



STANDARD OF CARE COMMITTEE CHAIR REPORT **August 25, 2022**

Seung Oh, Licensee Member, Chairperson
Maria Serpa, Licensee Member, Vice-Chairperson
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Jessica Crowley, Licensee Member
Nicole Thibeau, Licensee Member

I. Call to Order and Establishment of Quorum

II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

III. Approval of June 22, 2022, Committee Meeting Minutes

Attachment 1 includes a copy of the draft minutes from the Committee's June 22, 2022, Meeting.

IV. Presentation on Improving Patient Outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists. Presenters Include Dr. Steven Chen, Pharm D, FASHP; Dr. Richard Dang, Pharm D, APh, BCACP; Dr. Michael Hochman M.D., Dr. Alex Kang, Pharm D

During the meeting, members will receive a presentation, "Improving Patient outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists." Presenters include:

- Dr. Steven Chen, Pharm D, FASHP, Associate Dean for Clinical Affairs USC, Founder of California Right Meds Collaborative
- Dr. Richard Dang, Pharm D, APh, BCACP, Assistant Professor of Clinical Pharmacy, President of the California Pharmacists Association
- Dr. Michael Hochman M.D. CEO for Healthcare in Action and former Medical Director for Innovation at AltaMed Health Services
- Dr. Alex Kang, PharmD L.A. Care Health Plan Director of Clinical Pharmacy

Attachment 2 includes a copy of the presentation slides and research article.

V. Discussion and Consideration of Statistics Including Information on Pharmacy Ownership and Investigation Timeframes

As part of its last meeting members requested information on the number of pharmacies licensed in California by ownership to evaluate pharmacies that are owned by a corporation. Further, members requested information on investigation timeframes for disciplinary cases to evaluate closure times for the Board versus the closure times for cases completed by the Medical Board.

Pharmacy Ownership

Ownership Type	Number
Government Owned	138
Individual Unlicensed Owner	18
Individual Licensed Owner	116
Chain Owned	3,532
Other (Partnership, LLC, etc.)	2,618
Nonresident Pharmacy	632

AG Cases: Process Times

	2019	2020	2021
Medical Board	975	1,020	1,043
Pharmacy Board	893	876	875

VI. Discussion and Consideration of Development of Pharmacist Survey Related to Current Practice and Possible Movement to Standard of Care.

Relevant Law

Business and Professions Code Section 4301.3 requires the Board to convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the

regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussions through a report as specified.

For Committee Discussion and Consideration

Consistent with the provisions above, the Board established this ad hoc committee. As not all licensees are available to participate in meetings scheduled, it appears appropriate to consider if development and release of a survey of California licensed pharmacists is appropriate as another means of soliciting feedback for the Committee's future consideration.

Should the committee believe development and release of a survey is appropriate, it is recommended that the survey be finalized and released in advance of the October 24 meeting. This will ensure the committee has survey results available for its consideration as part of its next meeting. Provided below are some questions that may be appropriate for inclusion in the survey.

1. Demographic information – Working in California, Specify setting type.
2. Do you believe there are additional functions pharmacists should have authority to perform? If yes, please specify.
 - a. If you believe there are additional functions pharmacists should have authority to perform, do you believe that training or protocols should be established?
3. Do you currently work under a collaborative practice agreement? If yes, please specify the general conditions?
4. Do you believe there are barriers to providing appropriate patient care? If yes, please specify the types of barriers.
5. Do you believe you have sufficient time and autonomy to make patient-based decisions?
6. Does your employer develop policies and procedures that define how you must perform specified functions or apply clinical judgement? If yes, please provide examples.
 - a. If your employer has such policies and procedures, do they give pharmacists an opportunity to deviate from them to exercise their clinical judgment?
7. Has your employer developed policies related to dispensing of controlled substances?
 - a. If yes, does the pharmacist have the discretion to deviate from such policies to provide appropriate patient care?
8. Has your employer developed a system to block the dispensing of certain types of prescriptions?
 - a. If yes, does the pharmacist have the discretion to deviate from such blocks to prevent disruption in treatment or for any other reason?

9. Does your employer have policies that incentivize performing certain services (e.g., providing vaccinations, etc.)? If yes, please specify.

VII. Future Committee Meeting Dates

- a. October 25, 2022
- b. February 1, 2023
- c. May 10, 2023

VIII. Adjournment

Attachment 1



STANDARD OF CARE COMMITTEE
Draft MEETING MINUTES

DATE: June 22, 2022

LOCATION: Department of Consumer Affairs
 1625 N. Market Blvd. 1st Floor Hearing Room
 Sacramento, CA 95834

Public participation also provided via WebEx

COMMITTEE MEMBERS PRESENT: Seung Oh, Licensee Member, Chair
 Maria Serpa, Licensee Member, Vice Chair
 Indira Cameron-Banks, Public Member
 Jessi Crowley, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Nicole Thibeau, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel
 Debbie Damoth, Executive Specialist Manager
 Ann Altamirano, Associate Analyst

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Oh called the meeting to order at 9:00 a.m. Chairperson Oh reminded everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Oh took roll call. Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for

items not on the agenda; however, none were provided.

III. Approval of March 9, 2022, Committee Meeting Minutes

Chairperson Oh referenced the draft minutes for the March 9, 2022, Standard of Care Committee Meeting in the meeting materials. Counsel Smiley requested the word “enforcement” be placed before model on page 2 in the 3rd paragraph and on page 4 in the 2nd full paragraph.

Members were provided the opportunity to provide comment; however, no comments were made.

Motion: Approve the March 9, 2022, Standard of Care Committee Meeting Minutes with changes suggested.

M/S: Serpa/Cameron-Banks

Members of the public were provided the opportunity to provide comment; however, no comments were made.

Support: 4

Oppose: 0

Abstain: 0

Not Present: 1

Committee Member	Vote
Cameron-Banks	Yes
Crowley	Yes
Oh	Yes
Serpa	Yes
Thibeau	Not Present

IV. Presentation by Kerrie Webb, Attorney III, Medical Board of California, Perspective on Standard of Care Enforcement in the Practice of Medicine.

Chairperson Oh introduced and welcomed Counsel Kerrie Webb of the Medical Board of California to provide the Committee with a presentation on a perspective of standard of care enforcement model in the practice of medicine.

Ms. Webb advised she has been counsel for Medical Board for nine years and prior to that her experience was in medical malpractice. Ms. Webb noted the presentation represents her opinion.

Ms. Webb referenced Business and Professions Code (BPC) section 2234 that states the Medical Board of California (MBC) shall take action against any licensee who is charged with unprofessional conduct. Ms. Webb noted unprofessional conduct includes but is not limited to violating the Medical Practice Act (MPA); gross negligence; repeated negligent acts; and incompetence highlighting that the standard of care evolves.

Ms. Webb reviewed the definition of Standard of Care (SOC) as that level of skill, knowledge and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstance at the time in question. Ms. Webb noted SOC must be established through expert testimony.

Ms. Webb reviewed the benefits with the SOC Model. Ms. Webb noted the SOC Model is flexible and depends on the facts, circumstance, location, patient history, patient compliance and state of emergency. Ms. Webb added the SOC Model changes over time with advancement in medicine without the need for statutory or regulatory changes. Also noted was that the law cannot and does not have to cover every possible scenario as SOC controls most interactions.

Ms. Webb provided the MPA has a ban on the corporate practice of medicine pursuant to BPC section 2400, et seq. Ms. Webb added it was her understanding that this does not exist for pharmacy law. Ms. Webb noted it is important the SOC be set by licensees and NOT lay individuals or corporations. Licensees must put patient safety above profits and other interests. SOC must control over policies and procedures that require conduct below the SOC.

Ms. Webb provided challenges with the SOC Model including the MPA has few bright line rules which can be frustrating to licensees who want to know what is expected. Ms. Webb indicated case outcome is dependent upon the “winner” of the “battle of experts” noting the defense has a bigger expert pool and sets their own limit on what they pay whereas the MBC can pay very little for experts. Ms. Webb noted the SOC doesn't have to be the best care. Ms. Webb provided the example of the requirement for physicians to check CURES. It had to be placed into law to become a requirement for physicians prescribing Schedules II-IV.

Ms. Webb reviewed the challenges of working with experts in the SOC Model to include finding; training; monitoring; preparing; paying; retaining and defending the experts from lawsuits from disgruntled licensees.

Chairperson Oh stated the presentation underscored key differences between the regulation of medicine and pharmacy including a prohibition on the practice of corporate medicine and stated it was imperative the Committee remain mindful of these types of differences during the discussion. Members were provided the opportunity to provide comment and ask questions.

Member Serpa inquired about the use of expert witnesses and prolonged process for evaluating some disciplinary issues in some situations. Dr. Serpa inquired of estimates of cases that would require extended disciplinary hearings. Ms Webb provided the MBC receives over 10,000 complaints a year and takes action on three to four percent. Ms. Webb clarified all of the cases that require extended discipline require an expert report as the basis for the accusation. Ms. Webb added approximately 80 percent of cases settle with a stipulation rather than go to hearing.

Dr. Serpa inquired how many cases the Board receives and how many of those cases go to hearing. Ms. Sodergren advised the information could be provided to the Committee. Ms. Sodergren added one potential difference to consider is the Board regulates the business, the product, and the people. Ms. Sodergren noted the Board typically has multiple respondents in a case. Ms. Sodergren indicated a single investigation may involve the investigation of multiple individuals.

Chairperson Oh inquired if enforcement actions are driven by complaints. Ms. Webb advised the cases are mostly complaint driven with some proactive projects such as the prescription review project where the MBC reviews death certificates from the Department of Public Health when the death was related to a prescription overdose.

Member Cameron-Banks inquired if there were two different groups of experts used being the experts used by the MBC and the experts used by the defense. Ms. Webb indicated possibly but MBC must be careful and mindful of subjecting repeated experts to cross-examination with impeachment if not careful. Ms. Webb advised the MBC looks for both defense and plaintiff as it demonstrates the experts testify on what they believe to be accurate and not beholden to one side. Ms. Cameron-Banks inquired about overlap between two experts. Ms. Webb advised the Administrative Law Judge (ALJ) would have to determine which expert has more credibility (e.g., does the expert concede a point that should be conceded or does the expert take an unreasonable position on something that seems so obvious to others, etc.). Ms. Webb stated sometimes there is difference on whether a violation occurred or the degree of the departure of SOC. Ms. Cameron-Banks inquired about stipulated settlements how often it comes down to the credibility of the expert or how the expert performed. Ms Webb indicated the expert's performance was huge but also was related to the expert's performance prior to hearing.

Member Crowley inquired how often new laws must be implemented to adapt to the SOC Model. Ms. Webb indicated anecdotally not often. Dr. Crowley inquired if SOC Models (e.g., medicine, nursing, etc.) have contradicted themselves or where there have been issues. Ms. Webb couldn't think of an example. Dr. Crowley inquired about the impact on the Board to protect experts long term as well as what that looks like for the Board and if the Board would have to testify on behalf of the experts. Ms. Webb explained it could get to discoveries with interrogatories, request for production, depositions, and a trial. It is done through the Deputy Attorney General and includes a substantial cost.

Counsel Smiley inquired about the standard of care changing based on the location such as a rural area of California versus an urban area of California. Ms. Webb provided if the respondent physician practices in a rural setting, an expert from a different setting type could be impeached during cross examination because the tools and resources available, ability to have a specialist consult on a matter, the ability to refer someone in the locality for a specialist treatment is very different than in a rural setting and plays a role in who the experts are for the case. The experts must be familiar with the standard of care for that setting and location to be credible.

Ms. Smiley inquired if the MBC must agree to indemnify the experts or come to their defense in the contract with the expert. Ms. Webb provided the requirement is in the law and website. Ms. Webb noted there is an expert page on the MBC website.

Chairperson Oh inquired when there is a difference in opinion of experts on a treatment, modality, or what kind action to take how the difference is reconciled. Ms. Webb provided the MBC must prove its case by clear and convincing evidence to a reasonable degree of certainty which is determined at hearing and not stipulation. Ms. Webb advised the ALJ must make the determination and if the MBC didn't prove its case by clear and convincing evidence, the MBC would lose the case and the accusation is dismissed.

Chairperson Oh inquired if Ms. Webb had come across a situation where the physician group has a policy/procedure and the standard of care was impacted by the policy/procedure or is that not allowed by the MPA. Ms. Webb advised physician groups do have policies and procedures but they can't be set below the standard of care. Ms. Webb noted some cases have in their evidence of rehabilitation that policies and procedures have been changed. Ms. Webb provided an example of an urgent care physician who failed to document repeat vitals, where it should have been done but the medical assistant didn't do it and the physician is responsible. The physician put safeguards in place, did additional training and showed evidence the practice was updated. This demonstrated to the MBC that the physician could be rehabilitated.

Ms. Sodergren inquired if the standard of care could delay consumer protection. Ms. Webb advised enforcement cases tend to take about three years to get through the process from complaint to final decision. Factors involved in delaying include finding an expert, responsiveness of the expert, provision of an expert report that meets the requirements, accessibility of expert to provide testimony at hearing, and need for training.

Members of the public were provided the opportunity to provide comment.

Daniel Robinson inquired about the locality rules and geographic differences in standard of care and if a person in a rural location should expect a lower standard of care than someone in a suburban/urban location.

Steven Gray commented BPC 4036 defining a pharmacist should be considered and requested the type of liability should be clarified (e.g., civil, administrative, etc.). Dr. Gray noted all of the Board of Pharmacy Inspectors are pharmacists. Dr. Gray inquired if MBC licenses a location.

Michael Matz inquired about the cost of a case using the standard of care enforcement model.

Chairperson Oh thanked Ms. Webb for her presentation and participation in the meeting.

V. Discussion and Consideration of Actions Taken by Other State Boards of Pharmacy Related to Standard of Care

Chairperson Oh recalled at the last meeting, comments were received regarding efforts undertaken by Idaho and Washington. Dr. Oh referenced the meeting materials that provided a summary information as well as links to provisions of the respective laws. Dr. Oh noted published articles and other publicly available information was provided in the meeting materials. Dr. Oh noted meeting materials also included articles provided as requested by stakeholders. Dr. Oh also noted the meeting materials highlight authorities provided to pharmacists. Where pharmacists in California are authorized to perform similar duties, the relevant provisions of the law were provided.

Chairperson Oh advised some of the provisions related to expanded access to care for patients. Dr. Oh stated it was good to see that California patients appear to have in large part the same access to pharmacist care; however, the access to

care may be more prescriptive with requirements in pharmacy law and its regulation detailing out how the authority may be exercised. Dr. Oh commented it was important to learn about actions taken by other jurisdictions and for the Committee to recognize that an approach taken by one jurisdiction may not be appropriate for another. Dr. Oh stated these types of variances in state authority quite routinely and was incumbent upon the Committee to ultimately determine what is believed to be appropriate to recommend to the Legislature for California consumers given the state specific issues and mandate of consumer protection. Dr. Oh noted where there are differences between jurisdictions, for example in size, population, licensee population, etc., it was important to acknowledge those differences.

Members were provided the opportunity to provide comment; however, no comments were provided.

Members of the public were provided the opportunity to provide comment; however, no comments were provided.

VI. Discussion and Consideration of Policy Questions Related to Standard of Care in the Practice of Pharmacy

Chairperson Oh highlighted the meeting materials detail out some relevant provisions of pharmacy law. Dr. Oh advised from a process standpoint the Committee will discuss a question posed and then open for public comment. Dr. Oh recommended the Committee refrain from taking any action but look to reaching consensus. He stated it was very appropriate to indicate if additional information is required to make a judgement on a question. If additional information is needed, Dr. Oh requested sharing what information could be helpful in the decision-making process to allow staff to provide the information at a future meeting.

Chairperson Oh highlighted the discussion and whatever conclusions are ultimately reached impact practices that cross over into other areas under consideration by other committees of the Board. For example, what the Committee ultimately decides could impact workforce challenges which could then impact the work of the Medication Error Reduction and Workforce Committee.

Policy Question #1 – Does the Committee believe a transition to an expanded Standard of Care enforcement model is consistent with the Board’s consumer protection mandate?

Chairperson Oh advised the Board already uses a standard of care as part of its regulation. Dr. Oh provided as an example, the law requires pharmacists to exercise corresponding responsibility, but does not explicitly state the steps that must be taken. Dr. Oh stated he personally believed that in some instances, an expanded standard of care enforcement model could be consistent with the Board's mandate; however, it would depend on the specifics.

Members were provided the opportunity to provide comment.

Member Crowley referenced Member Thibeau's comment at the last meeting regarding data to support improved patient care outcomes in the standard of care enforcement models in other states and it appeared there is no data to support improved patient care outcomes. Dr. Crowley referenced the three-year time frame for the MBC and inquired of the Board's time frame. Ms. Sodergren provided each case is different based on complexity noting some of the Board's cases take three years but that is the exception rather than the rule. Additional information can be provided at a future meeting.

Member Crowley stated at this point the Committee doesn't have sufficient evidence to show an improved patient care protection if transitioned to a standard of care enforcement model. Dr. Crowley stated additional information and data demonstrating improved patient care under the standard of care enforcement model would be helpful.

