designation. Pharmacists who met certain criteria could be designated as an APh and unlock additional practice authority.

While the APh name itself was novel, the designation represented a newer version of an older concept in the pharmacy profession: tiered licensure. In a tiered licensure model, a subset of a profession is legally recognized as having higher-level education and training, and they are conceivably granted a broader scope of practice as a result.[4] Three previous states – Montana, New Mexico, and North Carolina – had each created a tiered pharmacist license named either "pharmacy clinician" or "clinical pharmacist practitioner."[5–7] All three previous attempts at tiered licensure had low uptake, with just 1% to 9.8% of the licensed pharmacists in the state achieving the advanced status despite more than two decades of implementation experience.[4] Previous research identified that the scope of practice gains from these tiered licenses were poorly linked to the high barriers to entry established and thus provided limited practical utility.[8,9]

This manuscript reviews the implementation experience of the APh designation in California over the past 10 years since the legislation passed, and the nearly six years since the first APh was issued. The primary goal was to assess if the APh followed the same path as the profession's three previous attempts at tiered licensure, or if the APh was the "breakthrough" and "huge step forward" heralded by pharmacy advocates. Reviewing the decade of actual implementation experience can be illuminating for other states and pharmacy advocates in determining the best ways to improve patient care.

1. Implementation of the advanced practice pharmacist (APh) designation

1.1. Barriers to entry

To become an APh, an actively licensed California licensed pharmacist must apply to the Board of Pharmacy, pay a registration fee of $300, and meet at least two of the following criteria:

1. Complete a postgraduate residency earned in the United States through an accredited postgraduate institution.
2. Possess a current certification in a relevant area of practice.

* Corresponding author.
E-mail address: AlexAdamsRph@gmail.com (A.J. Adams).

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3. Provide 1500 h of clinical experience under a collaborative practice agreement or protocol to patients within 10 years of application, where clinical experience includes initiating, adjusting, modifying or discontinuing drug therapy of patients.[10]

In looking at these options, postgraduate residency training capacity lags behind the number of graduates nationwide. The American Society of Health-System Pharmacists (ASHP) Residency Directory reveals 137 accredited post-graduate year 1 (PGY1) residency programs totaling 397 positions in California in 2023.[11] By contrast, California colleges of pharmacy reported at least 1190 graduates who made first time attempts at passing the North American Pharmacist Licensure Examination (NAPLEX) for initial licensure in 2022.[12] This means that even if all California residency positions were filled by California pharmacy graduates, just 1/3rd of each graduating class would be able to fulfill the first criterion using in-state capacity. Of course some graduates will pursue work out of state, and some residencies will be filled by non-California students.

For the second criterion related to certification, California lists eligible certifications including, but not limited to, "ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy."[13] These certifications generally follow the list of specialties adopted by the Board of Pharmacy Specialties (BPS). BPS provides certification statistics by location, noting 5497 total holders for California in 2023.[14] This equates to just 11% of all California licensed pharmacists. Since the criteria to sit for many of the specialty certifications is tied to residency training, the capacity challenges of the residency criterion may compound the ability to achieve the certification criterion.[15]

To partially address this, some organizations have collaborated to create certificate training program to provide broader access to APh designation.[16] The training program consists of 30 h of self-study modules, an eight-hour live training seminar, and a comprehensive final examination. The list price for the certification is $799 for organizational members and $1499 for non-members. Thus, the direct cost to a pharmacist for the training and APh registration fee through the Board of Pharmacy is a minimum of $1099.[17] When factoring in the opportunity cost based on the median annual hourly pharmacist wage, the indirect cost of the training may add nearly $2400.[18]

The final criteria requires a minimum number of hours (1500) practiced under a collaborative practice agreement (CPA). While harder to quantify, various publications document that CPA uptake is low within pharmacy, especially in outpatient settings.[19–21] This low uptake is due in part to the difficulty in finding a willing collaborator, especially when the services provided by pharmacists may be viewed as competing with other health professionals.[22] The 2022 National Pharmacist Workforce Survey estimated that the average chain pharmacist provides 10.2 h of "patient care services not associated with medication dispensing."[23] If we assume that all these services qualify under the California definition of "clinical experience" and are provided under a CPA, it would take about three years for a pharmacist to achieve this criterion. This is likely an overestimate, as one national survey of community pharmacists reported only 16.3% that had a CPA in their practice.[24]

Thus, achieving two out of three of these criteria as a pre-requisite can naturally limit uptake of the APh. When pharmacists do attain an APh, they must renew it every two years, pay a renewal fee of $300, and complete an additional 10 h of continuing education (CE) beyond the CE required by their base license. Factoring in the estimated cost per CE hour for pharmacists, this adds an estimated $100 in direct costs to the renewal.[25,26]

1.2. *Uptake of designation*

California issued its first APh in early 2017, approximately three years after the law took effect.[27] In the first year, just 130 pharmacists became APhs, representing 0.29% of licensed California pharmacists. In 2022, this grew to 1065 pharmacists, or 2.18% of licensed California pharmacists.[28] Thus, approximately 98% of California pharmacists have not become APhs nearly 10 years after the initial law passed.

