RESEARCH TO ACCELERATE PHARMACIST/PHARMACY INNOVATION AND DELIVERY
A Research Project in the National Science Foundation Center for Health Organization Transformation at the University of Louisville

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The RAPID Alliance Report

Evidence-Based Strategies for Protecting and Improving US Population Health and Wellbeing through US Pharmacists and Pharmacies During and After the COVID-19 Pandemic

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Abstract

Problem. In early 2020, COVID-19 brought into focus a set of emerging US population health risks that the pharmacist and pharmacy sector appeared well suited to help address. However, a number of barriers were limiting their ability to act. **Question.** This study asked: what strategies could help US pharmacists and pharmacy have the greatest impact on US population health and wellbeing during and after the COVID-19 pandemic? **Method.** A panel of US pharmacist/pharmacy sector leaders participated in surveys and roundtables; resulting data was analyzed; follow-up meetings were held to verify findings. **Findings.** Critical barriers in payment, practice, and health information sharing areas were identified. Priority strategies included practice transformation, payment reform, and development of advanced person-centered health IT infrastructure. Opportunities to protect and improve population health while reducing avoidable health costs by as much $200B per year were identified. **Recommendations.** Federal and state policy makers should consider recognizing pharmacists as providers, increase payments for valuable pharmacy services, reduce practice barriers and support improved data sharing. US purchasers, plans, and providers should support enhanced value-based services. US pharmacist and pharmacy sector leaders should consider unifying to advance strategies identified in this study. Researchers should conduct and disseminate research to provide evidence based to support changes.

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CONTENTS

Summary 4

1 Introduction 6

1.1 Problem 6

1.2 Definitions of Terms 6

1.3 Research Question 7

1.4 What makes this study unique? 7

2 Method 8

3 Findings 9

3.1 Unmet Patient Needs the US Pharmacist and Pharmacy Sector Can Help Address 9

3.2 Barriers Limiting US Pharmacist and Pharmacy Sector Ability to Meet Needs 9

3.3 Why Now? Change Drivers 10

3.4 Strategies (Overview) 11

3.5 COVID-19 Strategies 11

3.6 General Strategies 2021-2025 12

3.7 Overcoming Fragmentation: Need for "Triggering Mechanisms" 14

3.8 Transformational Strategies 15

3.9 Research Opportunities 17

4 Limitations 17

5 Implications and Recommendations for Action 18

6 Conclusion 20

References 21

7 Appendix 1. Table of Needs 24

8 Appendix 2. Table of Barriers 26

9 Appendix 3. Table of Strategies 28

Appendix 4. Transformational Strategies (Details) 35

10 Develop Transformational Practice/Payment Models 35

11 Develop Person-Centered, Pharmacy-Distributed "VISA-Like" Data Sharing Platform(s) 36

12 Form Unifying Steering Group 38

13 Form Research Consortia 42

The Rapid Alliance Report Infographic

Evidence-based strategies for improving US population health and wellbeing through US pharmacists and pharmacies during and after the COVID-19 Pandemic

Who May Be Interested in This Report?

U.S. Pharmacist and Pharmacy Connected Leaders and Policymakers

Policymakers (Federal and State), Patient Advocates, Pharmacists, Pharmacies, Purchasers, Plans/PBMs, Physicians, Health Systems, Aging Care, Pharma, Technology, Researchers and others interest in optimizing delivery of medications, vaccines and related services

What makes this study unique?

1. National Science Foundation supported | 2. Implementation science-based approach | 3. Fast-track process
4. Multi-disciplinary research team | 5. Input from representative panel of US pharmacist/pharmacy leaders

Research Question

What priority strategies implemented from 2020 – 2025 would maximize capacity of the US pharmacist and pharmacy sector to improve US population health and wellbeing?

Method

Implementation science-informed approach; Delphi method; input by representative panel of US sector leaders over 4 rounds of feedback

Summary of Findings

Unmet US Health Needs Addressable by Pharmacists and Pharmacies

1. COVID-19 related testing, immunizations and support | 2. comprehensive medication management, vaccines, tests, screening and support
3. Health education to maximize personal health and wellbeing | 4. Social support for low SES/at risk populations

Barriers to Meeting Needs

1. Payment Barriers | 2. Policy Barriers (Federal and State) | 3. Health IT / Health Information Exchange Barriers | 4. Profession Related barriers
5. Public awareness barriers | 6. Service delivery barriers | 7. Lack of collaboration across sector | 8. Legacy Barriers

Why Now?

1. COVID-19 pandemic needs | 2. Value-based care trends | 3. Political landscape | 4. Telehealth trends | 5. IT innovations
6. Personalized/precision medicine innovations | 7. "Last mile" logistics and delivery innovations

Scope of Opportunity

1. ~330 Million US residents | 2. Billions of COVID-19 tests and immunizations needed through 2022
3. Pharmacy driven increases in "Healthy Days": 10% by 2025?) | 4. $528B+ in excess health spending from non-optimal medication therapies

COVID-19 Response Strategies (2021-2022)

1. **Payment**: All plans reimburse for pharmacy-based COVID-19 tests, vaccines, cognitive services, telepharmacy, and at-risk/low SES support
2. **Policies:** Federal & state policymakers support provider status; vaccine authority; increased reimbursements; reduce practice barriers
3. **Health IT / Sharing**: Strengthen pharmacy standards; support patient-access rights; support COVID-19 tech innovation

General Strategies (2021-2025)

7 Strategy Areas; 42 Strategies

Area 1. Expand offerings of valuable pharmacy services (8 strategies) | **Area 2**. Policy reform to increase payments, strengthen practice (7 strategies) | **Area 3**. Position Pharmacists and Pharmacies for the Future (4 strategies) | **Area 4**. Collaborative action (12 Strategies)
Area 5. Develop Health IT / HIE platforms and services (2 strategies) | **Area 6**. Strengthen and disseminate evidence of value (5 strategies)
Area 7. Advance the profession (4 strategies)

Transformational Strategies

Transformational strategies are designed to stimulate change through "triggering mechanisms" – such as legislation or achievement of widespread stakeholder agreement about change

Develop Transformational Practice/Payment Models: Develop sustainable, scalable models; work with CMMI, others.
Develop Person-Centered Data Sharing Platform(s): Research to develop new, investable person-centered pharmacy-linked platform models
Form Unifying Steering Group: Consider a new unified group organized to drive towards a few high-level transformational goals.
Form Sector-Wide Research Consortia Organize new consortia to conduct projects prioritized by consortium members from across sector

Four Unifying Goals (for consideration)

For People: Increase CDC Healthy Days | **For US Healthcare:** Improve quadruple aims
For Pharmacy practices (all kinds): increase adoption of new value-driven services | for **Pharmacists and Other Practitioners:** strengthen reputation

What (If Anything) Might the RAPID Alliance Do to Support Priorities Moving Forward?