Member Serpa indicated comparing pharmacists to physicians and nurses seems to be similar but differs significantly when factoring in licensed premises and other licensing categories the Board licenses. Dr. Serpa noted concern about disciplinary issues for process and location as many Board regulations include controlled substance accountability, where products are obtained and acquired, cleanliness of pharmacies, etc. Dr. Serpa noted additional concern as to how standard of care would apply in these cases or if there would need to have standard of care for people licensed and standard of care for premises licensed. Dr. Serpa indicated additional evaluation is required.

Members of the public were provided the opportunity to provide comment.

Daniel Robinson commented reiterating the profession of pharmacy includes facilities, drug use control, warehousing, storage, etc. noting he wasn't sure standard of care should apply to those areas. Dr. Robinson noted in 2014 pharmacists were identified as health care providers in California; however, nothing changed in the law that allowed pharmacists to fully function as health care providers. He added about 43 percent of pharmacists practice in institutional and

ambulatory care settings so there are many people who are practicing and providing direct patient care as well as those in community pharmacies that provide patient care services. Pharmacists need flexibility to provide medication therapy and preventative health care services to have the practice evolve with the standard of care.

Nicki Chopski, Idaho Board of Pharmacy, commented she is available for questions about the Idaho's experience in transitioning to the standard of care enforcement model.

Richard Dang commented included in meeting materials was a paper from the Idaho Board discussing patient safety outcomes. Dr. Dang indicated he will continue to look for resources to provide to the Committee. Dr. Dang agreed with Dr. Robinson's comment that there are different regulations and expectations for facility licensees, wholesale licensees and pharmacist licensees. Dr. Dang encouraged the Committee to discuss and focus standard of care for pharmacists, pharmacy technicians and other licensing member but not necessarily the facility or other types of licensees.

Rita Shane, Vice President and Chief Pharmacy Officer, Cedar Sinai Medical Center in Los Angeles, commented what is compelling is what the patients need. Dr. Shane noted as previously discussed at a meeting the complexity of patients being seen across all types of care settings and the knowledge and skills of pharmacist to provide the care the patients need. Dr. Shane stated at Cedar Sinai in the inpatient and outpatient settings often times the physician has to be called and disrupt their workflow to get approval to ensure the optimal medication management that was intended for the patient. Dr. Shane referenced data about SB 1254 and demonstrating preventing patient harm on medication histories is a simple example and has been accepted throughout California. Dr. Shane encouraged the dialogue to determine details and best practice standards of practice for sterile compounding and management of control substances while advancing the care of patients. Dr. Shane noted data in California demonstrates Baby Boomers continue to age as well as the need for ensuring the knowledge and skills of pharmacists are leveraged on behalf of patients.

Steven Chen, Director of the California Rights Collaborative, commented although states with standard of care may not have the robust impact evidence regarding improved patient safety, he noted the published evidence regarding the impact of

pharmacists providing medication management services for patient safety and health outcomes is overwhelmingly positive. Dr. Chen stated value-based payments are key to ensuring that patient outcomes are attained safely and efficiently. Dr. Chen stated the tragedy is when pharmacists identify serious actual or potential drug-related problems and the pharmacists aren't able to help because contacting physicians can be an overwhelming barrier.

Steven Gray commented the need to separate the standard of care concept model for pharmacists with more of a regulatory permissive approach for facilities and for specific items such as inventory records, etc. Dr. Gray commented California has had the standard of care enforcement model for decades in the ambulatory care practices where pharmacists are managing drug therapy. This has been done for over 30 years and now there are thousands of pharmacists practicing their profession in California by managing patient therapy and the most complex therapies/highest risk patients without touching the actual medications. Dr. Gray noted advanced practice pharmacists can take over the management of therapy and they don't have to get prior permission from the physicians whereas the statute requires the pharmacist notify the physician. The standard of care enforcement model is used in collaborative practice agreements and in hospitals where the hospitals can delegate the authority for total medication management for patients in the hospital. Dr. Gray noted the need to not have the regulatory model delay the standard of care enforcement model.

Mark Johnston, CVS Health, commented CVS Health only has three pharmacies in Idaho. Mr. Johnston stated he thought Idaho was the only state where in pharmacy they enacted a standard of care enforcement model. Mr. Johnston highlighted items related to standard of care enforcement model: expanded pharmacist practice and reducing administrative burden to give the pharmacist the time to engage in these expanded practices.

Bill Cover, Associate Executive Director of National Association of Boards of Pharmacy (NABP), commented NABP continues to examine the NABP's model act and rules as well as where a standard of care approach can be incorporated into those vital roles that states can use as a guide. Many states vary in the use of regulations and standard of care. If standard of care enforcement model is not used, boards must keep rules and regulations up to date.

Policy Question #2 – As California law does not prohibit the corporate practice of pharmacy, does the Committee believe a Standard of Care Enforcement Model is possible?

Chairperson Oh noted there is an explicit prohibition on the corporate practice of medicine whereas there is no similar prohibition on the corporate practice of pharmacy. Dr. Oh encouraged the Committee to consider since California law does not prohibit the corporate practice of pharmacy, does the Committee believe a Standard of Care Enforcement Model is possible?

Chairperson Oh stated he found this question challenging especially because during a previous Committee meeting, the Committee received public comments indicating that at least in one pharmacy corporation to reduce liability, established policies and procedures to define, at least in part, how a pharmacist would need to perform functions. Dr. Oh stated he was not convinced a Standard of Care Enforcement Model is possible while California law allows for the corporate practice of pharmacy. Dr. Oh noted the complexity of the issue because it is possible that a pharmacist believes the corporate policy is contrary to standard of care. Dr. Oh noted he was unclear on how a pharmacist would reconcile this when it is their pharmacist license on the line. Dr. Oh stated he has seen this occur in some instances of corresponding responsibility where a corporation's policy has prevented a pharmacist from exercising corresponding responsibility and was not sure how this was to be reconciled.

Members were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to provide comment.

Richard Dang commented in his experience he believed the corporate policies and procedures are being put into place to protect the corporations because of the specific regulatory framework that currently exists. Dr. Dang stated these policy discussions are good to have.

Steven Gray commented on having 35 years of working with major medical groups in California and is very familiar with the law that prohibits the corporation from the practicing medicine. Dr. Gray stated he believed it was misunderstood in this context. Dr. Gray stated the Board will hold the pharmacist accountable for the standard of care despite whatever the employer may say and that is the difference in the corporate practice of medicine. Physicians generally can't be employees of a corporation unless it is a physician corporation with exceptions. He stated it ultimately resolved at the employee/employer relationship. He continued the pharmacist-in-charge (PIC) is already obligated to meet the roles and responsibilities of the PIC regardless of what the employer says currently. He continued he didn't think that was a barrier to going to the standard of care

enforcement model for the advancement of the practice and the greater service. He added many pharmacists in California are self-employed who establish their own policies and procedures practicing inside and outside of a pharmacy under their own responsibility and integrity which would be required in the standard of care enforcement model.

Member Serpa agreed with public comment that legality or the issue of corporate pharmacy may not be an issue but posed having further discussion on a hypothetical situation: If a pharmacist works for a large corporation and the standard of practice allows the pharmacist to be more advanced in care of patients but the corporation prevents the pharmacist from providing the services due to a concern of liability. Dr. Serpa suggested exploring the conflict between the employer and pharmacist where the employer wants a lesser provision of care based on perceived legal ramifications to the corporation.

Member Crowley commented she personally didn't see how the Board can continue allowing pharmacies to be corporate owned and transition to a standard of care enforcement model in this realm while it maybe appropriate for other areas of practice. Dr. Crowley expressed concern that many corporations required their pharmacists to have additional certifications (e.g., furnishing birth control, naloxone, immunizations, etc.). Dr. Crowley expressed concern for conflicting requirements of the corporation that may put pressure on their pharmacists to become certified without the pharmacist feeling comfortable but concerned for retaliation in a retail chain setting.

Member Cameron-Banks inquired how the expansion of the scope of practice of a pharmacist is consistent or inconsistent with the Board's mission of consumer protection. Ms. Cameron-Banks cautioned the Committee from conflating the impact to consumer protection and enforcement implications due to a change to a standard of care enforcement model as they are two separate issues. Ms. Cameron-Banks requested more data and the two issues to be considered separately.

Member Crowley agreed additional information was needed. Dr. Crowley explained the expansion of the pharmacists' role will increase consumer access to health care. Dr. Crowley explained in rural and urban areas there are hospital deserts or areas where patients don't have access to physicians or clinicians and pharmacists are often thought of as the most accessible health care provider. Dr. Crowley advised considering health equity in that patients should have access to health care but need to make sure facilities providing the services have sufficient resources to provide the same quality of care.

Members Cameron-Banks and Crowley agreed additional data demonstrating increased patient care with the standard of care enforcement model was needed.

A break was taken at approximately 10:46 a.m. and resumed at 11:00 a.m. Roll call was taken. Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

Policy Question #3 – Does the Committee believe it is appropriate to only transition to a Standard of Care enforcement model if such prohibition on the corporate practice of pharmacy is included as part of the transition? Note: California law prohibits the corporate practice of medicine.

Chairperson Oh advised the next policy question was if the Committee believes it is appropriate to only transition to an expanded Standard of Care if it includes a prohibition on the corporate practice of pharmacy. Dr. Oh noted the difficulty of the question. Dr. Oh stated he believed in part based on the information shared in the previous policy question, he wasn't sure how feasible such a bar would be. Dr. Oh noted the question was important to consider and if there was already such a bar, many of the questions before the Committee would be easier to consider.

Members were provided the opportunity to provide comment.

Member Crowley commented it would be necessary but didn't think it was feasible and inquired how many pharmacies were corporate pharmacies. Ms. Sodergren indicated chain versus independent pharmacies could be differentiated and by ownership type.

Member Serpa sought clarification on the difference between corporate practice of pharmacy and the corporate ownership of the physical facilities. Dr. Serpa indicated she thought it was impossible to bar corporate pharmacies.

Counsel Smiley clarified Dr. Serpa's question by asking if she was asking if the Board could separate out the ownership and maybe have the flexibility of the ownership of a facility that maybe has a high drug volume or would that reduce the number of pharmacies as well as competition. Ms. Smiley thought the ownership could be separated from the practice pharmacy or could be something the Committee could consider. Ms. Smiley noted commenters stated there can be provisions in the law or if the Legislature stated the clinical standard of care has to be determined by a licensee rather than the pharmacy.

Member Serpa inquired if the independent consultants working for corporate pharmacy and how that would affect employment contracts, labor law, and other issues that would need to be fully evaluated.

Member Cameron-Banks stated this would need to be answered before determining if standard of care was feasible and focusing on the issue of consumer protection.

Member Crowley referred to the public comment that stated the how California law already holds the pharmacist accountable in the situations where there is a corporate owned pharmacy. Dr. Crowley referenced a previous meeting where a Nursing Board disciplinary case was discussed where the facility didn't meet the standard of care but someone working at that facility would assume that their workplace is meeting the standard of care. Dr. Crowley noted that gets into a delicate situation of holding a licensee accountable and the concern is with a corporate owned pharmacy how the standard of care enforcement model is applied when the pharmacist isn't necessarily dictating the policies. Dr. Crowley noted another public comment indicated the corporate policies and procedures were created for the rules and regulations of pharmacy law and would be interested if additional information from corporate pharmacies within the states that have transitioned to standard of care have a similar number of policies and procedures. Ms. Sodergren recalled public comment at a previous meeting from a grocery chain pharmacist that when Idaho went to the standard of care enforcement model, the corporation developed policies and procedures to reduce the corporation's liability but will check the record to confirm recollection of the commenter.

Members of the public were provided the opportunity to provide comment.

Mark Johnston, CVS Health, commented based on his experience with three pharmacies in Idaho from a corporate perspective, CVS Health didn't change policies for three stores and stated it was their federal policies. Mr. Johnston explained his experience in Idaho when they were expanding the pharmacist's ability to add statin to a therapy, the medical society was initially against the change in rules but once the law was passed, physicians appreciated pharmacists filling the gap and identifying those areas in prescribing. He noted when pharmacists called to give notification, the physicians were too busy to take notification and now it has become the standard of practice. Mr. Johnston noted the challenge with rules and regulations is that sometimes there is a gap between the state requirements and the federal requirements (e.g., HIV prophylaxis that require following CDC guidelines but the CDC guidelines require a blood panel that can't be ordered by pharmacists).

Richard Dang commented on the discussion about corporate practices of pharmacy and who is responsible which also is part of the Medication Error Reduction and Workforce Committee. Dr. Dang noted the Virginia Board of Pharmacy recently put forth saying the PIC or pharmacist on duty shall control all aspects of the practice and any decision overriding such control of the PIC or

pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit. Dr. Dang noted this could be a way to differentiate different responsibilities and be able to separate the standard of care expected by the individual pharmacist providing the care and the expectation of the permit holder which may be corporate owned.

Daniel Robinson commented related to the barriers to providing consumer protection under the standard of care that the MBC is also a consumer protection agency and that is the regulatory model used to provide consumer protection. He stated the facility can define what services are being provided in the facility and the level of service of care can be optional.

Policy Question #4 – Does the Committee believe expansion of the scope of practice for pharmacists is appropriate? If yes, does the Committee believe the expansion of the scope is most appropriate to achieve through a transition to an expanded Standard of Care enforcement model or through targeted amendments to pharmacy law?

Chairperson Oh noted the next policy question related to some of the benefits expressed by public comment during the last Committee meeting discussion indicating that a transition to a standard of care enforcement model would expand opportunities for pharmacist to provide expanded services. Dr. Oh stated while considering this question, he reflected on the information under the prior agenda item and noted that many of the authority's pharmacists perform under a standard of care enforcement model in another jurisdiction are already authorized, at least to a large degree, in California. Dr. Oh added the deviation appears to occur if there are there are underlying regulations that further define the authority.

Chairperson Oh inquired if the Committee believed expansion of the scope of practice for pharmacists was appropriate. Dr. Oh believed there are additional opportunities for pharmacist to play an important role in patient public health; while not autonomous, pharmacists already have the authority to perform expanded duties under collaborative practice agreements. Dr. Oh explained under the collaborative practice agreements, pharmacists may initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority which is a very broad authority for pharmacists. Dr. Oh noted it was a possible argument to indicate that expanded authority already exists for pharmacists with these changes in collaborative practice. Dr. Oh also inquired if the Committee believed the expanded scope of practice should be achieved through a transition to an expanded standard of care enforcement model or through targeted amendments to pharmacy law. Dr. Oh stated the issue of pharmacist autonomy must be resolved.

Members were provided the opportunity to comment.

Member Serpa expressed intrigue and excitement for the potential of better patient care by expanding the scope of practice. Dr. Serpa was not clear if it is the individual being able to provide some services and not other services (e.g., the individual has expanded training, opportunities, experience, etc. to provide a particular service) and inquired how would that service be provided in a larger group where there are multiple pharmacists working and that service may not always be available during the pharmacy's hours. Dr. Serpa expressed concern about continuity of care for a patient if there is only one person who can provide the services and what would happen to the patients when the one person is out. Dr. Serpa commented targeted amendments to pharmacy law are very tricky and may include unintended consequences.

Member Crowley commented the Committee can't look at the extension of the scope of practice as an isolated issue because a lot of factors need to be considered. Dr. Crowley suggested possibly leveraging the work of the Board's Medication Error Reduction Committee to see what the Committee's findings are on working conditions. Dr. Crowley commented in support of the expansion of pharmacy practice but was hesitant to say for all settings as there were many factors to consider.

Members of the public were provided the opportunity to comment.

Mark Johnston, CVS Health, commented the collaborative practice agreement law change is fantastic and will increase patient outcomes. Mr. Johnston spoke of standard of care for facilities in corporations and individuals. One of the keys to standard of care in Idaho was the PIC was eliminated while holding pharmacists and technicians accountable for their actions as well as the corporations for their actions. Mr. Johnston provided the security of the pharmacy as an example of how in the standard of care enforcement model both the pharmacists and corporations are required to provide adequate security. He continued the standard of care in Idaho is holistic and not just for individualistic.

Richard Dang commented in support of the collaborative agreement in California in that it is broad and does mimic the standard of care environment. Dr. Dang encouraged having speakers with experience in practicing under a broad broadcast collaborative agreements to bring evidence of outcomes, benefits, and risk.

Policy Question #5 – Does the Committee believe a Standard of Care enforcement model is appropriate only in certain practice settings (e.g., hospitals)?

Chairperson Oh inquired if the Committee believes a Standard of Care enforcement model is appropriate only in certain practice settings. Dr. Oh shared his background is primarily in community pharmacy and had previously shared

some thoughts on possible challenges at least in the community setting. Dr. Oh stated his hope was that more pharmacists would work in clinics and coordinated care settings in the future. Dr. Oh stated there were two layers of transforming current community pharmacy dynamics and transforming utilization of pharmacists in non-community pharmacy settings. Dr. Oh encouraged discussion if this same dynamic exists in other settings such as hospitals.

Members were provided the opportunity to comment.