If the recent-year growth trajectory for both APhs and total licensed pharmacists continues indefinitely it would take until the year 2038 for APhs to become a majority (51%) in the profession, about 25 years after the initial law passed. In all likelihood it will take longer. Barring some major change, APhs will represent a minor fraction of the pharmacy profession for the foreseeable future, mirroring the experience of the other three states with tiered pharmacist licenses.

1.3. *Utility of scope of practice gains*

The 2% of California pharmacists who have attained APh status initially were allowed to perform five defined functions:

1. Perform patient assessments.
2. Order and interpret drug therapy-related tests.
3. Refer patients to other health care providers.
4. Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
5. Initiate, adjust, or discontinue drug therapy under a collaborative practice agreement.[13]

Several of these functions are vague and are rarely addressed in state pharmacy laws. For example, evaluation of diseases "in collaboration with other health care providers" and referring patients to other healthcare providers are general authorities that are unlikely to be prohibited in any state. Spelling them out as a matter of law for pharmacists may be unnecessary and generate confusion.

Only two of the five defined functions align with the full scope of practice articulated by Tsuyuki (2018): 1) ordering and interpreting drug therapy-related tests; and 2) initiating, adjusting, or discontinuing drug therapy.[29] Of note, these functions were allowed in the majority of states at the time of APh adoption without a tiered license requirement. For example, the 2016 National Association of Boards of Pharmacy (NABP) Survey of Pharmacy Law – chosen as it represents the year immediately preceding the issuance of the first APh designation – reported:

- 46 states already allowed pharmacists to initiate, modify, and/or discontinue drug therapy pursuant to a CPA or protocol; and
- 28 states reported pharmacists could already "administer" tests, and 25 reported pharmacists could already "interpret" tests.[30]

Both of these authorities are long-standing in the pharmacy profession. Washington State was the first state to allow pharmacists to initiate drug therapy under a CPA, starting in 1979.[31] That means that the ability to prescribe certain medications under a CPA preceded the APh by approximately 38 years.[31] Similarly, pharmacists had been early adopters of testing in pharmacy settings, and by 2015, approximately 20% of all pharmacies nationwide held waivers to provide testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[32]

It is likely of little surprise then that research by Lomanto and colleagues in 2021 found little effect of APh on scope of practice in California.[33] Specifically, APhs "did not report benefiting from licensure regarding expansion of scope of practice for any of the five specific APh-authorized responsibilities ($p<0.001$)." The authors concluded that "most pharmacists who obtained the APh license already held these responsibilities and thus benefited little from licensure."[33]

To be sure, recent articles do document APhs performing advanced duties. Tran and colleagues (2019) described an APh successfully managing an anticoagulation clinic in a correctional health setting and achieving good international normalized ratio (INR) control.[34]

Similarly, Lewis and colleagues (2019) demonstrated that APhs significantly lowered hemoglobin A1c in patients with diabetes mellitus.[35] Neither study included a comparison group of non-APhs, limiting the ability to evaluate the outcomes of APhs relative to other pharmacists providing similar clinical services. In addition, other prior studies demonstrate that pharmacists without APh credentials have also had success in managing diabetes and anticoagulation clinics, thus it is not possible to conclude that the APh alone was responsible for the clinical outcomes achieved.[36]

California updated the scope of practice for APhs in 2021 as part of Assembly Bill 1533.[37] No concomitant changes were made to the barriers to entry for prospective APhs. While four of the five functions remained the same, the authority to initiate, adjust, or discontinue therapy was streamlined to remove the requirement that it be conducted under a CPA. This conferred broad, independent prescriptive authority to APhs with just two articulated legal requirements:

1) A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider; and
2) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.[37]

The ability to independently prescribe has significantly enhanced the value proposition for the APh. Other states generally only allow independent prescriptive authority for specific drugs or drug categories like naloxone, tobacco cessation, epinephrine, hormonal contraceptives, tuberculosis skin tests, and HIV prophylaxis, among others.[31,38–41] Two states (Colorado and Montana) allow broad prescriptive authority for preventative care and post-diagnostic care.[42,43] Only Idaho provides broad independent prescriptive authority, inclusive of controlled substances.[44]

Thus, the APh now allows a relatively unique scope of practice that may conceptually incentivize additional growth in total APh licenses. However, since the legislation was signed in 2021, growth has remained modest. In the year prior to the prescribing expansion (2020), California reported 803 total APhs, and APh licensure grew to 1065 in 2022, representing just 262 new APhs in that time period. In fact, the reported growth rate in APhs has actually declined as a percentage relative to the years prior to 2020, so the scope of practice change has yet to materialize as a driver of APh attainment, though that could change in the future.