Organize research consortium | Facilitate "big-tent" model with room for all key parties | Focus on studies to advance identified priorities

More Information

www.rapidalliance.org | contact researchers at University of Louisville

SUMMARY

CONVENING. The project was launched in May 2020 with support from the National Science Foundation Center for Health Organization Transformation and Sanofi.

PROBLEM. In the COVID-19 era and beyond convenient access to tests, immunizations, medications, comprehensive medication management (CMM), and patient counseling are becoming increasingly important needs for Americans. The US pharmacist/pharmacy sector has potential to meet these needs and make a significant impact for millions of people. However, it is limited by significant barriers.

QUESTION. The study asked what priority strategies implemented from 2020 – 2025 would maximize capacity of the US pharmacist and pharmacy sector to improve US population health and wellbeing.

METHOD. Implementation science-informed approach; Delphi method; input by panel of 62 sector leader over 3 rounds of feedback; drafts reviewed by all interested stakeholders; modifications and refinements to strengthen relevance and value for different stakeholders in sector.

FINDINGS.

TOP NEEDS. COVID-19 testing, immunizations, support and access; new services including comprehensive medication management, testing, and convenient immunization services.

TOP BARRIERS. Payment barriers; policy barriers; Health IT and data sharing barriers.

COVID-19 RESPONSE STRATEGIES. Expand reimbursements for COVID-19 related services; expand pharmacist practice rights across all states and federal; strengthen interoperable data sharing.

SECTOR CHANGE STRATEGIES (7 STRATEGY AREAS; 42 STRATEGIES). 1. Develop/deliver new services; 2. advocacy to strengthen practice, pay for services; 3. messaging to reposition pharmacists for the future; 4. collaboration across healthcare sector; 5. strengthen health IT, data sharing*; 6. strengthen evidence base; 7. advance the profession.

NEED FOR UNIFICATION ACROSS SECTOR. Fragmentation limiting ability to make progress; COVID-19 and other factors opening doors to unify to add value.

TRANSFORMATIONAL STRATEGIES.

i. Develop Transformational Practice/Payment Model(s). Seek large-scale grants/contracts (e.g. CMMI); advance sustainable, scalable models
ii. Develop Person-Centered Data Sharing Platform(s). Do Research to develop new, investable person-centered pharmacy-linked platform models.
iii. Form Sector-Wide Research Consortia. Organize a new platform to conduct projects prioritized by consortium members from across sector
iv. Form Unifying Steering Group. Include entire sector; organize around a few high-level transformational goals.

FOUR UNIFYING GOALS TO CONSIDER

i. For patients/consumers: Increase CDC Healthy Days [10% by 2025?).
ii. For US Healthcare: Increasing quality, outcome and satisfaction while reducing US healthcare spending ($50B by 2025?).
iii. For pharmacy practices: Increase delivery of valuable pharmacy services (500% by 2025?).
iv. For pharmacist profession: strengthen pharmacist public reputation scores (from 33% to 75% by 2025?).

RECOMMENDATIONS

POLICYMAKERS. 1. Support funding for COVID-19 tests, vaccines and other valuable services by pharmacists/pharmacies; 2. Practice/payment reform (reduce federal and state practice and payment barriers); 3. support transformational pharmacy sector innovation research (e.g. through CMMI, states); 4. strengthen pharmacy-data interoperability; expand consumer data access rights.

HEALTH SECTOR LEADERS. 1. Support COVID-19 tests, vaccines and support delivered through pharmacists/pharmacies; 2. support value-driven pharmacist/pharmacy services; 3. support policy changes that remove pharmacist practice and payment barriers; 4. Develop, pilot and adopt new evidence-based pharmacist/pharmacy services; 5. help develop and implement pharmacy health IT interoperability solutions; 6. Support research to strengthen the evidence base; 7. recognize and empower pharmacists in your networks; 8. support transformational innovation research.

US PHARMACISTS AND PHARMACIES. 1. Develop and deliver valuable COVID-19 related services; 2. Implement priority strategies in seven areas, including practice reform, policy/payment reform, health IT; 3. Support transformational strategies such as: a) transformational payment/practice model innovations (e.g. with CMMI); b. person-centered health IT models; forming goal-oriented steering group, and research consortia; 4. Consider increasing unification of sector through steering group with balanced membership of pharmacists (professional) and pharmacies, and partners focused on a few high level goals.

RESEARCHERS. 1. Organize and support efficient, fast-cycle research consortia; 2. Develop and validate new practice models; 3. Strengthen and publish evidence of value; 4. Benchmark goals and measure progress; 5. Develop and pilot innovative technologies and services; 6. participate in transformational innovation research.

The RAPID Alliance Report

Evidence-Based Strategies to Protect and Improve US Population Health through US Pharmacists and Pharmacies During and After the COVID-19 Pandemic

1 INTRODUCTION

1.1 PROBLEM

In early 2020, the COVID-19 pandemic brought into focus a set of critical population health needs that the US pharmacist and pharmacy sector appeared well suited to help address. These needs went beyond what the US pharmacist and pharmacy sector has historically addressed in the US. They included COVID-19 testing and vaccine delivery, comprehensive medication management (CMM) related counseling services, other types of vaccines, screening and testing, personalized counseling, wellness and prevention support, filling gaps in primary care access, providing support for vulnerable and under-served populations and helping address social determinants of health needs. However, the US pharmacist and pharmacy sector's ability to provide services to meet these needs was limited by a number of barriers. The RAPID Alliance study was organized in March 2020 to conduct research to explore strategies that could, potentially, help the US pharmacist and pharmacy sector overcome barriers limiting ability to act to protect and improve US population health and wellbeing in the COVID-19 era and beyond. This report shares the results of this study.

1.2 DEFINITIONS OF TERMS

As used in this study, the following terms will have the following meanings.

- **US Pharmacist and Pharmacy Sector** is an umbrella term referring to all clinicians and organizations in the US healthcare sector involved in the research, production, distribution, delivery and support of medications, immunizations and other pharmacist-supported and/or pharmacy-distributed products and services to patients/consumers. This term includes patient/consumer advocates, health purchasers including Medicare, Medicaid, employers, pharmacists, pharmacy technicians, pharmacy practices, physicians, nurses, hospitals, health systems, aging care facilities, managed care plans, health plans, pharmaceutical firms, public health, digital technology firms, and policymakers.
- **Pharmacists** are health-care professionals licensed to engage in pharmacy with duties including dispensing prescription drugs, monitoring drug interactions, administering vaccines, and counseling patients regarding the effects and proper usage of drugs and dietary supplements (Merriam Webster, online, 2020).
- **Pharmacy** is: 1) the art, practice, or profession of preparing, preserving, compounding, and dispensing medical drugs; 2) a place where medicines are compounded or dispensed (Merriam Webster, online, 2020)
- **Pharmacy Practice Organizations and Systems ("Pharmacies")** are organizations that employ or contract pharmacists to provide pharmacy services. They include community pharmacy, hospital pharmacy, clinical pharmacy, consulting pharmacy, ambulatory care pharmacy,

regulatory pharmacy, home care pharmacy, managed care pharmacy, aging care pharmacy, and telepharmacy.