Members Serpa spoke of concern that level of service provided shouldn't be person specific but location specific such that service would be provided at all open hours and on all open days. Dr. Serpa provided examples such as hospice, home infusions, hospitals, etc. where the practice of pharmacy is not pharmacist specific but it is covered by pharmacists who are assigned a shift and their expertise has a minimum requirement for all pharmacists so that they provide the same advanced practice opportunities for patients at all times. Dr. Serpa indicated further discussion was needed.

Member Cameron-Banks agreed further discussion was needed and inquired about limiting/not limiting this model to certain practice settings and what that does for consistency of levels of patient care for patients based on where the patients are living and what the patients have access.

Ms. Sodergren provided the Committee's legislative mandate is to provide a report to the Legislature. At this time, the Committee needs to evaluate the policy questions to help to formulate what the recommendation and report will conclude.

Member Crowley expressed interest in hearing more input from pharmacists in variety of settings as her experience is primarily community setting.

Members of the public were provided the opportunity to comment.

Steven Gray commented there is already different standards for different practice settings and provided the examples what a pharmacist can do in a hospital. He continued if a pharmacy decided to assist in anti-coagulation therapy and the standard of care is that they have a pharmacist on call to answer the questions, that becomes a standard of care for that service. He added this is currently allowed in a collaborative practice where the individuals are qualified and they are given the ability to provide that service.

Daniel Robinson agreed with Dr. Gray and commented many of the medication management services being provided are provided on an appointment basis and not all services are always available. He strongly urged the Board not to restrict standard of care to a certain practice setting as many of the services are provided

in a community pharmacy but rather encourage the standard of care approach and stay current versus what is in statute.

Richard Dang agreed with the previous commenters and encouraged the Board not to restrict standard of care only to hospital settings. Dr. Dang explained as USC faculty and residency program director of community-based training program to provide clinical services in community settings for the past 20 years, he noted there is data that pharmacists can provide these services in the community setting. It is appropriate for community ambulatory care settings that have standard of care as well as in examples from Richard Chen's CRMC collaborative. Dr. Dang added restricting standard of care to only one setting would cause confusion and fragmentation of care especially during transition of care from hospital to the community.

Stephen Chen commented he has participated in many meetings where health systems are struggling when patients are released from hospitals or clinics. With health system partners that aren't equipped to manage the patients, the patients will return to hospitals and utilize resources unnecessarily. He noted community pharmacies are the essential piece of that health care system that haven't been empowered. He added it would be a mistake to not include community pharmacists in the standard of care enforcement model. With the California law for collaborative practice and technology capability, there are data platforms that can provide real-time sharing of clinical information between health systems, hospitals, health plan pharmacies, etc. and combined with value-based payments used in his program, they have proven they can drive health outcomes through community pharmacies. By having health plan partners equip community pharmacies with social support resources our community pharmacists can connect and close the loop on essential services.

Chairperson Oh stated it would be difficult to have certain practice settings excluded from standard of care.

Policy Question #6 – Does the Committee believe that specific provisions included in a pharmacist defined scope of practice that require compliance with specific pharmacy regulations would be appropriate to transition to a Standard of Care enforcement model, (e.g., provisions for providing naloxone, hormonal contraception, travel medications, etc.)?

Chairperson Oh noted previous discussion on the scope of practice for pharmacists and that for many authorized duties, there is regulation that further defines how a pharmacist must fulfill those duties at least in part. When considering the transition to a standard of care enforcement model, Dr. Oh inquired how this transition could take place without wholesale changes in pharmacy law. Dr. Oh stated his opinion was to step into a transition. For example, under existing law a pharmacist may provide hormonal contraception under specified conditions. As part of this

question, Dr. Oh believed the Committee is being asked to consider if the scope of practice related to a pharmacist's authority to provide hormonal contraception is appropriate but the additional requirements to exercise such authority would be repealed. He stated in hope the example was helpful, the question specifically inquires if the Committee believes that specific provisions included in a pharmacist's defined scope of practice that require compliance with specific pharmacy regulation would be more appropriate to transition to a standard of care enforcement model. Dr. Oh stated he believed there was an opportunity here depending on the guardrails in place to ensure a pharmacist is empowered to operate under a standard of practice.

Members were provided the opportunity to comment.

Member Serpa commented historically the Board has been limited to be extremely detailed on the provisions of providing medicine such as smoking cessation and by having standard of care apply to these types of services, it would take a lot of the details out of standard of regulation and revert it back to what is the standard of care which is always changing and emerging. Dr. Serpa provided the example of PrEP and PEP that can change multiple times a year and need to keep up with the emerging information so that the patient is receiving the most up to date care.

Member Cameron-Banks commented data is missing. Ms. Cameron-Banks inquired what percentage enforcement or investigations involves compliance in that type of setting. She noted standard of care seems like it could play out differently for the types of investigations the Board has now. She added looking at historical data in California would help her understand this better. If the issue is compliance with specific pharmacy regulations and the ones being discussed, she inquired if it resulted in investigations or discipline.

Member Serpa provided an overview of pharmacy laws that allow pharmacists to provide therapies to patients with very specific limitations such as trainings or specific instructions that require little judgement. Dr. Serpa added in her experience, there have been two issues. First, because of specific regulations and processes, many pharmacists choose not to provide the services because of the requirements and there is no reimbursement for the services. This results in the services not being provided when they could be. Second, those that are trained do it well and except for recently vaccines, didn't recall citations or disciplinary actions regarding these because those trained are typically higher performers.

Member Crowley commented based on her understanding, vaccine errors specifically increased due to the pandemic and was aware of pharmacists who have been required to administer over 100 vaccines a day with no additional assistance. Dr. Crowley advised considering all elements involved including staffing,

demographics, training, and experience with many of these being circumstantial and situational.

Chairperson Oh noted reimbursement is a large issue obviously that may not be in Committee or Board's jurisdiction but without changes in reimbursements all the discussions may not be impactful.

Ms. Sodergren responded to Ms. Cameron-Banks' question regarding what the data is showing as it is hard to compare disciplinary cases. She noted many cases are for failure to exercise corresponding responsibility and the Board hears from the licensee involved that the licensee didn't understand what that meant; however, that is an area where there is a lot of use of standard of care as the law requires the pharmacist must do it but doesn't say how. It does make it difficult to draw connection then to an investigation. Ms. Sodergren provided an example where a pharmacist didn't fulfil the requirements of the hormonal contraception. Ms. Sodergren advised cases for the misuse of education can be reviewed but for most of the cases, it is hard to say because you can't determine the causality.

Member Crowley commented the Board's guidelines on hormonal contraception and naloxone are extremely useful in practice. Dr. Oh agreed and noted pharmacists fall back on those guidelines the Board provides as the guidelines provide a level of comfort for the pharmacist.

Members of the public were provided the opportunity to comment.

Mark Johnston, CVS Health, commented standard of care involves trust. The standard of care is developed by the profession. The standard of care that is prohibited in one setting but not another is contrary to the standard of care where the standard of care develops on its own and it's the profession determining where and when it can be used to serve the public.

Stephen Chen commented he's been integrating pharmacists with medical practices for over three decades. He shared an example from the Center for Medicare and Medicaid innovation program when initially started there were legal red flags and questions but once they got past that there was zero pushback and physicians were thrilled and viewed as an additional layer of patient safety. Diabetic statin uses were increased. Collaborative practice agreements were permission based and while protocols are good they are not always the best and giving permissions for pharmacists as physicians to utilize best evidence as it evolves is helpful to the patients. He noted California collaborative to be sustained they targeted enrollment for each pharmacy sufficient to support at least one full-time pharmacist and technician. Training is perennial, required by the health plans live learning sessions and webinars to ensure pharmacists are up to date. A

combination of continuous quality improvement and value-based payments ensured that patients receive the highest level of patient care.

Daniel Robinson commented the problem with the statutory involvement of some of the practice guidelines that are currently being used is that it creates a limitation in being able to adjust as necessary. He provided the example of the law needing to be changed to provide the COVID vaccine when it was available. He added the guidelines can still be available on the Board's website but do not need to be included in statute. He noted Nursing developed a decision-making framework asking important questions (e.g., Is the activity you're planning to provide prohibited by any law? Is performing the activity with consistent with evidence-based medicine? Are there practice settings policies and procedures in place that allow you to perform the activity? Do you have the necessary education, training, and safety to perform the activity? etc.). If the requirements are met, they can do the activity based on the standard of care. Dr. Robinson stated a decision-making framework model was developed to clarify the process, qualifications, setting requirements, etc. to be considered to provide activities without specifically detailing for pharmacy. He offered to share the model.

Steven Gray reemphasized the problem with the detail in all of SB 493 required writing detailed regulations and protocols. Dr. Gray opined regulations are a barrier, do not keep up with standards (e.g., PrEP and PEP) and are harder to amend. He added the details of some of the regulations including naloxone are more detailed than what physicians are held to so the pharmacist must go through more detail than a physician, nurse practitioner, or other prescriber of the opioid. Both naloxone and hormonal contraceptions have been recommended to be OTC but now there is a protocol in place that is more detailed than what is required for physicians. The standard of care offers the flexibility and improves patient access to the care that pharmacists are uniquely trained and experienced to provide.

Richard Dang commented in support of previous commenters. Dr. Dang noted protocols and algorithms to providing clinical that is in statute is helpful but removing it from statutes and laws and moving to the standard of care but the documents can still be provided as guidance.

The Committee did not have time to review the following policy questions:

Policy Question #7 – If a transition to a Standard of Care enforcement model is determined appropriate, does the Committee believe it is appropriate to allow a business to develop policies and procedures for pharmacists to follow, or could such practice impede a pharmacist's ability to operate under a Standard of Care enforcement model?

Policy Question #8 – Does the Committee believe there are areas of pharmacist practice that are not appropriate for Standard of Care, (e.g., compounding)?

Policy Question #9 – Does the Committee believe changes to the Board's unprofessional conduct provisions would be necessary?

VII. Future Committee Meeting Dates

Chairperson Oh reported the next Committee Meeting was scheduled for August 24, 2022.

VIII. Adjournment

The meeting adjourned at 12:00 p.m.

Attachment 2

Improving Patient Safety and Outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists

CA Board of Pharmacy Standard of Care Ad Hoc Committee Meeting
August 25, 2022

Richard Dang, PharmD

Steve Chen, PharmD

Michael Hochman, MD

Alex Kang, PharmD

Introductions

- **Steven Chen**, PharmD, FASHP, FCSHP, FNAP, Associate Dean for Clinical Affairs, USC School of Pharmacy
- **Richard Dang**, PharmD, BCACP, APh, FCPHA, Assistant Professor of Clinical Pharmacy, USC School of Pharmacy and President, California Pharmacists Association
- **Michael Hochman**, MD, MPH, Chief Executive Officer, Healthcare in Action
- **Alex C. Kang**, PharmD, MBA, APh, BCPS, BCACP, Director of Clinical Pharmacy, L.A. Care Health Plan.

Framing & Purpose

- To provide a summary of evidence and real-world application in California of how pharmacists enabled to practice at top of licensure provide an added layer of patient safety/protection while improving health outcomes.
- What will be shared:
 - Big Picture Overview
 - Evidence
 - The California Right Meds Collaborative (CRMC)
 - Physician Experience
 - Health Plan Perspective
- Questions to Run On
 - What critical barriers does SoC remove that currently limit the impact pharmacists have on patient safety and outcomes?
 - What value does SoC add to health plans / payers and physicians?

Big Picture Overview

How Standard of Care fits into the Business and Professions Code

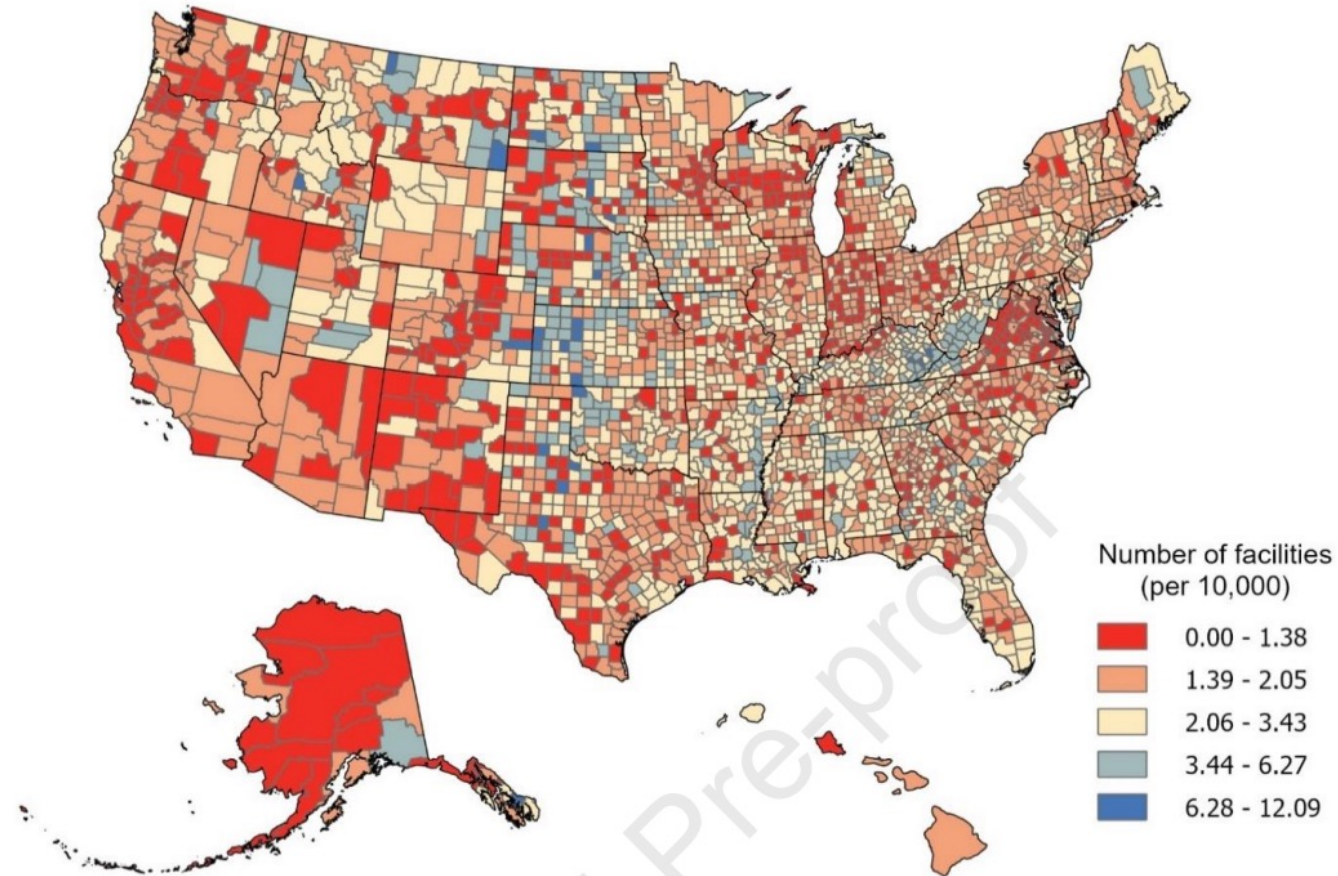
Richard Dang

Community Pharmacy: Equity & Access

- *Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis*. Published July 2022.
- 61,715 pharmacies, including 37,954 (61.5%) chains, 23,521 (38.1%) regional franchises or independently owned pharmacies, and 240 (0.4%) government pharmacies
- **In large metropolitan areas, 62.8% of the pharmacies were chains**
- **In rural areas, 76.5% of pharmacies were franchises or independent pharmacies**
- Across the overall U.S. population:
 - 48.1% lived within 1 mile of any pharmacy
 - 73.1% within 2 miles
 - 88.9% within 5 miles
 - 96.5% within 10 miles

Figure 1. Number of Pharmacy Locations per 10,000 Residents by County.

CA had 25 counties (43.1%) with low pharmacy density (fewer than 1.38 pharmacy per 10,000 residents)



We used geometric intervals to classify the pharmacy density (number of pharmacies per 10,000 residents), because the variable was not normally distributed.