2. Discussion

Ten years in, the implementation experience with the California APh mirrors its tiered license forerunners in Montana, New Mexico, and North Carolina. It suffers from low uptake – just 2% of total state-licensed pharmacists have attained in through 2022, likely due to the high and costly barriers to entry. For those who have gotten credentialed as an APh, there has been little reported pay off in terms of scope of practice gains. Future research may wish to survey APhs on their job satisfaction and career progress. Even without scope of practice gains, there may be direct or indirect benefits to APhs and this should be explored further.

The major ray of hope for the APh is the scope of practice expansion adopted in 2021 to enable broad, independent prescriptive authority. The extent to which the APh gains traction in the future will likely depend on the practice integration of independent prescribing models. Still, compared to other states, the barrier to entry may not justify the gains.

For example, Idaho, too, allows broad, independent prescriptive authority.[44] Rather than creating a tiered license, all Idaho pharmacists have this authority as part of their base scope of practice. Thus, any Idaho pharmacist can prescribe for minor ailments like urinary tract infections or influenza, or for chronic conditions like diabetes and asthma. All Idaho pharmacists can order and interpret laboratory tests, assess patients, refer patients to other providers, and collaborate with other health professionals. Thus, the APh provides no advantage in terms of scope of practice beyond what all entry-level Idaho pharmacists are allowed to do. Similarly, Colorado and Montana avoided the tiered licensure approach in their continued path toward achieving full scope of practice, including independent prescriptive authority for preventative and post-diagnostic care.[45]

Idaho does not impose the costs that are required with an APh and instead governs according to a "standard of care."[46,47] That means that if a pharmacist deviates from an accepted standard of care in prescribing for a patient, the Board of Pharmacy may pursue a disciplinary case against the pharmacist. This broad authority, adopted in 2018, has a safe track record in Idaho none-the-less.[48–50] Notably, Washington and Iowa have followed suit and formally pursued a "standard of care" governance, albeit still mostly confined by the limits of collaborative practice.

Idaho's approach reflects that the services pharmacists provide may not warrant high barriers to entry. For example, it is likely that a board certified and residency trained pharmacist can skillfully diagnose and prescribe a cold sore, but it is unlikely that cold sores represent a significant portion of the training such a pharmacist attained through certification and residency. Rather than limit the number of pharmacists who can prescribe for cold sores through a mismatched tiered license, Idaho's standard of care approach maximized patient access to services while retaining accountability at the Board of Pharmacy level for deviations from a standard of care. Idaho pharmacists are further spared the cost associated with obtaining and renewing the tiered license, as well as the costs to attain the associated pre-requisites.

Montana also provides a unique comparison because it started with a tiered license, called the clinical pharmacist practitioner (CPP). Just 1% of Montana pharmacists had obtained CPP status in its first decade.[4] Montana CPPs gained little authority relative to other licensed pharmacists, with prescribing still occurring under a CPA. Perhaps learning from this model, Montana in 2023 passed a standard of care bill that allowed any Montana pharmacist – not just CPPs – to independently prescribe medications for conditions that do not require a new diagnosis, are for conditions that are minor and self-limiting, or for conditions that can be diagnosed through simple testing.[45] Enabling all pharmacists to provide these services, rather than building off the CPP framework, may be illustrative of the direction California may wish to pursue in the future.

It is notable that other health professions such as medicine have not pursued tiered licensure as a matter of law. There are many specialties within the practice of medicine – internal medicine, surgery, pediatrics, etc. – but each hold the same license: physician.[51] Rather than tier licensure as a matter of law, the profession has used a host of private credentialing and privileging mechanisms to reflect specialties in practice, while adopting a standard of care regulatory model as a matter of law. As pharmacists further gain traction toward achieving provider status, the profession should follow the successful model of other professions like medicine rather than attempting to create new licensing systems.

3. Conclusion

California's APh is but the latest iteration of tiered licensure attempted in the pharmacy profession. Three states have now dabbled with the creation of tiered licenses every five to ten years since New Mexico's advent of the pharmacy clinician designation in 1993. Given this pattern, we will likely see another state propose a tiered license in the coming years. Will the next one prove successful where the others have not, namely achieving high uptake and useful scope of practice gains? Or will the states with current tiered licenses follow Montana's lead in pivoting to an independent prescriptive authority approach for

all pharmacists, consistent with appropriate standards of care. Given the thirty-year track record observed to date, we doubt that tiered licensure will ever prove successful in the pharmacy profession. Instead, state policymakers and pharmacy advocates should consider adopting a "standard of care" regulatory approach to improve patient access to safe and beneficial pharmacist services.

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Declaration of Competing Interest

The authors declare no conflicts of interest.

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