- **Schools of Pharmacy** are accredited schools that educate pharmacists and other pharmacy practitioners.
- **Pharmaceutical Firms (Pharma)** are organizations that develop and manufacture medications, vaccines and precision medicine solutions distributed through pharmacies and pharmacists.
- **Health Sector Partners** are any kind of organization that teams with US pharmacists, pharmacies, and other sector organizations to deliver services to patients.

1.3 Research Question

This study was organized to answer the following research question:

> **Based on conditions in the US environment in summer, 2020, including the COVID-19 pandemic, what prioritized strategies could be implemented to maximize ability of the US pharmacist and pharmacy sector to act to protect and improve the health and wellbeing of the US population from Fall 2020 through year-end 2025?**

1.4 What makes this study unique?

This is the first study of its kind to look at the US pharmacist and pharmacy sector as a whole considering changes affecting the sector during the COVID-19 era. Supported by the National Science Foundation and Sanofi, it used an implementation science-based approach and a fast-track process. Input was provided by panel of US leaders representing patients/people, pharmacists, pharmacies, pharmacy schools, pharma and providers. Analysis was conducted by a multi-disciplinary research team in a school of public health and information sciences.

2 METHOD

An implementation science-based framework, Delphi method for gathering data, literature review, and mixed-methods analyses were used to develop answers to the research question.[1-4] Data about needs, barriers and strategies were gathered and refined using input from a representative panel of US pharmacist and pharmacy sector leaders. Four rounds of input were held from June – November 2020. The first three rounds, in June, July, and August, involved reviews of information, a virtual roundtable and feedback in written and verbal forms. A fourth round was conducted from September through November 2020. This involved 15 private meetings with leaders from major participant groups to review drafts of the report, discuss implications and refine approaches.

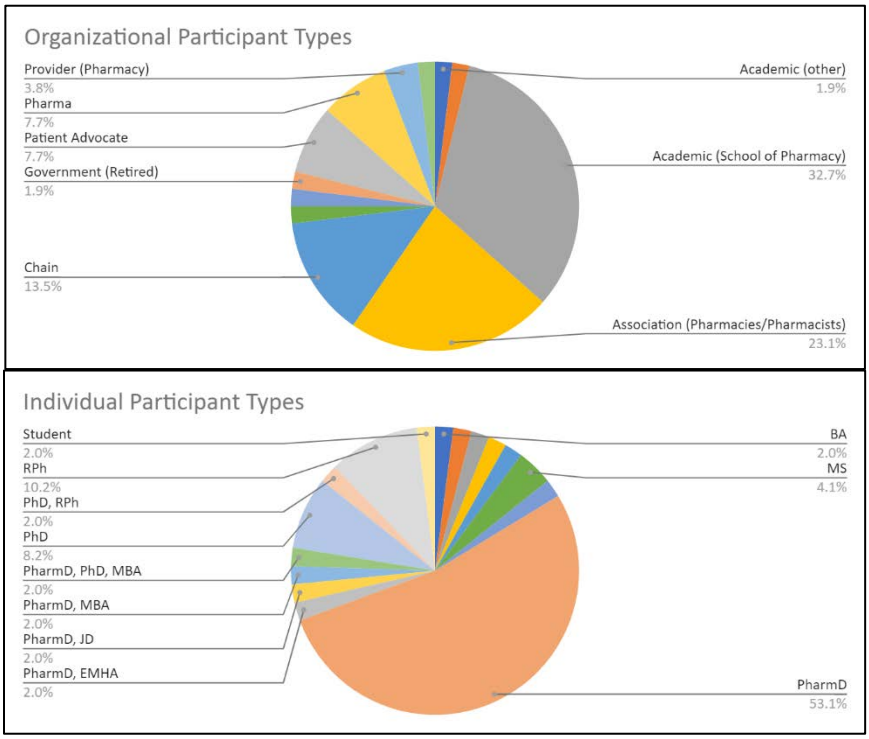


Figure 1. Registered Participants

Analysis was conducted by a multi-disciplinary research team at the National Science Foundation Center for Health Organization Transformation at University of Louisville.

The participant list satisfies initial sampling criteria set by the researchers. We believe the panel provides a reasonably balanced set of US pharmacist and pharmacy sector leaders at this stage.

One note: most of the "academic" organizations listed are schools of pharmacy. Many of the academic leaders are also affiliated with associations and with health sciences centers. Thus the "association" representation, and "health system" and "health plan" perspectives are arguably higher than shown.

All data was assembled and coded using excel spreadsheets. About 200 source documents, twenty tabs with over 2000 rows of data and coding and a literature review with over 80 papers were developed. Data interpretations were reviewed and discussed by the four researchers as a team, using best practices for mixed methods studies of this kind.[3,5,6]

The study was approved as exempt by the University of Louisville IRB. All identifiable information is kept confidential by the research team. No identifying information of participating individuals or organizations is included in reports.

3 FINDINGS

Findings are organized in the following areas: needs, barriers, change drivers, strategies and recommendations. Numbering of items in each area should be interpreted with caution. The numbering reflects overall levels of interest identified by the panel in different areas. However, each element in the framework, no matter the number, may be highly important to some stakeholders, or serve as an important input into another element. Thus, numbers do not necessarily denote importance.

3.1 UNMET PATIENT NEEDS THE US PHARMACIST AND PHARMACY SECTOR CAN HELP ADDRESS

The study identified twelve unmet patient/personal needs that the US pharmacist and pharmacy sector appears to be well suited to address. These are organized in four areas.

1. **Cross-cutting needs.** These are needs that cut across and affect all other needs. They include needs for: 1) health data sharing between pharmacies and other care providers; and 2) social determinants of health (SDOH) related services and support.
2. **Service needs.** These include needs for: 3) Comprehensive medication management (CMM) services with potential to reduce drug-related harm to millions of people while reducing excess health spending by billions of dollars[7]; 4) Immunizations and prevention services including for COVID-19; 5) Screening and testing including for COVID-19; 6) Chronic disease management support including diabetes, cancer and CVD; 7) Behavioral health and substance use disorder screening and support services; and, 8) Wellness support services.
3. **Public education needs.** These include needs for: 9) Health education to care for patient and significant others; and 10) Unique role of the US pharmacist and pharmacy sector in protecting and improving health.
4. **Access needs.** These include needs for: 11) Transportation to pharmacies / last mile services so that people can get medications and other products and services reliably and on time; and 12) Filling primary care access gaps for patients in underserved areas where pharmacies operate.

Details about these needs are contained in Appendix 1.