Community pharmacies

- Community pharmacies are suited for the provision of clinical pharmacy and health services
- Community pharmacies, especially independent pharmacies, are important for equitable access to care
- Limiting the settings in which standard of care would apply would be a step backwards

CA Business and Professions Code - BPC

DIVISION 2. HEALING ARTS [500 - 4999.129]

CHAPTER 9 Pharmacy

ARTICLE 1. Administration 4000-4013

ARTICLE 2. Definitions 4015-4046

ARTICLE 4. Requirements for Prescriptions 4070-4079

ARTICLE 5. Authority of Inspectors 4080-4086

ARTICLE 6. General Requirements 4100-4107.5

ARTICLE 7. Pharmacies 4110-4126.10

ARTICLE 7.5. Sterile Drug Products 4127-4127.8

ARTICLE 7.6. Centralized Hospital Packaging Pharmacies 4128-4128.7

ARTICLE 7.7. Outsourcing Facilities 4129-4129.9

ARTICLE 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies 4130-4135

ARTICLE 9. Hypodermic Needles and Syringes 4141-4149

ARTICLE 10. Pharmacy Corporations 4150-4156

ARTICLE 11. Wholesalers, Third-Party Logistics Providers, and Manufacturers 4160-4169.1

ARTICLE 11.5. Surplus Medication Collection and Distribution Intermediaries 4169.5

ARTICLE 11.7 Cancer Medication Collection and Distribution: Registry of Participating Practitioners 4169.7-4169.8

ARTICLE 12. Prescriber Dispensing 4170-4175

ARTICLE 13. Nonprofit or Free Clinics 4180-4186

ARTICLE 13.5. Correctional Clinics 4187-4187.5

ARTICLE 14. Clinics 4190-4195

ARTICLE 15. Veterinary Food-Animal Drug Retailers 4196-4199

ARTICLE 16. Applications 4200-4211

ARTICLE 17. Continuing Education 4231-4234

ARTICLE 18. Poisons 4240

ARTICLE 19. Disciplinary Proceedings 4300-4317.5

ARTICLE 20. Prohibitions and Offenses 4320-4343

ARTICLE 21. Pharmacists Recovery Program 4360-4373

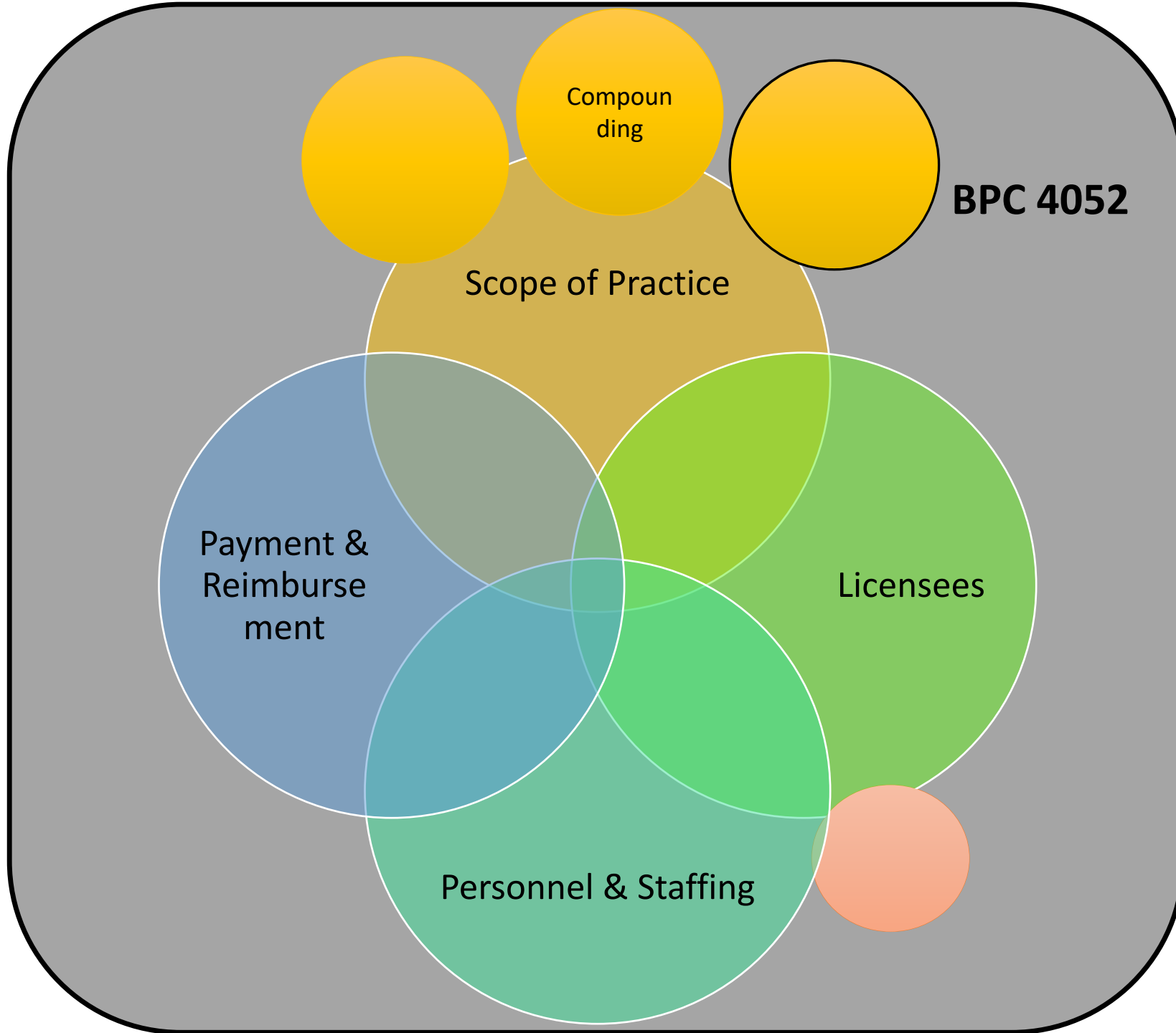
ARTICLE 22. Unfair Trade Practices 4380-4382

ARTICLE 23. Revenue and Renewal 4400-4409

ARTICLE 24. Prescription Rates for Medicare Beneficiaries 4425-4426

ARTICLE 25. Automated Drug Delivery System 4427-4427.8

CHAPTER 9.5. Audits of Pharmacy Benefits 4430-4441



Compounding

BPC 4052

Scope of Practice

Payment & Reimbursement

Licensees

Personnel & Staffing

BPC
BOP Regulations

ARTICLE 3. Scope of Practice and Exemptions

- **4050 – 4068**

- **4052**

- **4052.01**

- **4052.02**

- **4052.03**

- **4052.1**

- **4052.2**

- **4052.3**

- **4052.4**

- **4052.5**

- **4052.6**

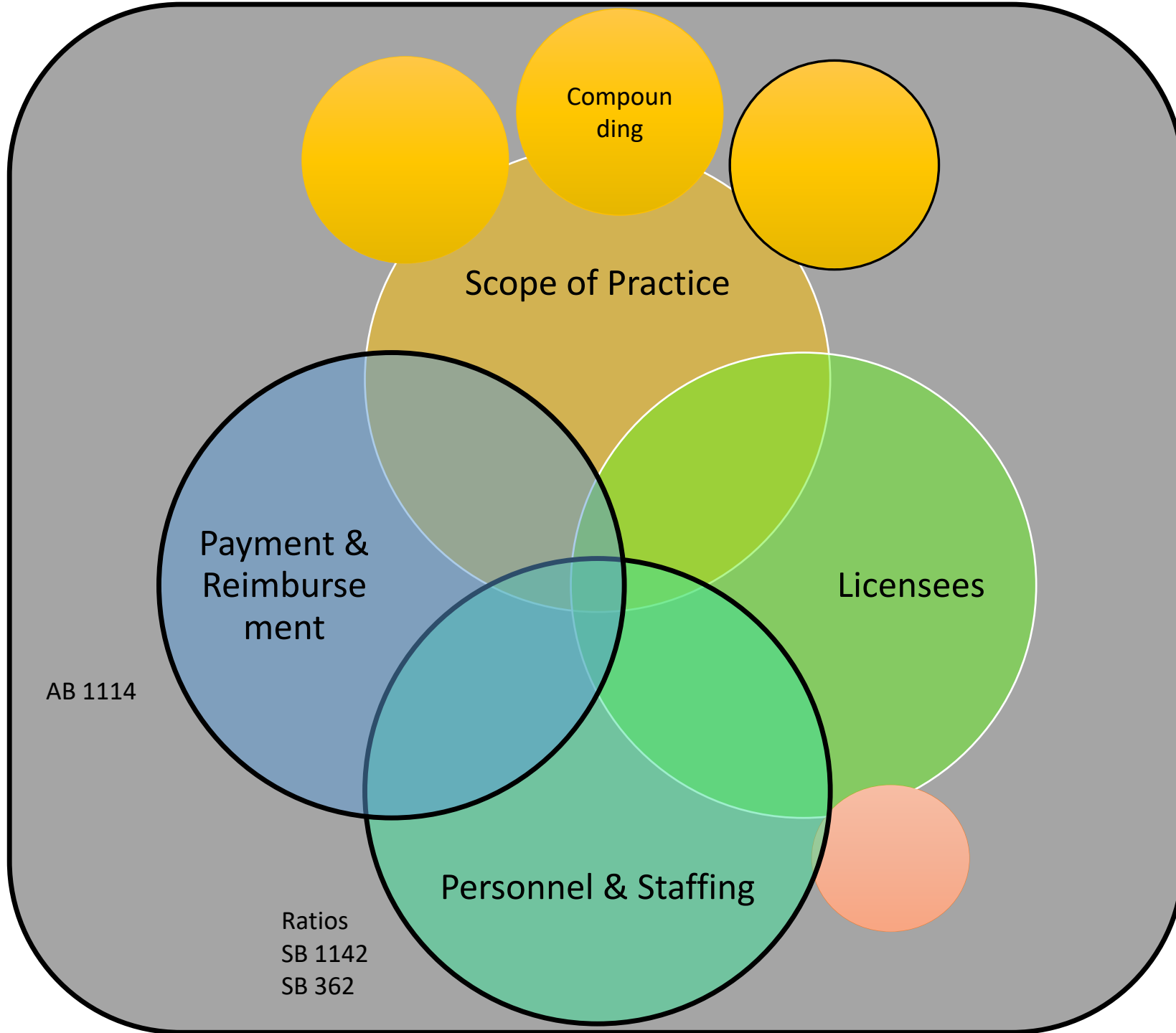
- **4052.7**

- **4052.8**

- **4052.9**

- **4052.10**

“What you are *allowed* to do”



**BPC
BOP Regulations**

Evidence and the California Right Meds Collaborative

Steven Chen

MEDICATIONS MATTER

Adverse effects from medications are estimated to be the

4th leading cause of DEATH in the U.S.¹



1/2 of the prescription medications taken every year in the US are used improperly⁴.

WHY?

\$528.4 BILLION
of avoidable spending annually is due to MISUSE or suboptimal use of medications².




75% of hospital readmissions among seniors in the U.S. are avoidable, primarily through better use of medications³.

WHAT can I do next to start benefitting from CMM?

Healthcare professionals:
For more information, go to:

to include a one-stop-shop for CMM resources
<http://calrightmeds.org/>

High-Risk Patients:

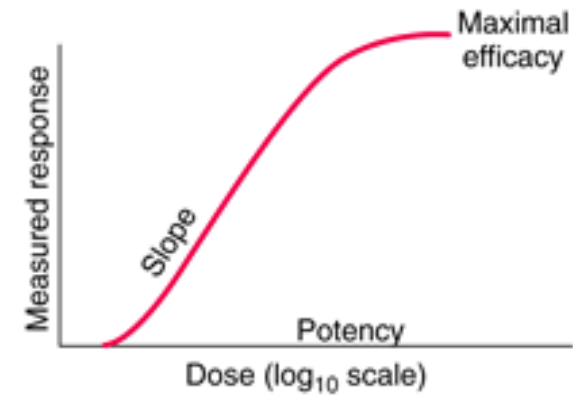
Talk to your physician and ask for CMM



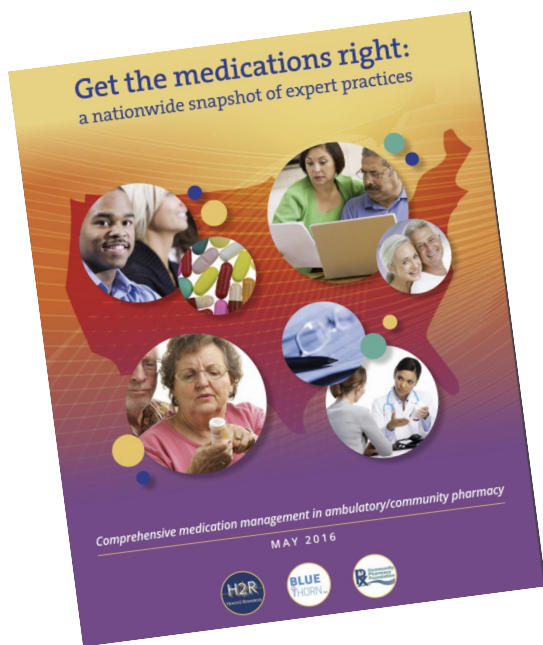
Comprehensive Medication Management: Standard of Care for Optimizing Medication Therapy



Right choice



Comorbidities and other medications



The role of the pharmacist has evolved beyond dispensing medication into active participation in disease management and prevention. By including pharmacists on the care team, published evidence and health system experience consistently demonstrate that mortality is reduced, disease outcomes improve, healthcare costs are reduced for high-risk patients, hospital readmission rates are reduced and patients are more satisfied with their healthcare. This evidence has been demonstrated in a broad range of conditions including cardiovascular diseases, diabetes management, asthma/COPD, oncology, and psychiatry¹.

A Need for Improved Medication Management

The cost of illness and death resulting from nonoptimized medication therapy reached \$528.4 billion, equivalent to 16% of total U.S. health care expenditure, in 2016². A pharmacist on the care team can help to optimize medication therapy outcomes and reduce cost.

Recognition of Pharmacists on the Clinical Care Team

The California Department of Public Health, U.S. Surgeon General, CDC, and Agency for Healthcare Research and Quality (AHRQ) all support the value of pharmacist on the care team interventions for proven improved quality of care and high return on investment^{1,3,4}.

Five Recent Studies Bolster Evidence for Clinical and Economic Benefits of Adding Pharmacist on the Care Team

Pharmacists Working in Los Angeles Barbershops Improved Hypertension (HTN) Control (Cedars-Sinai, California, 2018)⁵

In a 2018 published NIH-funded study, a much larger percentage of patients who had their medications managed by a pharmacist in their barbershop achieved HTN control compared to those for whom the

Mortality Rate Declined Dramatically for Recently Hospitalized Coronary Artery Disease Patients (Kaiser Permanente, Colorado, 2007)⁸

CAD patients receiving comprehensive cardiac care from a collaborative practice of pharmacists and nurses soon after hospital discharge were 89% less likely to die as compared to patients not enrolled in the program.

Using the Pharmacists' Patient Care Process to Manage High Blood Pressure:

A Resource Guide for Pharmacists

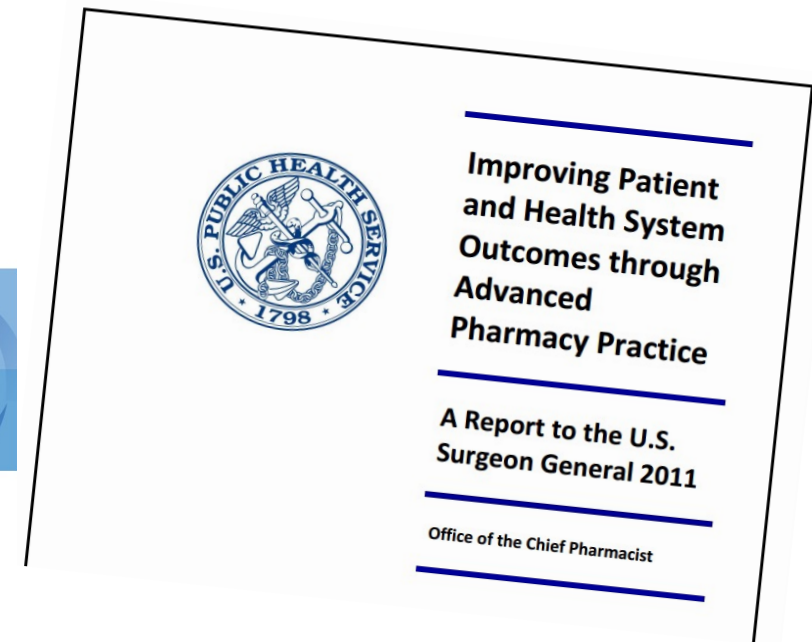


A PROGRAM GUIDE FOR PUBLIC HEALTH



Partnering with Pharmacists in the Prevention and Control of Chronic Diseases

National Center for Chronic Disease Prevention and Health Promotion



<http://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2016/10/GetTheMedicationsRight.v22final-5.20.pdf>

<http://www.pccp.net/files/medmanagepub.pdf>

<https://rightcare.berkeley.edu/wp-content/uploads/2018/05/RCI-Pharmacist-on-Care-Team-Brief-5.25.18-1PM-FINAL.pdf>

<http://www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011advancedpharmacypracticereporttotheussg.pdf>

<https://www.cdc.gov/dhdp/pubs/docs/pharmacist-resource-guide.pdf>

ORIGINAL ARTICLE

A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops

Ronald G. Victor, M.D., Kathleen Lynch, Pharm.D., Ning Li, Ph.D.,
Ciantel Blyler, Pharm.D., Eric Muhammad, B.A., Joel Handler, M.D.,
Jeffrey Brettler, M.D., Mohamad Rashid, M.B., Ch.B., Brent Hsu, B.S.,
Davontae Foxx-Drew, B.A., Norma Moy, B.A., Anthony E. Reid, M.D.,*
and Robert M. Elashoff, Ph.D.

Why Involve Pharmacists?