3.2 BARRIERS LIMITING US PHARMACIST AND PHARMACY SECTOR ABILITY TO MEET NEEDS

Barriers limiting the US pharmacist and pharmacy sector from meeting these needs were identified in eight areas. These are:

1. **Payment barriers** limiting ability for the US pharmacist and pharmacy sector to be reimbursed and/or paid for providing services
2. **Policy barriers** at Federal and state levels limiting ability of government programs to pay for value and constraining pharmacists from working at the top of their professional abilities.
3. **Health IT and health information exchange (HIE) barriers** limiting patients and those who serve them to access and share pharmacy related data needed to support personalized services
4. **Profession related barriers** including concerns about the future of the profession

5. **Public awareness barriers,** where the public lacks knowledge about the role and value offered by the US pharmacist and pharmacy sector in today's world
6. **Service delivery barriers** limiting ability to deliver convenient services when, where and how wanted
7. **Lack of collaboration** with other healthcare stakeholders across the health system
8. **Legacy Barriers** such as legacy facilities or technologies that are not conducive to providing new kinds of services.

Details about these barriers are contained in Appendix 2.

3.3 WHY NOW? CHANGE DRIVERS

Change drivers that the US pharmacist and pharmacy sector may be able to leverage to strengthen ability to meet these needs were identified in seven areas. These are:

1. **COVID-19 Pandemic** creating rapidly emerging needs for new testing, vaccines and support by the US pharmacist and pharmacy sector and increasing policymaker willingness to make rapid changes to meet those needs
2. **Value-Based Care Trends** focused on paying for value (e.g. quality, outcomes, cost-efficiency and satisfaction) instead of volume
3. **Political Landscape** with 2020 elections likely to result in new policy directions for the country no matter who wins
4. **Telehealth Trends** with rapid shift to telehealth and telepharmacy because of COVID-19 social distancing requirements, government policy changes, and other factors.
5. **IT Innovations** making it increasingly feasible to access, share and use health data to deliver increasingly personalized services to patients across the care continuum.
6. **Personalized/Precision Medicine Innovations** in areas including genomics, proteomics and microbiome areas creating a new generation of products and services.
7. "**Last Mile" home-based delivery** and health care trends changing how patients/people get their medications and other health related products and services.

3.4 STRATEGIES (OVERVIEW)

Analysis of the data combined with feedback from sector leaders on multiple drafts of the report led to the development of three strategy streams: *COVID-19 Strategies (2020-2022*), *Sector Change Strategies (2020-2025)* and *Transformational Strategies*.

3.5 COVID-19 STRATEGIES

The *COVID-19 Strategies* focus on addressing payment, practice and technology barriers limiting the sector's ability to act to meet patient/population needs for COVID-19 testing, immunizations, support and guidance, and access. These recommendations drew significantly from the *Pharmacy Organization's Joint Policy Recommendations to Combat the COVID-19 Pandemic* (2020), which was put together by many of the panel participants in tandem during the time of the study.[8]

3.5.1 Payment/Practice Reform Strategies

Four areas of change to payment and practice were identified with potential to make a difference in COVID-19 related care for US populations through pharmacies/pharmacists.

1. **Authorize Test-Treat-Immunize and other pharmacist-provided services**: This entails allowing licensed pharmacists across all states order, obtain specimens, carry out and interpret crucial tests. Also, enable them to initiate appropriates treatments when necessary for infectious diseases such as COVID-19, flu, strep and interpret and consult with patients. Increasing immunizations authority across all states for pharmacists that will include every FDA approved vaccine such as future vaccines for COVID-19. In addition, ease access to personal protective equipment(PPE) to those involved with testing and allow pharmacists to independently access and manage medications through different forms of prescription adaptation.

2. **Ease Operational Barriers to address workforce and workflow issues that prevent full and effective pharmacist engagement in COVID-19 response**: Allow interstate operation of licensed pharmacists and pharmacy technicians, including telehealth utilization. Authorize them to carry out routine pharmacy duties such as medication review and script verification remotely. Also, ensuring optimum workforce protection through the provision of adequate PPEs. Providing family support for pharmacy personnel to address staffing levels and provision of funds for the continued education of pharmacists.

3. **Address Shortages and Continuity of Care**: Entails addressing barriers from medical products scarcity, which hampers continuity of care. Allowing pharmacists to carry out therapeutic interchange with the notification (but without authorization) of a prescriber when product scarcity occurs. Increase FDA transparency regarding drug scarcity, through public reporting, providing guidance on compounding and proactive extension of the expiry dates of drug at-risk of shortages where applicable.

4. **Reimburse for services by removing reimbursement barriers that prevent pharmacists from fully and effectively engaging in COVID-19 response**: Ensuring continuous patients access to critical medications such as insulin, during scarcity through the removal of restricted day's supply requirement from co-pay waivers. Authorize coverage of home or mail delivery, increase access to treatment, testing, and pharmacy services for clients with inadequate healthcare access. Enable provision care flexibility, delay time-consuming

pharmacy audits, and ensure prompt reimbursements and payments from payers such as PBMs and healthcare plans.

3.5.2 Health IT Related Strategies for COVID

Lack of ability to access and share COVID-19 related digital data was identified as a critical challenge. The recommendation is to support and fund rapid innovation and action to strengthen sharing of COVID-19 related tests, vaccines and other relevant pharmacy-related data with patients and across the spectrum of care.

3.6 General Strategies 2021-2025

The *General Strategies* section contains forty-two (42) strategies, organized into seven strategy areas. Details about each strategy area and strategy are provided in the Appendices.

Strategy area 1. Expand Offerings of Valuable Services. This area focuses on developing and delivering services which deliver measurable value to patients and the healthcare system. Strategies included development and delivery of:

- **1.1** Unique pharmacist/pharmacy-based services for selected high priority patients / use cases
  - i. For example, potential exists to improve health for millions of people while saving the US healthcare system as much as $528B per year by providing comprehensive medication management (CMM) and other services for people living with diabetes, cancer, CVD, behavioral health challenges, and during transitions of care.[7]
- **1.2** Unique services for underserved and high-risk populations
- **1.3** Pharmacies as "Vaccine Hubs" (including for COVID-19)[9,10]
- **1.4** Value-Driven Care Support Services
- **1.5** Telehealth/Telepharmacy Services
- **1.6** Digital Technology Driven Services
- **1.7** Psychosocially Informed Services[11-13]
- **1.8** Define/Certify "*More than Just Medications"* Suite of Services

Strategy area 2. Advocacy to Increase Payments and Strengthen Practice. This area focuses on passing new policies to allow the US pharmacist and pharmacy sector to be paid for providing services that are known to offer value, while also removing limitations to practicing at the "top of their professional abilities and licenses. Strategies included advocacy to achieve the following results:

- **2.1** Pharmacists recognized as providers by CMS
- **2.2** All states allow pharmacists to practice at "top of professional abilities"[14]
- **2.3** CMS, CMMI, Medicaid, Commercial Payers, and others provide new mechanisms to pay for value
- **2.4** Telehealth and telepharmacy authorizations: keep/make permanent
- **2.5** Emergency pharmacist provider status – keep/make permanent
- **2.6** Pharmacist authorized to provide all FDA authorized vaccines
- **2.7** Sustainable product margins, e.g. reduced margin compression

Strategy area 3. Position the US Pharmacist and Pharmacy Sector for the Future. This strategy area focuses on educating the public, healthcare stakeholders and policymakers about significant underappreciated value the US pharmacist and pharmacy sector has brought and continue to bring to millions of people each year for improving health and wellbeing. Strategies include:

3.1. Develop/implement evidence-driven "One Voice for Patients" campaign(s) and messaging strategies that bring the entire sector together to speak with a unified voice about the value of pharmacists and pharmacy in the US. This may include leveraging existing strategies like Pharmacist for Healthier Lives.

3.2 Extend existing campaigns and efforts such as Pharmacists for Healthier Lives; keep doing what is working.

3.3 Explore new campaigns and messages for different contexts and groups.

3.4 Educate and engage other health stakeholders like physicians and plans directly and as part of collaborative action activities (see below).

Strategy area 4. Collaborative action. This area focuses on using modern collaboration science methodologies, including new virtual collaboration methods,[15-18] to strengthen pharmacist/pharmacy sector collaborations with health sector stakeholders, with a focus on learning, together, how to improve health and wellbeing for patients/people. Many of these collaborative activities are already occurring. Making strategic decisions about where to focus limited resources is important. Strategies include:

4.1 Develop collaborative action plans and priorities aligned to strategic goals (know when to say no)

4.2 Physician-based collaboratives

4.3 In-patient care collaboratives

4.5 Care coordination collaboratives

4.4 Aging care collaboratives

4.6. Value-based care collaboratives

4.7 State/local pharmacy transformation collaboratives

4.8 Pharma collaboratives

4.9 Public health collaboratives

4.10 R&D collaboratives

4.11 Technology collaboratives

4.12 Multi-sector collaboratives (like GTMRx).

Strategy area 5. Strengthen health IT / HIE platforms and services. This area focuses on strengthening Health Information Technology (Health IT), Health Information Exchange (HIE), and related technologies that can be used to strengthen pharmacist and pharmacy capacity to deliver valuable products and services to patients/people and care partners across the spectrum of care. Strategies include:

5.1 Stay the course – stay aligned with current status quo including ONC driven initiatives.

5.1a Support relevant infrastructure projects through Pharmacy Health IT Collaborative, Pharmacy Quality Initiative, NCPDP, HL7 and other groups.

5.1b support existing initiatives like the NCPDP Pharmacists eCare Plan[19]

5.2. Create the future – support high-risk high return research and action focused on *person-centered* and *personally-owned* technology platforms and services that can drive new value.

5.2a. Strengthen pharmacist and pharmacy sector *innovation ecosystem*

5.2b. Develop/strengthen *pharmacy-distributed lifetime analytics, data and sharing* (PLADS) infrastructure (see Appendix 4 for details)

5.2c. Develop, source, sell new PLADS connected products/services

Strategy area 6. Strengthen and disseminate evidence of value. This area focuses on a lack of public and business awareness of the value offered by the US pharmacist and pharmacy sector. A significant volume of evidence exists demonstrating the value of the US pharmacies and pharmacy sector beyond simply dispensing medications.[14,20-33] The value of pharmacist and pharmacy sector services for many use cases and disease states has been well established.[14,34-40] Strategies included:

6.1 Develop/strengthen the US pharmacist and pharmacy sector research infrastructure
6.2.Demonstrate value in value-based care contexts
6.3. Strengthen/disseminate evidence of value to other health stakeholders
6.4. Disseminate evidence of value to the public
6.5. Organize strategic pilots to demonstrate new value (CMMI, NIH, NSF, private sector, etc.)

Strategy area 7. Advance the profession. There was significant interest from the panel in advancing the profession in support of advances in the field. However, there were cautions about training for new competencies that are not supported by payment reform and/or policy changes. Strategies included:

7.1 Strengthen Professional Development / Add New Competencies
7.2 Train pharmacists and technicians to support new value-driven services like CMM
7.3 Offer advanced licenses and certifications to enable pharmacists and technicians to operate at "the top of their professional abilities"
7.4. Strengthen training on high-impact communication skills (e.g. motivational interviewing, culturally responsive communications).[11-13]

Details about general strategies are provided in Appendix 3.

3.7 Overcoming Fragmentation: Need for "Triggering Mechanisms"

The initial goal of the study was to identify ten ranked strategies for strengthening US pharmacist and pharmacy capacity to act to improve health and wellbeing for patients/people. In seeking to do this, the researchers encountered challenges. Many of the strategies were interconnected. Many were already being implemented by one group or another. Different groups in the industry valued different strategies in different ways. Criteria for deciding on which strategies to include or exclude seemed unclear. There were a lot of strategies (42).

More broadly, the data gathered pointed to significant levels of pharmacist/pharmacy sector fragmentation, going back 40 or more years. Fragmentation was identified by virtually all panel participants as a critical challenge limiting sector progress. This is understandable, in that pharmacists partner with physicians, nurses, clinics, hospitals, aging care contexts, health plans, pharmaceutical companies, researchers and others in a myriad of settings across the healthcare ecosystem. Nevertheless, it clearly exists.

How to Overcome Fragmentation?

"The key lessons are that change can be stimulated in many ways, but a triggering mechanism is needed, such as legislation or widespread stakeholder agreement; that feedback loops are crucial to continue change momentum; that extended sweeps of time are involved, typically much longer than believed at the outset; and that taking a systems-informed, complexity approach, having regard for existing networks and socio-technical characteristics, is beneficial."