- 40-50 studies demonstrate effectiveness of pharmacists
- Recent CDC review confirmed pharmacists are effective at lowering BP
- First 5 medication choices are effective, generic, inexpensive, widely available
- Blood pressure under control within ~3 months (6-7 visits)
- Provide services in any setting
- Comprehensive Medication Management and Medication-Related Problems

Pharmacists Role in Barbershop HTN Program

- At least monthly appointments in barbershops
- Check BP
- Modify drug therapy under full scope collaborative practice agreement
- Monitor electrolytes
- Send progress notes to PCP
- South Central LA pharmacy delivered medications to barbershops



Barbershop Project: Results

Outcome	Intervention Group (N=132)	Control Group (N=171)
Systolic Blood Pressure- mmHg		
Baseline	152.8 +/- 10.3	154.6 +/- 12.0
6 months	125.8 +/- 11.0	145.4 +/- 15.2
Hypertension Control at 6 mos.- no. (%)		
BP < 140/90 mmHg	118 (89.4)	55 (32.2)
BP < 135/85 mmHg	109 (82.6)	32 (18.7)
BP < 130/80 mmHg	84 (63.6)	20 (11.7)
Mean no. of blood pressure medications per participant	2.6 +/- 0.9	1.4 +/- 1.4
Drug Class- no. (%)		
ACEi or ARB	130 (98.5)	71 (41.5)
Calcium channel blocker	125 (94.7)	56 (32.7)
Diuretic	61 (46.2)	49 (28.7)
Aldosterone antagonist	14 (10.6)	2 (1.2)
Beta-blocker	14 (10.6)	33 (19.3)

\$12 Million USC / AltaMed Center for Medicare and Medicaid Innovation Healthcare Innovation Award: Specific Aims



10 teams
Pharmacist + Resident +
Clinical Pharmacy Technician



Telehealth clinical
pharmacy

OUTCOME MEASURES

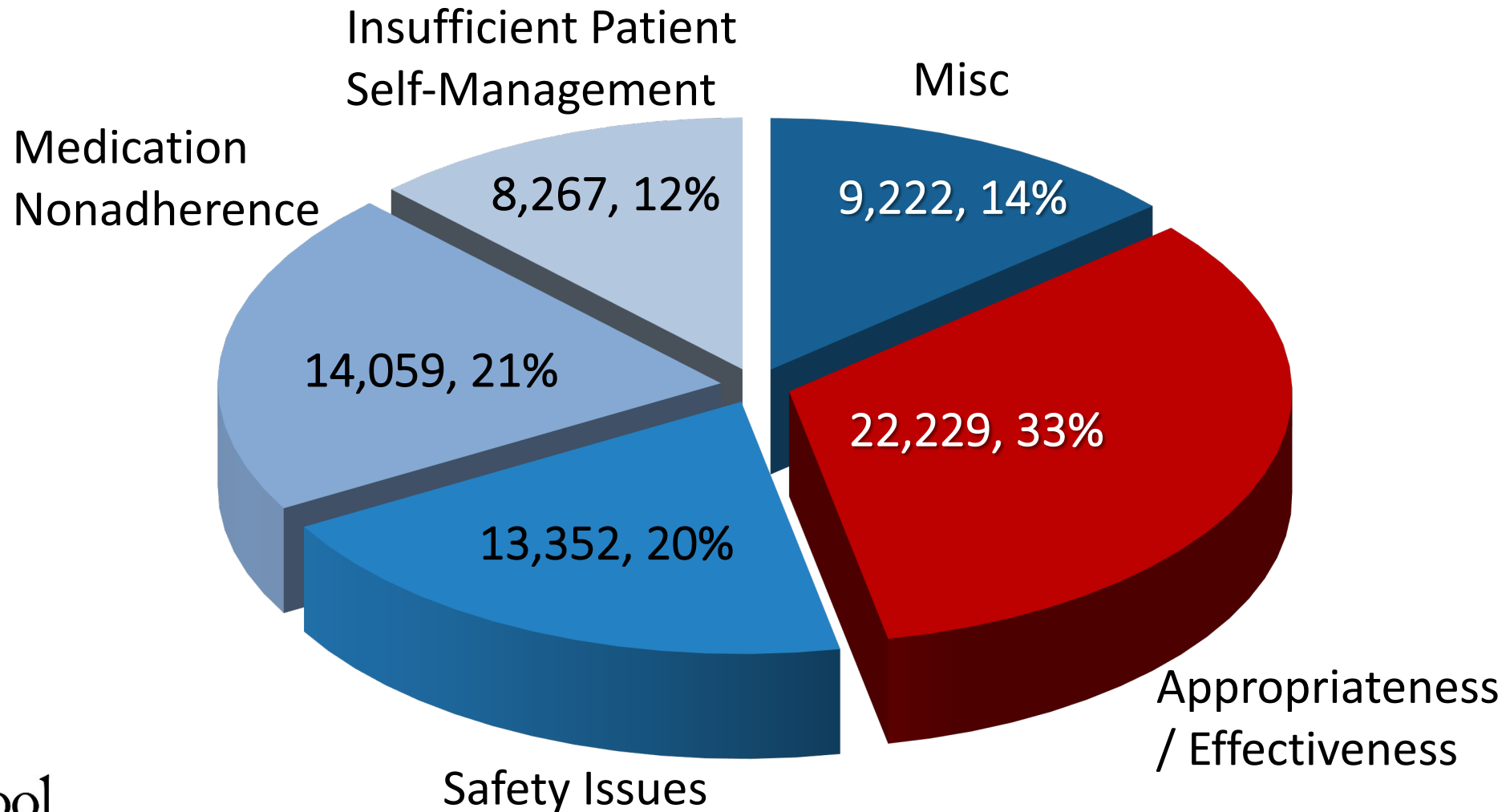
- ✓ Healthcare Quality
- ✓ Safety
- ✓ Total Cost / ROI
- ✓ Patient & provider satisfaction
- ✓ Patient access

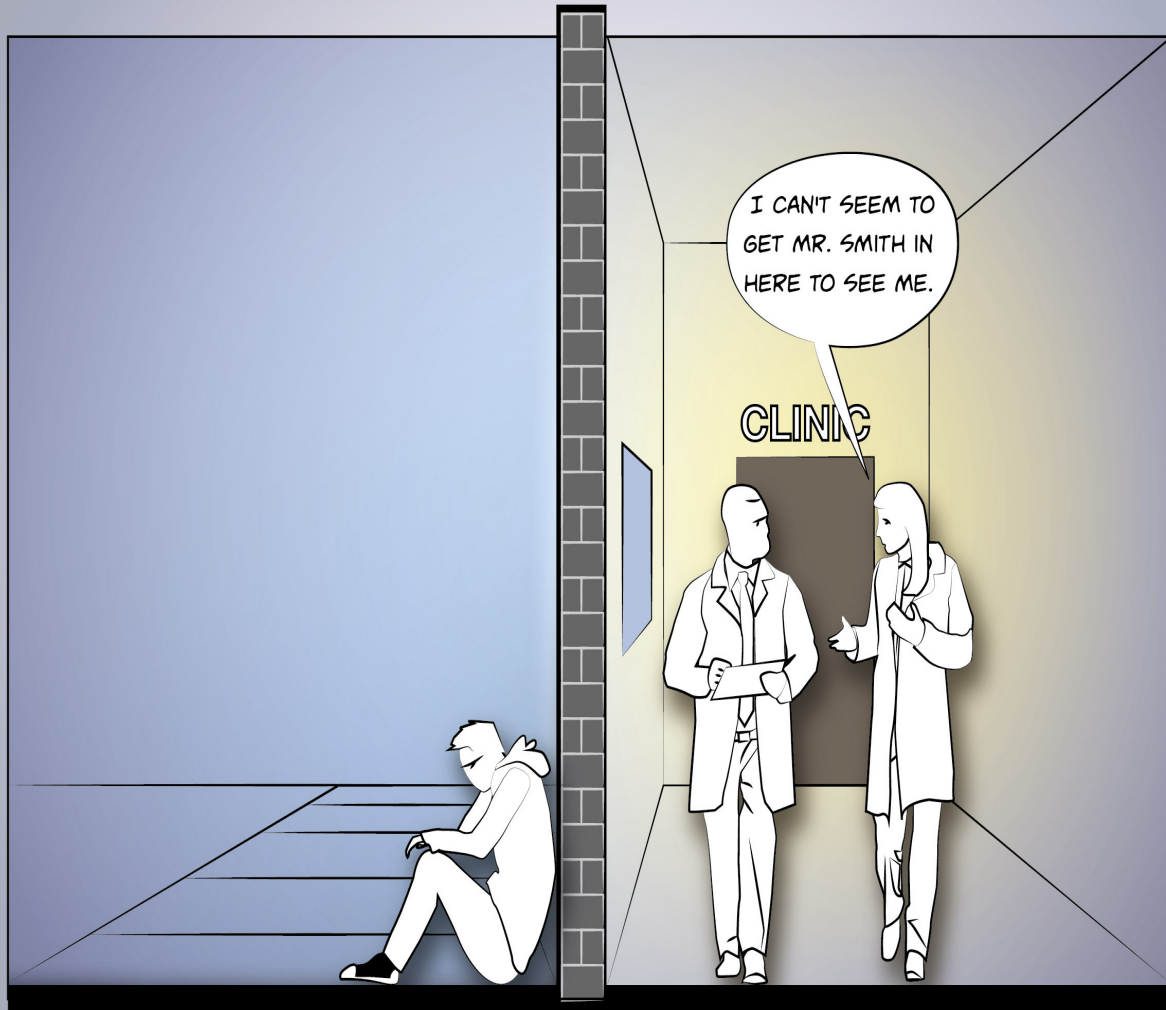
USC CMMI Comprehensive Medication Management Program: Value Proposition

- *Lowers healthcare costs (for patients at risk for readmissions)*
- *Improves healthcare quality measures*
- *Resolves medication-related problems / medication safety*
- *Improves physician access / availability*
- *Improves physician satisfaction (avoid burnout)*
- *Improves patient satisfaction (patient retention)*
- *Lowers mortality*

Medication-Related Problems Identified Through CMMI Program

67,169 problems among 5,775 patients (Avg 11.6 per patient)



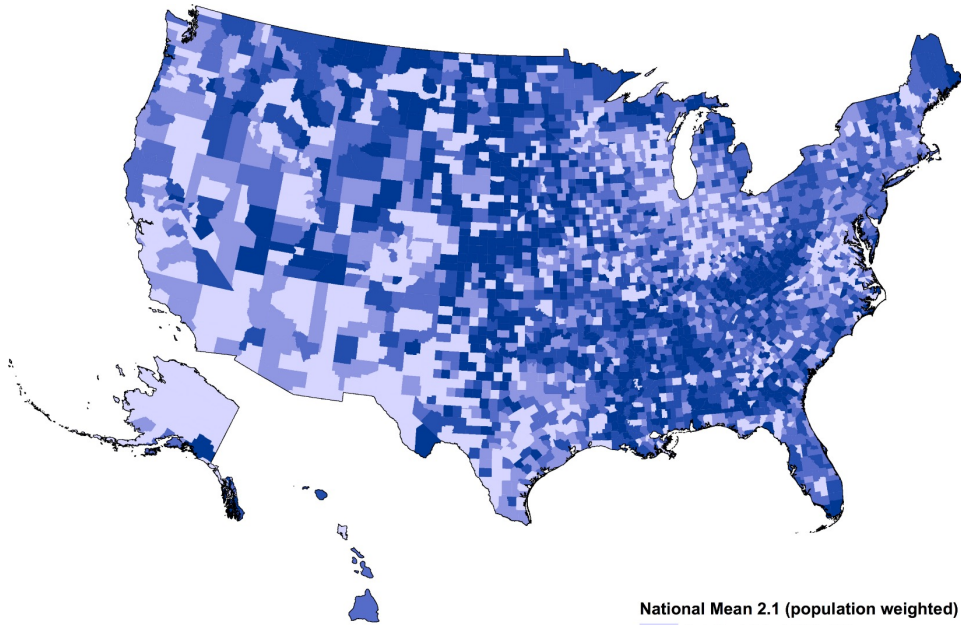


California Right Meds COLLABORATIVE

- **Vision:** To provide optimal medication therapy for high-risk patients in their communities
- **Mission:** Create a network of pharmacists in the community that provide sustainable high-impact Comprehensive Medication Management (CMM) Services in alignment with health plan and health system population health priorities

USC School of Pharmacy

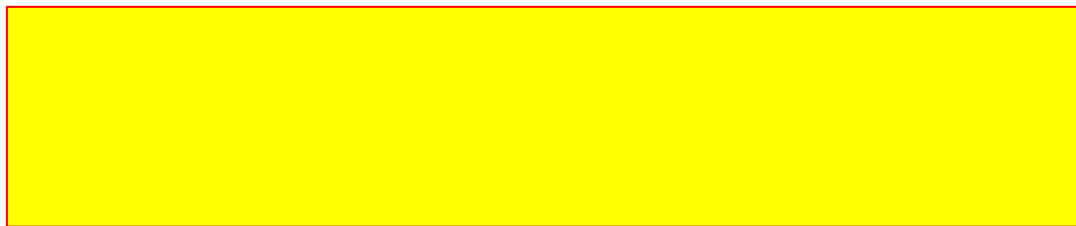
Pharmacies per 10,000 People by County in the U.S., 2015



National Mean 2.1 (population weighted)

Quintile 1 (0 to 1.6) N=629
Quintile 2 (1.6 to 2.0) N=629
Quintile 3 (2.0 to 2.4) N=627
Quintile 4 (2.4 to 3.1) N=628
Quintile 5 (3.1 to 13.7) N=628

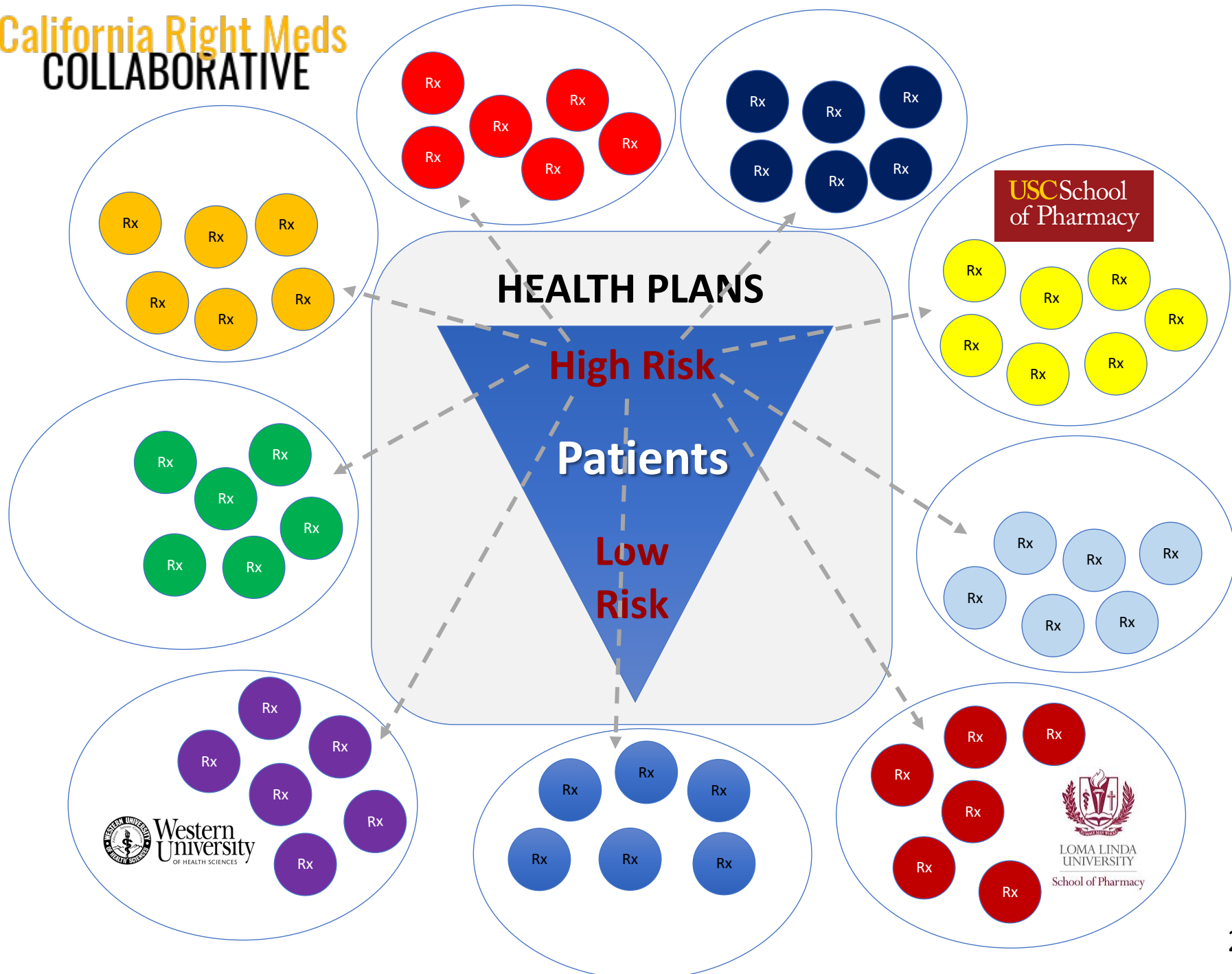
<https://doi.org/10.1371/journal.pone.0183172>