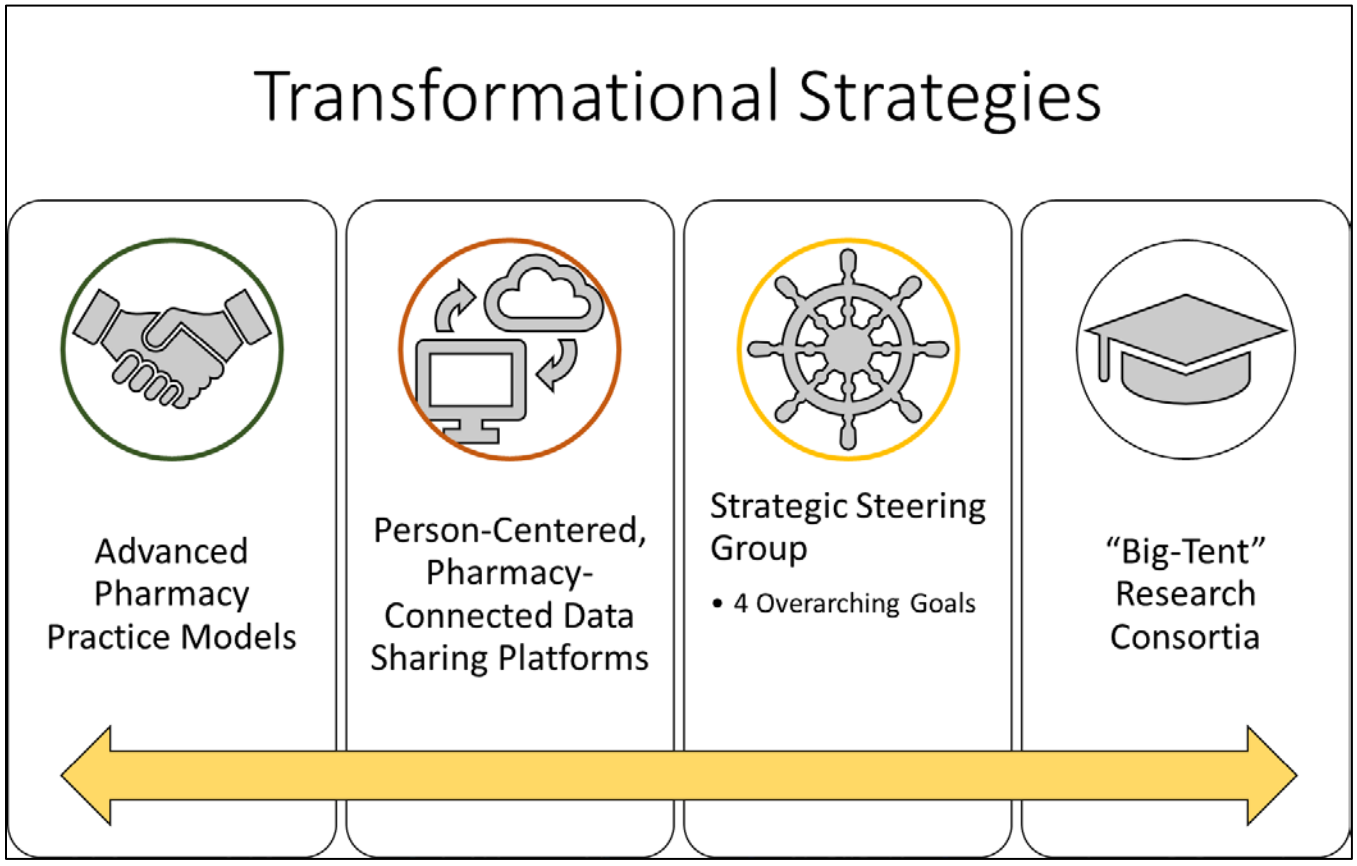
BRAITHWAITE ET AL (2018), WHEN COMPLEXITY SCIENCE MEETS IMPLEMENTATION SCIENCE: A THEORETICAL AND EMPIRICAL ANALYSIS OF SYSTEMS CHANGE

Given this, the researchers asked: what might be done to reduce this fragmentation in order to help the profession and sector improve ability to care for patients?

Implementation science research points towards an answer. It is well understood that perception and/or reality of fragmentation in external environments can limit organizational capacity to adopt health and wellbeing improving innovations.[1,2,41] Research has identified *triggering mechanisms* such as new legislation, and/or widespread stakeholder agreement, as key factors that can drive change.[42] The researchers analyzed the strategies to identify potential triggering mechanisms that could support transformational change. We called these *transformational strategies*.

3.8 Transformational Strategies

The researchers identified four *transformational strategies* with potential to be implemented at a national level to support implementation of new services. As shown in the figure, the transformational strategies are self-reinforcing. The goal is to achieve widespread stakeholder agreement and support for new policies, practices, and technologies, to help "trigger" systemic change.



I. Develop Advanced Pharmacist/Pharmacy Practice Model(s)

The first transformational strategy is a sector-wide effort to develop one or more *advanced pharmacist/pharmacy practice model(s)* that are nationally scalable, financially sustainable, and value driven. A goal is to develop a model that demonstrates enough returns on spending (e.g. quantitative improvements in quality, outcomes, satisfaction and costs) to be underwritten by underwriters in the Congressional Budget Office (CBO), and in Medicare, Medicaid, and commercial plan contexts.

II. Develop Person-centered, Pharmacy-connected Data Sharing Platforms

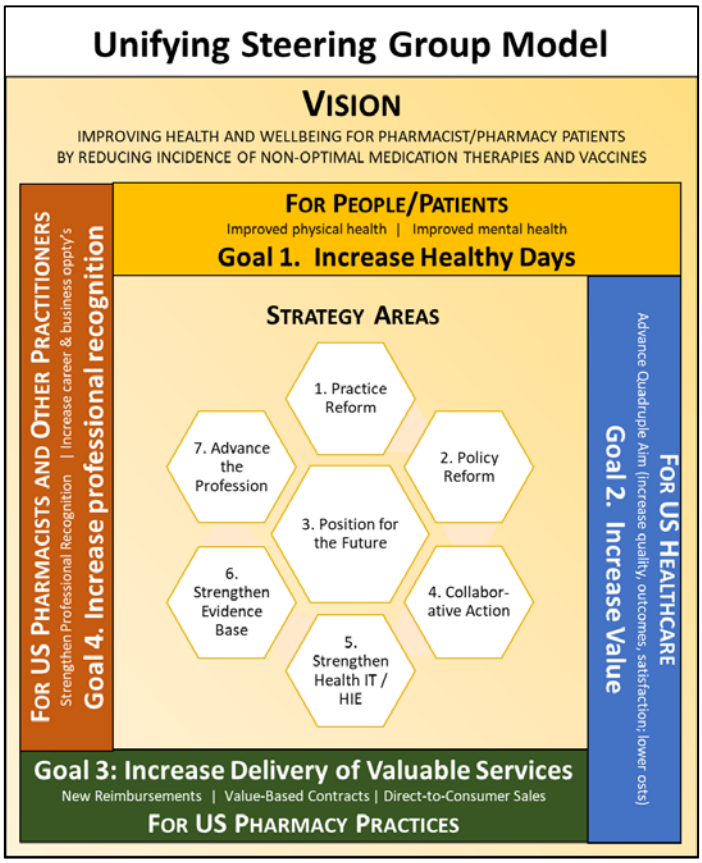
The second transformational strategy is to design and support implementation of one or more market-based *person-centered, pharmacy-connected data sharing platforms.* We believe an optimal approach could be structured similarly to the way VISA was structured for banking in the 1970s , featuring a multi-business association model to start. The platform should be engineered so that multiple parties compete to add value at every level, on a common branded platform. It should be consumer controlled, with data moving with the consumer everywhere s/he connects across the nation and world. The analysis points to an opportunity for the US pharmacist and pharmacy community to play an essential role in helping develop early use cases for the platform, and, to aid in distributing such services to patients/people across the US.

It should be noted that the goal of a platform like this goes well beyond pharmacy. It could be designed to work across the entire healthcare ecosystem and beyond, including banking transactions, groceries, consumer goods, genomics and a broad array of social determinants of health.

The expectation is that, in general, *pharmacists and pharmacies would get paid* for supporting development and distribution of such a platform. Other parties – big data and analytics firms, researchers, providers, plans, banks, digital health firms, and of course, consumers – would be the biggest beneficiaries of such a platform, and should thus be willing to help invest in it. We believe that in order to bring many competing parties together to design and implement such a platform, initial design and testing should be conducted in a "pre-commercial" university research context. Otherwise, competing entities may have a difficult time being able to participate and trust difficult to maintain.

III. Organize Strategic Steering Group

The third transformational strategy is to organize some kind of a *strategic steering group* in which all US pharmacists and pharmacies, supported by all those with whom they team across the health sector, can work together collaboratively. This steering group, likely operating in a non-profit association context, may benefit by focusing on a single measurable vision, and 3-4 key goals that can be measured nationwide over time, and used to prioritize action. Limiting the focus to one vision and 3-4 high level goals is consistent with best practices for strategic planning.[43,44]



For discussion purposes only, a draft vision and four goals were drafted. The vision is tied to improving health and wellbeing measures generally, and to the model developed by Watanabe et al specifically.[7] The *vision* is to improve health and wellbeing for pharmacist/pharmacy patients by reducing incidence of non-optimal medication therapies and vaccines. *Goal 1* is to increase healthy days. Healthy days are a

simple proxy measure for health and wellbeing developed by and widely used by CDC, as well as, increasingly, by large health plans including Humana.[45,46] *Goal 2* is to increase value for healthcare generally, by focusing on the quadruple aims of improving quality, outcome, satisfaction and cost measures. *Goal 3* is to increase delivery of valuable services by and through pharmacies, to provide additional revenues needed to support delivery of more services to patients. *Goal 4* is to increase professional recognition for pharmacists across the US, strengthening awareness by all of their unique, irreplaceable, highly valuable capabilities to provide value.

More detailed descriptions of each of these transformational strategies are included in the Appendices.

IV. Develop "Big Tent" Research Consortia

The fourth transformational strategy is to form one or more "*big tent" research consortia* designed to bring many parties from across the pharmacist/pharmacy ecosystem together to collaboratively identify, fund, conduct and disseminate high quality research to support transformational change. Established researchers from multiple universities should be involved to help propose and conduct the research, supported by students, and in collaboration with government and industry partners.

Potential exists to use new virtual collaboration technologies to engage many individuals, organizations, and researchers to work together on rapid-cycle research projects. We recommend use of *collaborative action research* protocols in research university settings, to support this effort. The research consortium/consortia should initially focus on research to design and develop *Advanced Pharmacy Practice Models, Person-Centered, Pharmacy-Connected Data Sharing Platforms,* and key goals and measures to support a *Strategic Steering Group*.

3.9 Research Opportunities

The study identified a preliminary list of opportunities to strengthen progress through research. Research priorities identified include:

- COVID-19 strategy related topics.
- Organization of research consortia
- Develop, test and implement scalable, sustainable pharmacy practice models
- Studies to strengthen and disseminate the evidence base about the sector's value.
- Develop, pilot and validate new pharmacist/pharmacy services and solutions.
- Develop, pilot and validate new digital technology infrastructures and applications
- Develop measures for sector-based visions, goals and progress over time.
- Implementation sciences-based research to inform large-scale transformation strategies.
- Many more ideas.

4 Limitations

This study analyzed data gathered during a time of rapid change in the spring, summer and Fall of the COVID-19 Pandemic as the 2020 Presidential election was approaching. During this time, there was much uncertainty about the future in general, as well as for the US pharmacist profession, pharmacy sector and healthcare more broadly. In addition, the amount of information gathered and processed in this study was larger than initially expected. Despite best efforts to be as objective as possible, the researchers recognize significant limitations because of these dynamics. Given this, these findings

should be interpreted with caution. They are offered as a high-level guide to support strategic planning and action.

5 IMPLICATIONS AND RECOMMENDATIONS FOR ACTION

Strategies along the lines identified in this study, if implemented successfully, have implications for the health and wellbeing of the US population, the efficiency and effectiveness of the US healthcare system, the future of the US pharmacist and pharmacy sector, and for policymakers interested in taking action to protect and strengthen the health and wellbeing of the US population during and after the COVID-19 pandemic.

- **For the US population**, the strategies offer potential to significantly improve population health and wellbeing measures (e.g. *CDC Healthy Days*) in the coming years. The US pharmacist and pharmacy sector is well positioned to provide a host of valuable and convenient services to people/patients. They can educate patients/people on healthy behaviors, provide health guidance and support, provide convenient screening, testing, vaccines and support, and provide personalized services for low SES and vulnerable populations. They can play a key role in understanding and addressing social determinants of health (SDOH) related challenges affecting people across the US.

    - **Recommendations for Action by Patient/Consumer Advocates.** Let relevant government representatives know about your support for policy changes to increase payments, reduce practice barriers, and support technology innovation to strengthen capacity of the US pharmacist and pharmacy sector to meet the needs of US populations during and after the COVID-19 pandemic.

- **For US Policymakers at Federal and State Levels.** The analysis points to an opportunity to act strategically at Federal and state levels to achieve goals including: rapid action to protect US population health during the COVID-19 era by supporting pharmacy-based testing, immunizations, support services, and access support; increasing health and wellbeing measures of the entire US population by empowering the US pharmacist/pharmacy sector to provide more value-driven services; reducing US health spending by tens of billions of dollars while improving quality, outcomes and satisfaction by reducing non-optimal medication therapies, and increasing immunization rates, with a special focus on at risk and low SES populations; strengthening economic development at scale for the sector including through advanced technology innovation.

    - **Recommendations for Action by US Policymakers.** Support policy changes to increase payments for valuable services, reduce practice barriers, and strengthen health IT and interoperability, support sector-level research and innovation.

- **For the US healthcare sector**. The strategies offer potential to strengthen the nation's ability to protect population health and wellbeing during the COVID-19 pandemic; reduce avoidable healthcare costs associated with non-optimal medication therapies, and improve quality, outcome, patient satisfaction and cost measures (the quadruple aim). These include opportunities to generate billions of dollars in cost savings for US healthcare through reduction

of medication-related costs such as avoidable emergency room visits, hospitalizations, and chronic illness management (cf. Watanabe, 2018)[7]

  - **Recommendations for Action by US Healthcare Sector Leaders.** Support policy changes to increase payments, reduce practice barriers, strengthen health IT and interoperability, and support innovation.

- **For the US pharmacist and pharmacy sector.** The strategies offer potential to substantially improve population health and wellbeing through pharmacists and pharmacies; help advance the profession; reduce barriers to helping protect patients health during the COVID-19 pandemic; support development and delivery of new generations of value-added services supported through funding mechanisms including: A. reimbursement for services; B. direct-to-consumer sales of services; and C. value-based contracts with health organizations; and other benefits.

  - **Recommendations for Action by US Pharmacist and Pharmacy Sector Leaders.** Consider how the strategies identified may align with internal strategic plans and directions; implement strategies to strengthen ability to provide COVID-19 related services; consider participating in a collaborative steering group or committees representing the whole sector, with a goal of better unifying the sector around a few high level goals; advocate for and support payment and practice reform; advocate for policy changes to remove barriers to payment and practice; support Health IT development and innovation; help spread the word about the value of the profession.