In the US:

- 67,000 pharmacies, 90%+ of US population lives within 5 miles
- 5,500 hospitals
- 5,400 emergency rooms
- 1,400 community health centers





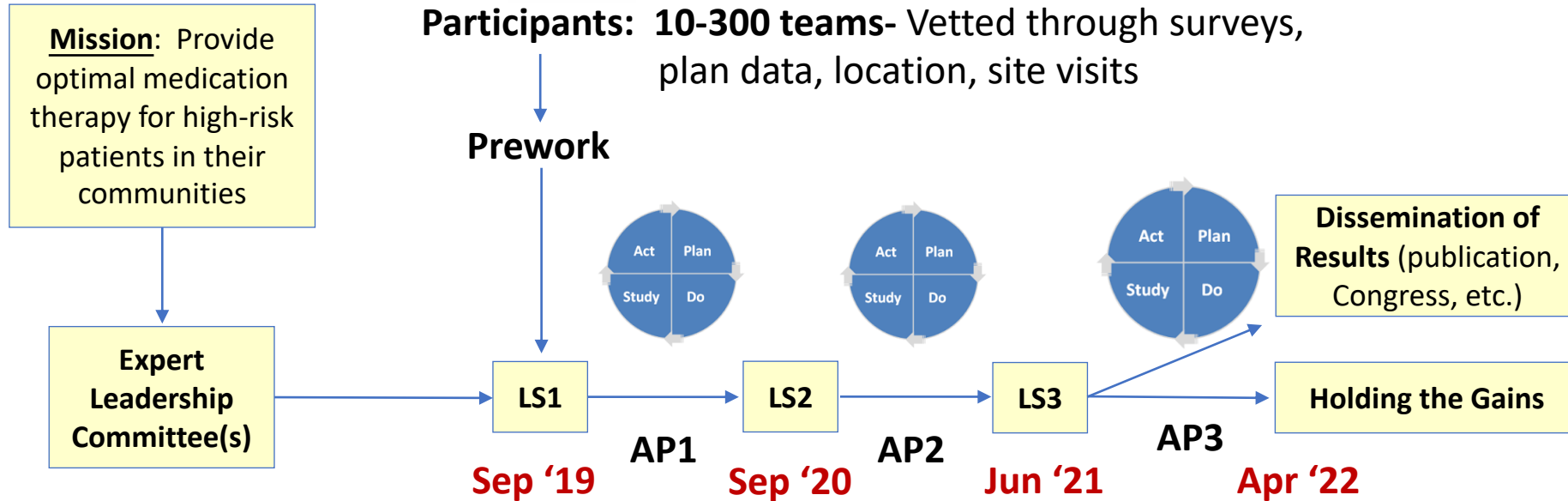
California Right Meds Collaborative Partners



IHI Breakthrough Series Collaborative Process

LS: Learning Session

AP: Action Period



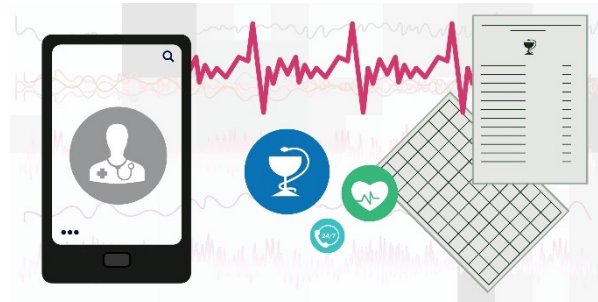
Ongoing Support:

- Additional live trainings, including standardized patients
- **Virtual care training (phone and video telehealth)**
- Biweekly webinars (Comprehensive Medication Management, CQI, managing social determinants, culturally competent care, MI and SDM, etc.)
- Local 1:1 coaching
- Data sharing for quality improvement and aggregation of impact measures

California Right Meds Collaborative: **What Makes it Work?**



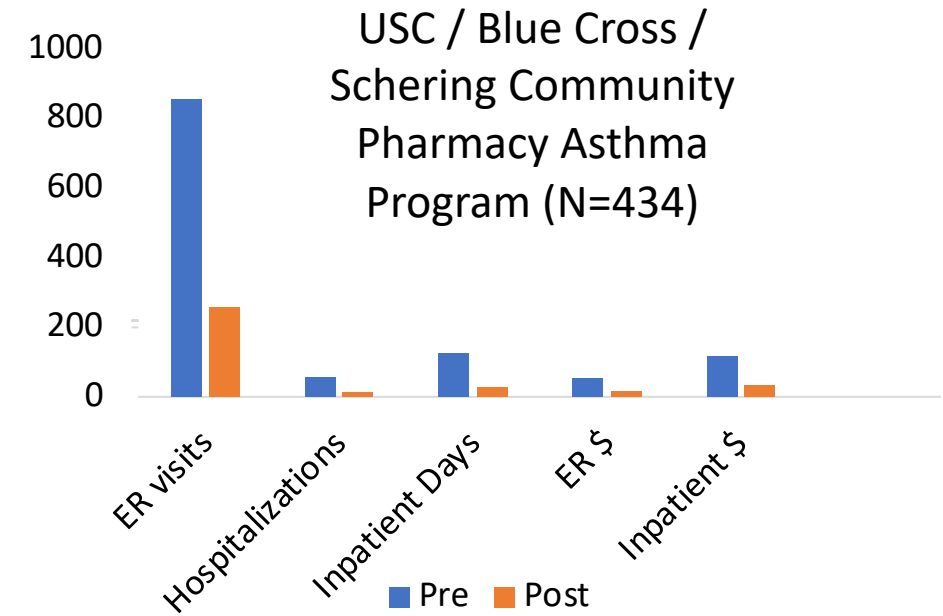
Stringent pharmacy vetting process



Clinical documentation platform, CQI



Clinical Pharmacy Technician



Developing Value-Based Payment for CMM


- CMM cost per patient
 - Average enrollment period and number of visits
 - Enrollment size needed to ensure payment sufficient for at least 1 pharmacist + 1 pharmacy technician
 - ~10% indirects to pharmacy
-

Proposed full payment (FFS + bonus if targets reached)

Example: QI Report Card

Pharmacy	%PT w MRP	Ave MRP/Patient	% of Pt with at least 1 A1c documented	Mag reduction avg latest	% latest A1c <9%	SBP mag reduction latest to baseline	%BP <140/90 latest	% Pt with 1 BP documented	% PT with 1 follow up BP documented
A	40%	5.0	53%	-2.5	37%	4	50%	53%	40%
B	50%	2.5	50%	N/A	0%	1	0%	100%	0%
C	51%	1.5	100%	-1.1	0%	-6	75%	82%	13%
D	0%	0.0	0	N/A	0%	0	0%	0%	0%
E	11%	2.0	0%	N/A	0%	N/A	0	11%	0%
F	100%	5.0	95%	-2.7	66%	1	88%	65%	45%

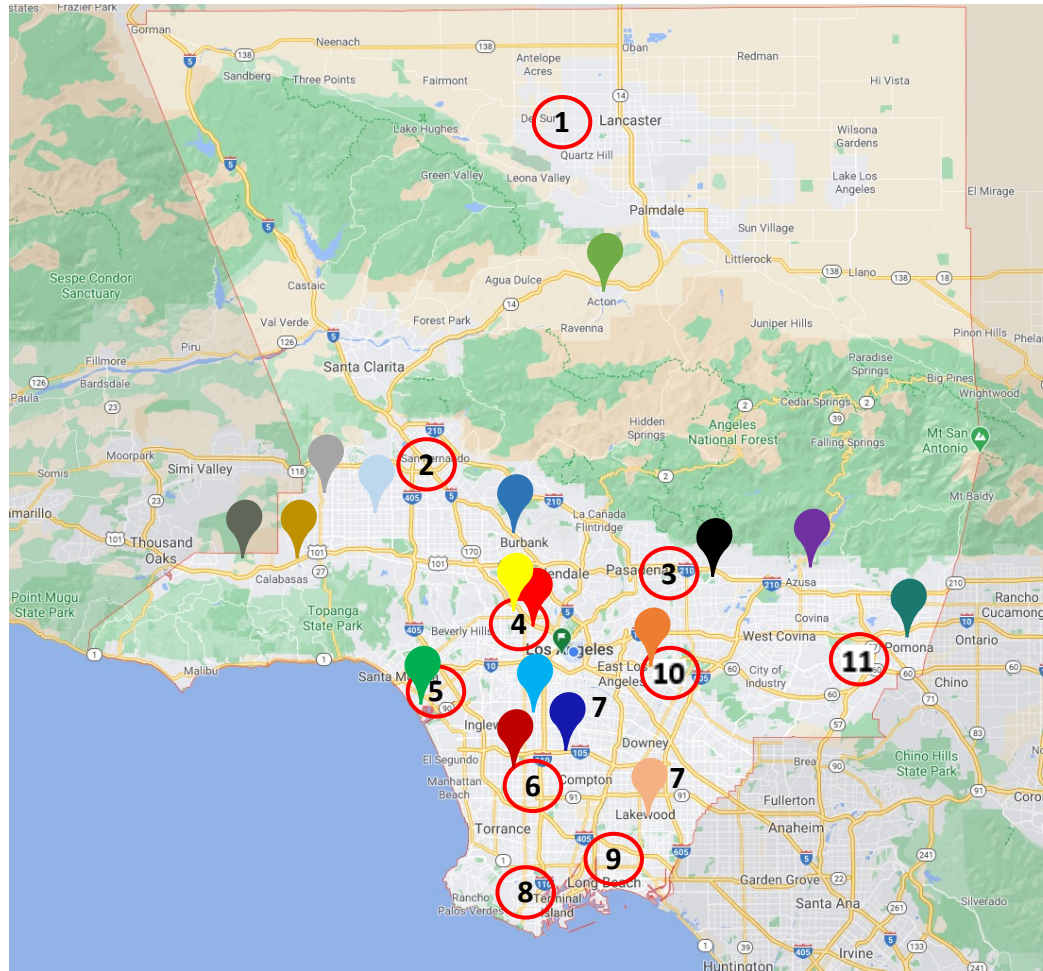
Health Plan Partnership

- Weekly -> biweekly meetings
 - Evaluation of progress with CRMC pharmacy sites and health plan support
 - Appropriate payment models
 - Patient stratification / eligibility
 - Target potential clinic partners
 - Ensure health plan needs are met and surpassed for further expansion
 - Discuss additional opportunities for improvement (e.g. documentation platform, reporting, research and data analysis)
- 

Pilot Calif Right Meds Collaborative Pharmacies and FQHCs



Participating pilot pharmacies



Legend

- Acton Vale Pharmacy
- St. Mary Pharmacy
- CliniCare Pharmacy
- Courtyard Pharmacy
- Kanan Pharmacy
- Quality Home Infusion (QHI) Pharmacy
- Sierra Pharmacy
- Pacific Oak Compounding Pharmacy
- Echo Rx Pharmacy
- Vermont VO Pharmacy
- Western University Pharmacy
- The Prescription Shop
- Playa Pharmacy
- Manchester Professional Pharmacy
- West Alondra Medical Pharmacy
- Econo Pharmacy
- Bellwood Medical Center Pharmacy
- # Regional Community Advisory Committee (RCAC)



Preliminary Impact Results

California Right Meds Collaborative Pilot, LA Care Health Plan

- Enrollment Proxy: A1c > 9%*
- Comprehensive Medication Management goals and shared-risk value-based payment is aligned with HEDIS and STAR measures
 - Diabetes: A1c at least < 8%
 - Hypertension: Blood pressure at least < 140/90 mmHg
 - Statin: Initiate a statin if clinically appropriate

*CRMC enrollment criteria has expanded in 2022 to include additional high risk groups beyond the DM Cohort (i.e. CVD cohort, Adherence/MTM Cohort, BH Cohort)

LA Care CRMC Impact

- As of 7/19/22, enrolled 460 members with a focus on reducing health disparities:
 - 242 (53%) members in Antelope Valley and South LA
 - 123 (27%) members self-identified as Black/African American
- CRMC Partners (growing)
 - 17 Community Pharmacies
 - 15 Clinic / FQHC partners
- Average age = 53 yo (Range 16-81 yo)
- 46% male

L.A. Care Updated Outcomes, as of 2/28/2022

- Average A1C ↓ by 3.3 points*, with baseline A1c of 11.6%
- Average SBP ↓ 34mmHg and average DBP ↓ 11mmHg*
- 89.4% of members with diabetes are on a statin if not otherwise contraindicated
- Ongoing rigorous impact analysis to compare intervention with a control group
- Expanding patient eligibility / enrollment

*Data is for members that have had 5+ visits with a CRMC Pharmacist

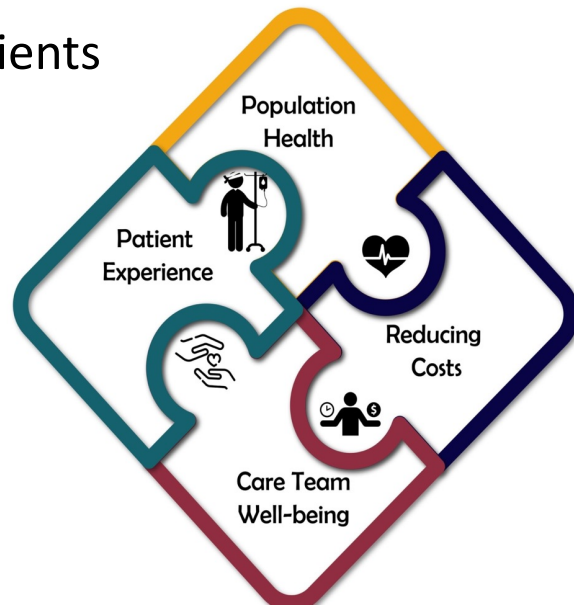


California Right Meds COLLABORATIVE

What's Next...



↑ pharmacies and patients



↑ Health plan partners



**COVERED
CALIFORNIA**



Psychiatry for Population
Health Pharmacists
Collaborative

crmc@usc.edu

Value Summary

	PATIENT	FRONT-LINE PROVIDER	DHCS/HEALTH PLANS/PAYERS
Drug Cost Savings	↓ out-of-pocket \$ (↑ generic drug use)	↑ generic & preferred drug use	
Total Healthcare Costs	NA	Beneficial for capitation / full risk or incentive payments tied to acute care utilization	Maximum ROI when targeting high-risk / high-cost patients. Shared risk / value-based payments
Patient Satisfaction	Convenient access to a trusted provider, culturally & linguistically aligned. Off hours & weekend availability.	Improved patient retention and patient satisfaction surveys	Improved patient enrollment / retention, marketing opportunities
Provider Satisfaction	NA	↓ burnout, ↑ patients seen, medication management shifted to pharmacist	↑ provider retention, ↑ Rx adherence
Quality of Care in collaboration with medical providers	↑ patient health literacy, self management skills	Improves measures tied to performance-based incentives, resulting in ↑ reimbursement	Improves impacts measures for key rankings, e.g., HEDIS, Medicare Stars
Patient Safety	↓ medication-related harm, liability, and costs through close monitoring and safe medication titration		

Physician Experience with Pharmacists

Michael Hochman

Primary Care Clinician Perspective



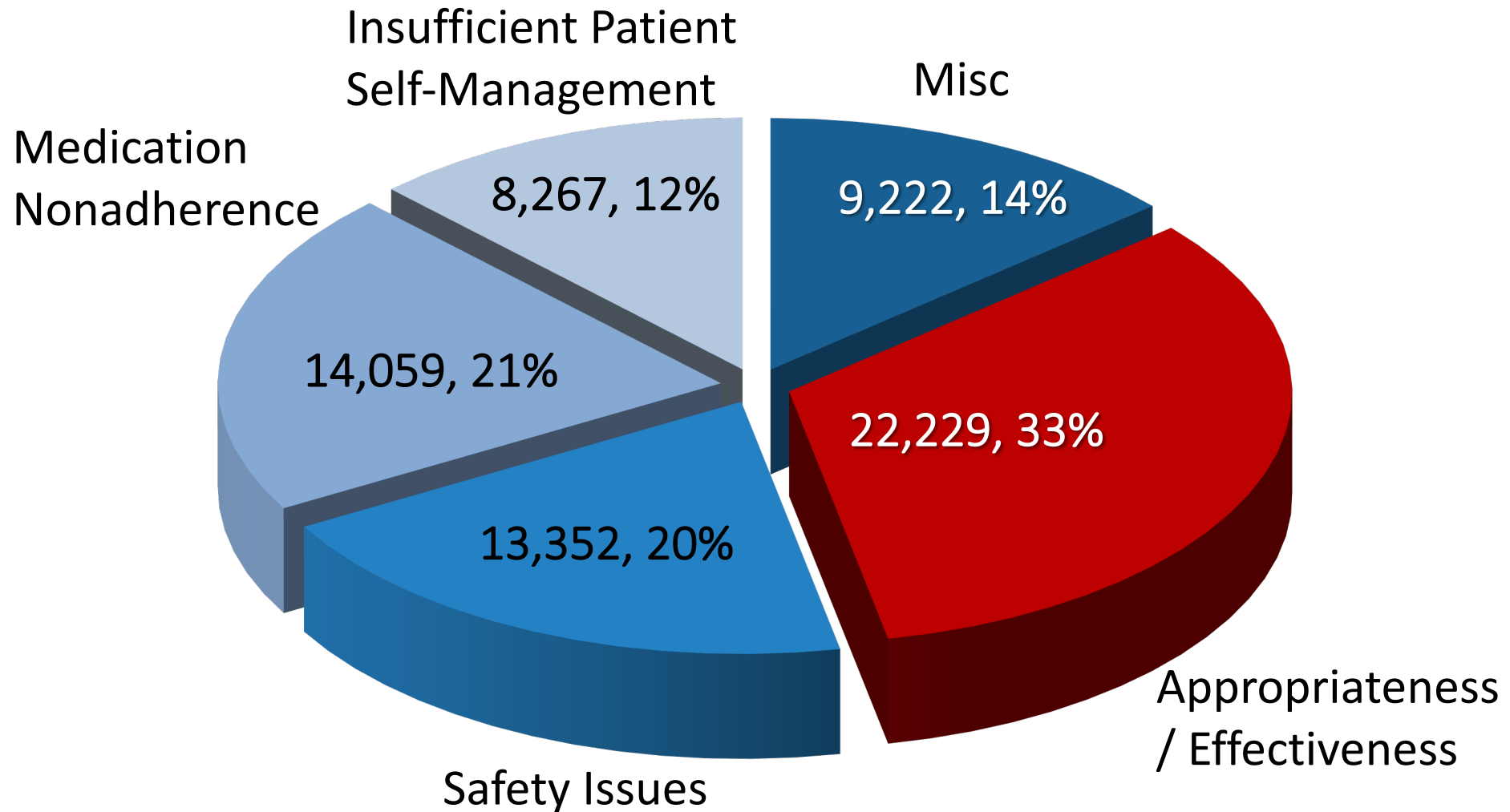
Traditional Model



CMM Model

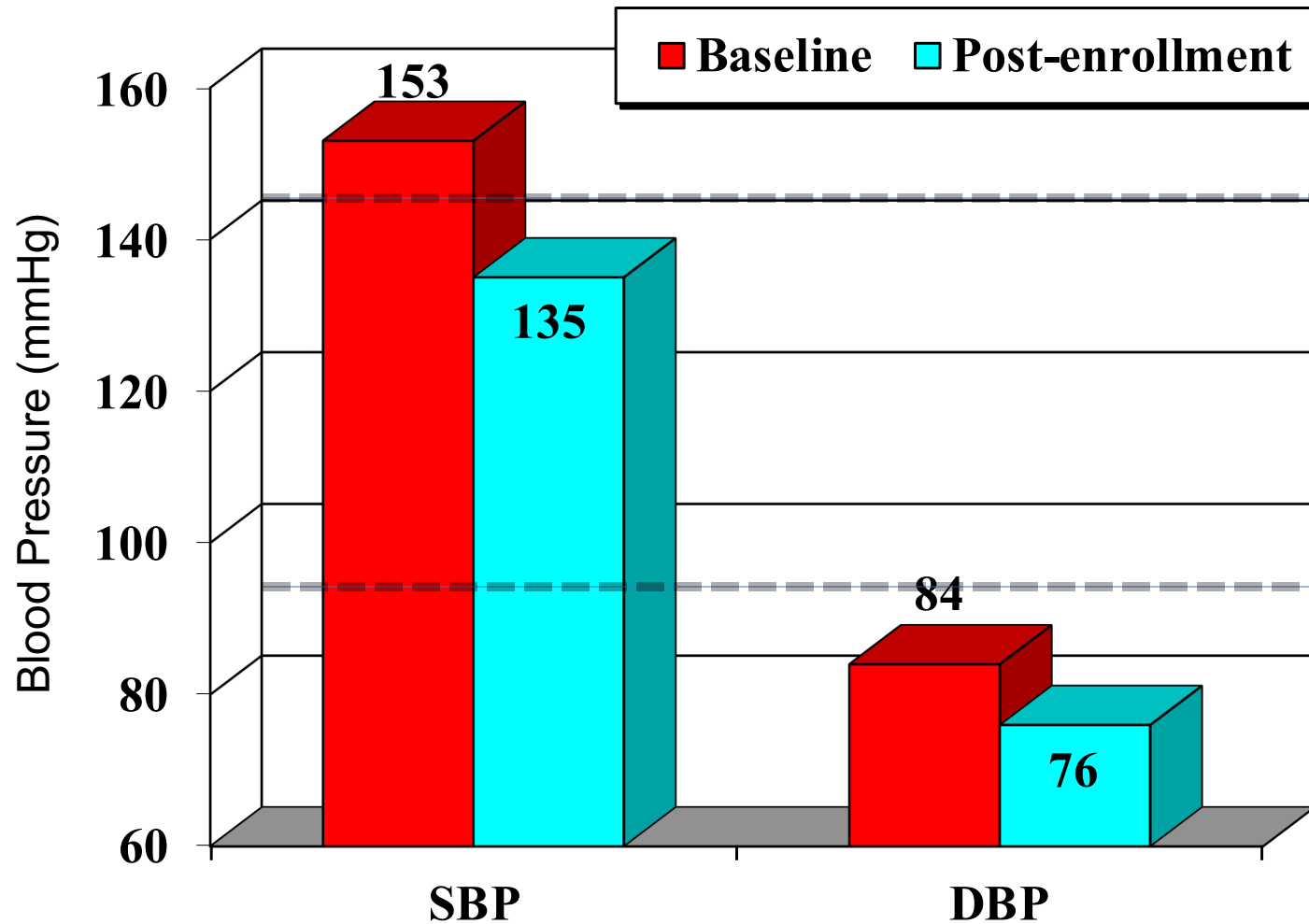
Medication-Related Problems Identified Through CMMI Program

67,169 problems among 5,775 patients (Avg 11.6 per patient)



Blood Pressure Changes at 45 Days (n=356), Patients with BP > 140/90 mmHg Upon Enrollment

87% achieved BP < 140/90 mmHg within 45 days



Quadruple Aim



Business Case



Street Medicine Opportunities?



Payer Perspective on Pharmacist Clinical Services

Alex C. Kang

Thank you!
Questions?

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RESEARCH

Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis

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ABSTRACT

Background: Pharmacy accessibility is key for the emerging role of community pharmacists as providers of patient-centered, medication management services in addition to traditional dispensing roles.

Objective: To quantify population access to community pharmacies across the United States. **Methods:** We obtained addresses for pharmacy locations in the United States from the National Council for Prescription Drug Programs and geocoded each. For a 1% sample of a U.S. synthetic population, we calculated the driving distance to the closest pharmacy using ArcGIS. We estimated the proportion of population living within 1, 2, 5, and 10 miles of a community pharmacy. We quantified the role of chain vs regional franchises or independently owned pharmacies in providing access across degrees of urbanicity.

Results: We identified 61,715 pharmacies, including 37,954 (61.5%) chains, 23,521 (38.1%) regional franchises or independently owned pharmacies, and 240 (0.4%) government pharmacies. In large metropolitan areas, 62.8% of the pharmacies were chains; however, in rural areas, 76.5% of pharmacies were franchises or independent pharmacies. Across the overall U.S. population, 48.1% lived within 1 mile of any pharmacy, 73.1% within 2 miles, 88.9% within 5 miles, and 96.5% within 10 miles. Across the United States, 8.3% of counties had at least 50% of residents with a distance greater than 10 miles. These low-access counties were concentrated in Alaska, South Dakota, North Dakota, and Montana.

Conclusions: Community pharmacies may serve as accessible locations for patient-centered, medication management services that enhance the health and wellness of communities. Although chain pharmacies represent the majority of pharmacy locations across the country, access to community pharmacies in rural areas predominantly relies on regional franchises and independently owned pharmacies.

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Background

The nature of patient-pharmacist encounters has recently evolved from its traditional focus on medication dispensing to the provision of patient-centered, medication management services, including vaccinations, point-of-care testing, and chronic disease state management.^{1,2} Most recently,

community pharmacies have become vital for the success of COVID-19 testing and vaccination.^{3,4} With drive-up windows, extended hours of operation, and flexible scheduling, the accessibility and convenience of pharmacies have been critical in the expansion of services offered by community pharmacists. Recent research has demonstrated that patients visit community pharmacies almost twice as often as primary care providers and that community pharmacies are particularly successful at reaching rural residents and patients who otherwise would not be reached by other health care providers.^{5,6}

In supporting the expanded role of the pharmacist, pharmacy organizations have often claimed that over 90% of Americans live within 5 miles of a community pharmacy, though this statistic is not peer reviewed, limiting credibility

Disclosure: The authors declare no relevant conflicts of interest or financial relationships.

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Key Points**Background:**

Pharmacist accessibility is key for the emerging role of community pharmacists beyond traditional dispensing roles.

Pharmacy organizations claim that over 90% of Americans live within 5 miles of a community pharmacy, but the methods used to generate this statistic remain unclear.

No peer-reviewed study has previously measured distance to community pharmacy across the United States.

Findings:

Using geographic information systems analysis and a 1% random sample of a US synthetic population, we demonstrate that nearly 90% of Americans live within 5 miles of a community pharmacy. However, large variation in access to community pharmacies exists across the United States.

Community pharmacies are highly accessible health care locations for the majority of the U.S. population.

and impact.⁷ A recent systematic review compiled studies of geographic accessibility to pharmacies and found only one peer-reviewed analysis documenting pharmacy availability nationwide in the United States.⁸ This study, however, reported trends in the number of pharmacies but did not measure distance to pharmacy locations.⁹ Quantifying access to community pharmacies nationwide is the next step to determine patient access to pharmacies and pharmacist provided across the United States.⁸ Access to community pharmacies is of major public health relevance due to (1) the expected shortage of physicians in the next decade^{10,11}; (2) the recent trends of pharmacy closures, which have disproportionately affected independent pharmacies¹²; and (3) the essential role of pharmacy locations in the administration of COVID-19 vaccines.

Objectives

We used data for all pharmacy locations, a synthetic population of the U.S., and geographic information systems (GIS) methods to quantify population access to community pharmacies in a nationally representative sample of the U.S. population.

Methods*Data sources*

We obtained the DataQ Pharmacy Database from the National Council for Prescription Drug Programs. DataQ contains comprehensive information for all pharmacy locations in the United States, including but not limited to physical location

address, provider type, and dispenser class.¹³ We identified community pharmacies, Indian Health Service pharmacies, Department of Veterans Affairs pharmacies, and compounding pharmacies. We classified pharmacies into 3 categories by ownership type: chain, regional franchise/independently owned, or government pharmacy (Indian Health Service pharmacies or Department of Veterans Affairs pharmacies). Coordinates of each pharmacy location were generated with ArcGIS World Geocoding Service.

We characterized the U.S. population using the publicly available 2010 U.S. Synthetic Household Population developed by RTI International.^{14,15} This database provides statistically precise representations of the U.S. household and person populations; therefore, it was an ideal data set to perform our nationwide analyses.¹⁴ We selected a 1% random sample of the synthetic population ($n = 2,982,194$) due to the high computational power required to calculate driving distances for the total U.S. population, as previously done.¹⁶ Most recent U.S. Census Bureau data (2019) were used to obtain state and county population estimates.¹⁷ The road network was characterized using the U.S. Geological Survey National Transportation Dataset.¹⁸

Analyses

We mapped pharmacy locations open as of October 1, 2020, who also provided immunization services using ArcGIS Desktop, version 10.7 (Esri). For each individual in the 1% random sample, we calculated the network driving distance to the closest pharmacy location using road networks from the ArcGIS Network Analyst.¹⁸ We calculated driving distances at a person-level using the household coordinates available in the RTI U.S. Synthetic Household Population.¹⁹ This approach enabled us to estimate distance to the closest community pharmacy for an individual with higher precision than methods based on centroids of census tracts or other geographic units.¹⁹ We calculated the proportion of population living within 1, 2, 5, and 10 miles to the closest pharmacy, for the overall sample and for counties in 4 categories of urbanicity defined using the U.S. Department of Agriculture Rural-Urban Continuum Codes (RUCC) which characterizes metropolitan counties by population size and nonmetropolitan counties by urbanization and adjacency to metro areas: large metropolitan areas (RUCC code 1), small metropolitan areas (RUCC codes 2-3), nonmetropolitan urban areas (RUCC codes 4-7), and rural areas (RUCC codes 8-9).²⁰

For each county, we calculated counts of total pharmacies, counts of pharmacies by type, and the proportion of total pharmacies represented by each pharmacy type. We reported summary statistics across 3142 counties in the United States and across groups of counties classified by urbanicity. Additionally, we reported and mapped the pharmacy density, defined as the number of pharmacies per 10,000 residents and the proportion of population within 1, 2, 5, and 10 miles to the closest pharmacy. A Shapiro-Wilk test was performed and suggested that the distribution of pharmacy density at the county-level departed from normality ($W = 0.89$, P -value < 0.01). As a result, geometrical interval classification was used to visualize the spatial distribution of pharmacy density.

Table 1
Summary statistics for pharmacy type by county

	Chains	Government	Independent and franchise	All pharmacy types
All counties (n = 3142)				
Mean	12.09	0.08	7.49	19.65
Median	3	0	3	5
Number (%) of counties with at least 1 pharmacy	2373 (75.0%)	157 (5.0%)	2835 (90.2%)	3003 (95.6%)
Proportion of all pharmacies accounted for by each pharmacy type	61.5%	0.4%	38.1%	100.0%
Counties in large metropolitan areas (n = 432)				
Mean	49.13	0.17	28.91	78.21
Median	17	0	6	23
Number (%) of counties with at least 1 pharmacy	406 (94.0%)	31 (7.2%)	411 (95.1%)	426 (98.6%)
Proportion of all pharmacies accounted for by each pharmacy type	62.8%	0.2%	37.0%	100.0%
Counties in small metropolitan areas (n = 734)				
Mean	16.55	0.11	8.11	24.77
Median	9	0	5	15.5
Number (%) of counties with at least 1 pharmacy	643 (87.6%)	50 (10.6%)	701 (95.5%)	720 (98.1%)
Proportion of all pharmacies accounted for by each pharmacy type	66.8%	0.4%	32.8%	100.0%
Counties in nonmetropolitan urban areas (n = 1331)				
Mean	3.27	0.05	3.18	6.5
Median	3	0	3	5
Number (%) of counties with at least 1 pharmacy	1161 (87.2%)	53 (4.0%)	1243 (93.4%)	1326 (99.6%)
Proportion of all pharmacies accounted for by each pharmacy type	50.32%	0.73%	48.95%	100.00%
Counties in rural areas (n = 643)				
Mean	0.37	0.04	1.31	1.72
Median	0	0	1	1
Number (%) of counties with at least 1 pharmacy	163 (25.3%)	23 (3.6%)	480 (74.7%)	531 (82.6%)
Proportion of all pharmacies accounted for by each pharmacy type	21.3%	2.2%	76.5%	100.0%

Sensitivity analyses

We conducted sensitivity analyses to test the robustness of our findings to our sampling method. For 5 states (Arizona, Montana, South Carolina, Texas, and Virginia), we reran our analyses using a 10% sample of the synthetic population. These states were purposefully chosen because their populations include varying degrees of urbanicity. Then, we compared county-level average driving distances between the 1% and the 10% sample analyses using Wilcoxon signed-rank tests because the data were not normally distributed according to a Shapiro-Wilk normality test [$P < 0.05$].²¹

Results

Summary statistics for the synthetic population

The 1% random sample of the synthetic population included 2,982,194 individuals; 74.7% were white, and 51.5% were female; 25.8% were under the age of 18 years, and 12.8% were above 65 years. The mean (median) age was 36.9 (37.0) years.

Summary statistics for pharmacy count

We identified 61,715 pharmacies, including 37,954 (61.5%) chains, 23,521 (38.1%) franchises or independent pharmacies, and 240 (0.4%) government pharmacies. The mean (median) number of pharmacies per county was 19.6 (5), [Table 1](#). Across the country, 3003 (n = 95.6%) counties representing a population of 327.8 million had at least one pharmacy. In rural areas, 112 counties representing 0.3 million people had no pharmacies.

The mean (median) number of all pharmacy types per county ranged from 1.72 (1) in rural counties to 78.21 (23) in large metropolitan counties ([Table 1](#)). In large and small metropolitan areas, chains represented 62.8% and 66.8% of pharmacy locations, respectively, compared to 50.32% in nonmetropolitan urban areas and 21.3% in rural areas. Independent and franchise pharmacies accounted for 76.5% of pharmacy locations in rural areas.

Pharmacy density

[Figure 1](#) represents the pharmacy density (number of pharmacies per 10,000 residents) at the county level, using a geometrical interval classification method. The highest concentrations of counties with the lowest pharmacy density (fewer than 1.38 pharmacy per 10,000 residents) were in Alaska (17 counties, 58.6% of Alaska counties), New Mexico (15 counties, 45.5% of New Mexico counties), and California (25 counties, 43.1% of California counties).

Driving distance to closest pharmacy, overall population

Across the overall U.S. population, 48.1% lived within 1 mile of a pharmacy, 73.1% within 2 miles, 88.9% within 5 miles, and 96.5% within 10 miles ([Figure 2](#)). There was large variation in access to community pharmacies by urbanicity: In large metropolitan areas, 58.6% of the population lived within 1 mile of a pharmacy, compared to 39.7% in small metropolitan areas, 26.9% in nonmetropolitan urban areas, and 20.4% in rural areas ([Figure 3](#)). In large metropolitan areas, 99.3% of the population lived within 10 miles of a pharmacy, compared to 97.0% in small metropolitan areas, 87.1% in nonmetropolitan urban areas, and 68.1% in rural areas.

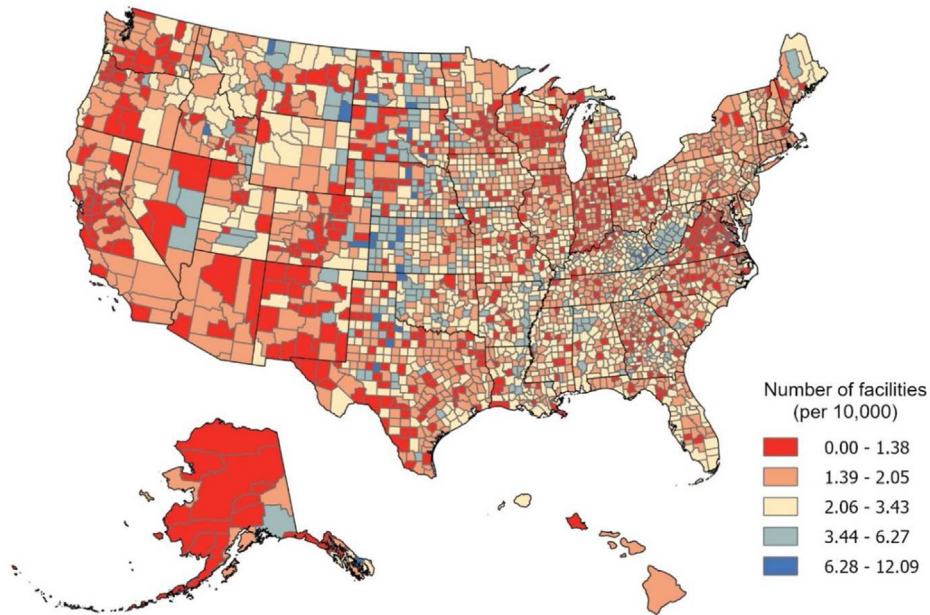


Figure 1. Number of pharmacy locations per 10,000 residents by county. We used geometric intervals to classify the pharmacy density (number of pharmacies per 10,000 residents) because the variable was not normally distributed.

Driving distance to closest pharmacy, county level

In 11.6% of U.S. counties (364 out of 3142 counties, representing 142.8 million people), more than 50% of the population lived within 1 mile of a pharmacy. In 74.0% of counties (2325 out of 3142 counties, representing 315.8 million people), at least 50% of the population lived within 5 miles of a pharmacy (Appendix 1 and Figure 4). In 91.9% of counties (2886 out of 3142 counties, representing 326.8 million people), at least 50% of the population lived within 10 miles of a pharmacy

(Appendix 1 and Figure 4). Only 8.3% of counties (256 out of 3142 counties, representing 1.5 million people) had at least 50% of residents with a distance greater than 10 miles. Counties with at least 50% of residents with a driving distance greater than 10 miles were concentrated in Alaska (14 counties, 48.2% of Alaska counties), South Dakota (27 counties, 40.9% of South Dakota counties), North Dakota (17 counties, 32.1% of North Dakota counties), and Montana (17 counties, 30.3% of Montana counties).

Results of sensitivity analyses

Appendix 2 shows the results of sensitivity analyses sampling 10% of the synthetic population for 5 states (Arizona, Montana, South Carolina, Texas, and Virginia). There was no statistically significant difference in the proportions of population within 1, 5, and 10 miles of the closest pharmacy estimated for the 10% sample and 1% random sample.

Discussion

We leveraged GIS methods to conduct the first nationwide study to measure access to community pharmacies for a nationally representative sample of the U.S. population. We estimate that across the overall U.S. population, 48.1% lived within 1 mile driving distance of a pharmacy, 73.1% within 2 miles, 88.9% within 5 miles, and 96.5% within 10 miles of a community pharmacy. Although chain pharmacies represent the majority of pharmacy locations across the country, access to community pharmacies in rural areas predominantly relies on franchise and independent pharmacies. Access to community pharmacies varied substantially with the degree of urbanicity; still in 91.9% of U.S. counties representing 99.5% of

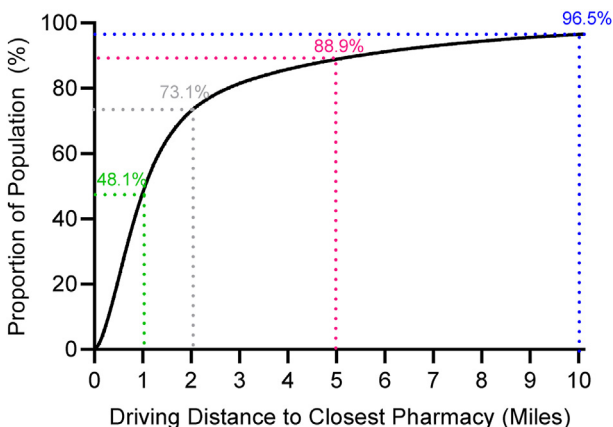


Figure 2. Cumulative distribution function of distance to the closest pharmacy location, overall population. The figure represents the cumulative distribution function of driving distance to the closest pharmacy for the 1% random sample of the synthetic population selected. Across the overall population, 48.1% lived within 1 mile of a pharmacy, 73.1% within 2 miles, 88.9% within 5 miles, and 96.5% within 10 miles.

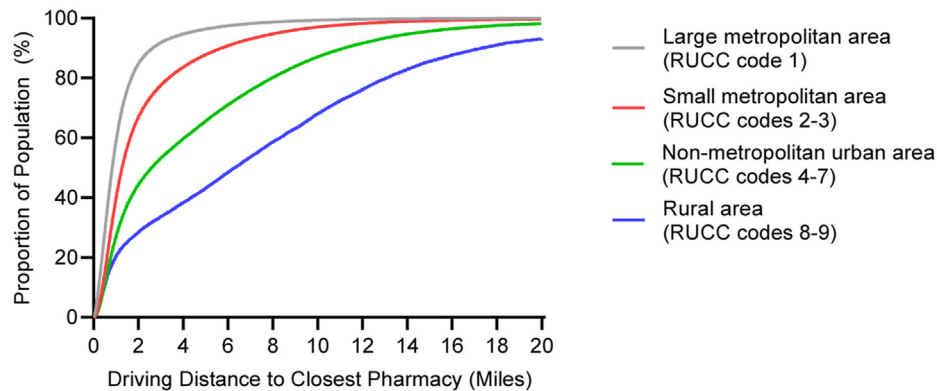


Figure 3. Cumulative distribution function of distance to the closest pharmacy location, by urbanicity. Abbreviation used: RUCC= rural-urban continuum codes. The figure represents the cumulative distribution function of driving distance to the closest pharmacy by urbanicity.

the U.S. population, at least 50% of the population lived within 10 miles of a pharmacy.

Prior investigations have evaluated access to community pharmacies.⁸ According to a recently published systematic review, only one study has measured pharmacy availability nationwide. However, this study did not measure distance to pharmacy locations.⁹ The same research team identified pharmacy deserts but limited analyses to urban areas. The report estimated that around 14.8 million or 32.1% of urban residents in the top 30 most populated U.S. cities live in pharmacy deserts, defined as census tracts where at least half of the population has a distance greater than 1 mile to the closest community pharmacy.²² These prior analyses are different from ours in that they were performed at the census tract level (distance calculated from the centroid of a census tract) and were limited to urban areas. Our analyses were performed at the person level (distance calculated from an individual address) and were summarized at the county level. Due to our sampling methods, summarizing results at the census tract level was not feasible. As a result, we could not identify pharmacy deserts using the census tract-level definitions previously referenced in the literature.

Nevertheless, our study is a major contribution to the literature because it is the first to quantify access to community pharmacies across the entire United States. The inclusion of suburban and rural counties, which differentiates our study from prior work, is important for 2 reasons. First, persons living in suburban and rural areas encounter different barriers to accessing health care than urban residents. Second, pharmacy closures in the recent years have disproportionately affected independent pharmacies, which play a prominent role in the provision of pharmacy services in rural areas.^{12,23} Despite these trends, our analysis demonstrates that community pharmacies remain as highly accessible health care locations for the majority of the U.S. population. Because of the accessibility to community pharmacies, pharmacists are well positioned to become providers of patient-centered, medication-related clinical services. These include the provision of vaccinations, point-of-care testing, and chronic disease state management. The expanded role of the pharmacist beyond medication dispensing is of relevance for achieving equitable and timely health care access in light of the expected shortage of physicians in the next decade^{10,11} and the evidence

suggesting that community pharmacists are particularly successful at reaching patients who otherwise would not be reached by other health care providers.^{5,6}

Although the majority of the sampled population lived within 10 miles of a pharmacy, access to community pharmacies differed greatly with the degree of urbanicity, and we identified a substantial number of rural counties with low access to community pharmacies. Specifically, 256 U.S. counties had at least 50% of residents with a distance greater than 10 miles to the closest community pharmacy. Although these counties only represent 1.5 million or 0.5% of the entire U.S. population, their low access to community pharmacies is concerning because prior work has shown that community pharmacies are particularly important in providing access to health care in rural areas.^{5,6,24}

Independent and franchise pharmacies play a prominent role in the provision of pharmacy services in rural areas, as demonstrated by our analysis. However, recent closures of independent pharmacies in both urban and nonurban areas will likely impact patient access to pharmacy services.¹² Independent pharmacies are particularly susceptible to closure due to decreased reimbursement associated with increased spread pricing and direct and indirect remuneration fees by pharmacy benefit managers.^{12,25} It is unlikely that the current trend of pharmacy closures will revert without state and federal policies that increase medication dispensing fees or create new billing opportunities for pharmacist-provided services in rural and medically underserved areas. As policymakers discuss reforms to drug reimbursement, they should consider solutions that improve the sustainability of local community pharmacies, such as fair and transparent dispensing fees and payment for medication management services provided by pharmacists. The financial sustainability of independent pharmacies is crucial to maintain population access to pharmacies in rural areas and to prevent a further exacerbation of the urban-rural divide in health care access.²⁴

Our findings are subject to 4 limitations. First, due to the high computational power required to calculate driving distances for a large number of observations, we performed analyses on a 1% random sample of the U.S. population, as previously done.¹⁶ We demonstrated the robustness of our findings when our analyses were reproduced for a 10% random sample of residents in select states. The execution of our GIS

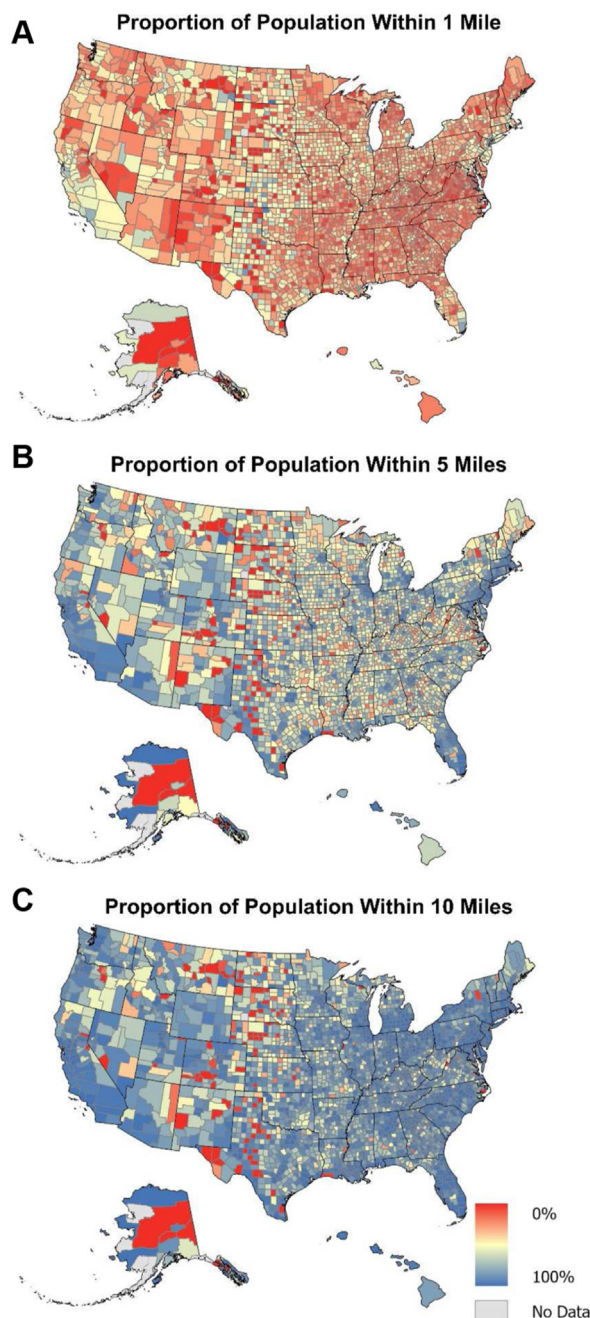


Figure 4. Proportion of population within 1, 5, and 10 miles of the closest pharmacy location by county. The figure represents the proportion of population within 1 mile (panel A), 5 miles (panel B), and 10 miles (panel C) of the closest pharmacy, measured at the county level.

analysis at the person level is a unique strength of our study because calculating distances for the centroid of census tracts or other geographic units would have led to error due to the large number and spread distribution of community pharmacies. However, due to the sampling of the population, we did not have statistical power to compare access to community pharmacies across racial/ethnic groups. Executing analyses for a larger sample was not feasible due to the large computational power required to run analyses at the person level

(approximately 1 month for a 1% random sample). As applications to execute GIS methods in high-performance computing environments arise, we plan to reproduce our analyses in a larger sample of the U.S. population and evaluate whether underrepresented groups are more likely to live in areas of low access than White Americans. Second, we defined our main outcome as driving distance. Future studies may better estimate pharmacy accessibility using drive time instead of distance and accounting for different modes of transportation. Additionally, other socioeconomic or environmental factors that influence accessibility for a given driving distance were not incorporated in analyses, such as car ownership or availability of public transportation. Third, our cross-sectional analysis did not examine changes in geographic access to community pharmacies as the number of locations varies over time.¹² Finally, our analysis included government pharmacies which may exclusively serve Veteran or Native American populations. We chose to include these pharmacies in our analysis to represent populations who may not have access to other pharmacy locations. This could have underestimated driving distance for the general population; however, the impact of their inclusion is likely small given that government pharmacies represented only 240 or 0.4% of total pharmacies in the United States. Future studies should evaluate to what extent geographic access to pharmacies is associated with medication-related outcomes, and how this association varies with urbanicity and over time.

Conclusion

Community pharmacies are highly accessible health care locations for the majority of the U.S. population and may serve as accessible locations for patient-centered, medication management services that enhance the health and wellness of communities. Although chain pharmacies represent the majority of pharmacy locations across the country, access to community pharmacies in rural areas predominantly relies on franchise and independent pharmacies.

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Appendix

Appendix 1

Counts of counties with at least 50%, 80%, 90%, and 95% of the population within 1-, 2-, 5-, and 10-miles driving distance to the closest pharmacy

	Within 1 mile	Within 2 miles	Within 5 miles	Within 10 miles
Counties with at least 50% of population	364	1312	2325	2886
Counties with at least 80% of population	42	250	854	2138
Counties with at least 90% of population	19	107	461	1503
Counties with at least 95% of population	13	56	279	1039

Appendix 2

Results of sensitivity analyses sampling 10% of synthetic population

State	Proportion of population within 1 mile			Proportion of population within 5 miles			Proportion of population within 10 miles		
	Primary analysis 1% sampling	Sensitivity analyses 10% sampling	<i>P</i> -value ^a	Primary analysis 1% sampling	Sensitivity analyses 10% sampling	<i>P</i> -value ^a	Primary analysis 1% sampling	Sensitivity analyses 10% sampling	<i>P</i> -value ^a
AZ	51.8%	51.7%	0.454	91.0%	91.1%	0.489	94.8%	95.1%	0.252
MT	38.7%	37.9%	0.454	73.5%	73.2%	0.335	85.2%	84.9%	0.854
SC	26.5%	26.6%	0.961	81.7%	81.6%	0.312	96.2%	96.0%	0.154
TX	48.5%	48.6%	0.678	90.0%	90.0%	0.462	96.6%	96.5%	0.423
VA	38.3%	38.6%	0.567	85.1%	85.4%	0.200	95.4%	95.6%	0.629

^a *P*-values were calculated using Wilcoxon signed rank tests because the data were not normally distributed.