- **For Researchers:** Dissemination of existing studies about the value offered by the US pharmacy and pharmacy sector is lagging. In general, neither the public nor health system leaders have sufficient knowledge about the documented value the sector offers. In addition, there is need for many ongoing studies to document and demonstrate the value being offered to improve patient/population health and wellbeing by the US Pharmacist/Pharmacy sector.

  - **Recommendations for Action include:** 1. Help organize more efficient, fast-cycle research infrastructure and studies; 2. Develop and validate new service models; 3. Strengthen and publish evidence of value; 4. Benchmark goals and measure progress; 5. Develop and pilot innovative technologies and services; 6. help disseminate research results; 7. support industry and government leaders.

6 CONCLUSION

Thank you for the opportunity to conduct this study and present these findings.

We are also preparing one or more academic papers based on these findings, to be submitted to a journal such as Health Affairs. This report will be referenced as an "input" into those papers.

If you have any questions or would like to discuss this report, please don't hesitate to reach out to us.

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7 APPENDIX 1. TABLE OF NEEDS

The following list of needs were developed and refined through the following process. The list began with 168 descriptions of needs provided by the panelists. These were added to a spreadsheet. They were then reviewed, refined, standardized, and combined by the four researchers. Each was analyzed looking at four factors: 1.) popularity (# times mentioned by the panel); 2.) estimated US population size affected; 3.) estimated increase in health and wellbeing of that population if the need was met; and 4.) relevant insights from the literature related to the topic. The refined list was then sent back to the panelists for a second round of feedback and discussed in a round table. Feedback was added into the spreadsheet. The refinement process was then repeated by the researchers to end up with the categories and needs shown.

UNMET US PATIENT NEEDS (IDENTIFIED BY PANEL)
Need Area 1. Cross-Cutting Needs
Social Determinants of Health: services to assess and address people living with disparities and challenges related to social determinants of health, including access challenges including transportation, financing, language, trust and other barriers.
Health Information Exchange and Access
Need Area 2. Health and Wellbeing Services There are many gaps in service that pharmacies and pharmacists are well suited to address that can help people/patients improve their health and wellbeing
Health and Wellbeing Services (in general)
Immunizations (all kinds)
Test and Treat for Infectious Diseases (Flu, Strep, UTI, COVID-19, etc.); * includes addressing underserved populations; social determinants of health
Chronic Disease Management Support; includes underserved populations* * includes addressing underserved populations; social determinants of health.
Comprehensive Medication Management (CMM) Services; includes underserved populations/addressing social determinants of health. * includes addressing underserved populations; social determinants of health
COVID-19: Testing, Vaccines, Guidance * includes addressing underserved populations; social determinants of health
Addiction Screening / Referrals (Opioid, Tobacco, Etc.)
Wellness and prevention support
Social Determinants of Health: Screening, Referrals, Support
Behavioral Health Screening / Referrals
Maternal Child Health Screening / Referrals
Care Coordination / transitions of care services
Need Area 3. Public Education Pharmacies and pharmacists can meaningfully help people/patients improve their health and wellbeing through public education about medications, immunizations, testing, wellness, prevention, and other products and services that pharmacies and pharmacists are uniquely qualified to support.

Public Education (in general)
Education about Comprehensive Medication Management: What it is, how it works, how pharmacists/pharmacies can help
Education about Healthy behaviors, Wellness and Prevention, and their effects on health and wellbeing: what it is, how it works, actions to take.
Education about COVID-19 and Flu: how they interact; how to protect and manage risk.
Education about Role of Pharmacists/Pharmacies as Trusted Experts
Education about Medication Adherence: what it means, how it helps, risks of not adhering, actions to take to improve.
Debunking Myths: what is true; who to trust; how to protect yourself from misinformation.
Health Literacy Support: health literacy assessments; personalized education; actions to take to improve
Need Area 4. Access Patient needs for access to healthcare systems and services
Access (in general): includes addressing underserved populations; social determinants of health; cultural sensitivity, transportation issues, insurance, affordability.
Access to Affordable Medications
Access to Pharmacy/Pharmacist Services via Telehealth / Telepharmacy
Access to Convenient Primary Care Services through Local Pharmacies where Gaps in Primary Care Exist
Pharmacy Billing Codes to Fund Pharmacy/Pharmacist Services for Patients
Need Area 5. Personal Health IT / HIE
Personal Health IT / HIE Related Products and Services (in general)
Home and Self-Monitoring Devices
IT Related Transition of Care Services
Single Healthcare Record for each Patient
Need Area 6. Emergency Preparedness, Surveillance, Response Services by pharmacies and pharmacists
Emergency Preparedness, Surveillance, Response, especially related to COVID-19.

8 APPENDIX 2. TABLE OF BARRIERS

The following list of barriers were developed through the following process. The list began with 177 barriers to meeting patient/peoples' needs provided by the panelists. These were reviewed, refined, standardized, and combined by the four researchers. Each barrier was analyzed looking at factors including: 1.) popularity (# times mentioned by the panel); 2.) estimated difficulty of removing the barrier; 3.) estimated US population size affected by the barrier; 4.) estimated increase in health and wellbeing of that population if the need was met; and 5.) relevant insights from the literature related to the topic. The refined list was then sent to the panelists for a second round of feedback and discussed in a roundtable. Feedback was added into the spreadsheet. The refinement process was then repeated by the researchers to end up with the categories and needs shown.

BARRIERS (IDENTIFIED BY PANEL)
Barrier Group 1. Payment Barriers Note overlap between some payment and policy barriers (below).
Lack of Provider Status / lack of reimbursement for services *includes lack of provider status mentioned in "policy barriers" section.
Payment Barriers: unspecified further
Product Margin Compression; DIR fees; clawbacks
Lack of mechanisms to easily bill and be paid
Lack of aligned incentive systems: need to align to value
Lack of one voice to unite around payment reform
Barrier Group 2. Policy Barriers Note overlaps between some policy and payment barriers (above).
Federal / CMS Policies: lack of provider status, lack of Medicare Part B billing authority* *This count includes lack of provider status mentioned in "payment barriers" section.
State-Level Policies: high variation by state; complex local rules; most pharmacists unable practicing at top of profession
COVID-19 Guidance Confusion at Federal and State Levels: what gets paid for?
Barrier Group 3. Health IT / HIE Barriers
Lack of standards; lack of interoperability
Lack of data sharing with providers
Lack of person-centered data sharing across the continuum of care
Lack of sharing with payers
Lack of sharing with public health
Lack of pharmacy/pharmacist-based patient monitoring tools
Lack of pharmacy/pharmacist-based decision-support tools and systems
Lack of sharing with patients; lack of patient-centered services and tools; lack of personalized messaging and support services and pharmacy linked apps

Barrier Group 4. Profession Related Barriers
Lack of expertise in areas including: Social Determinants of Health (SDOH), Quality Improvement (QI), population health, best practices, adherence, motivational interviewing, behavior change skills, assessment skills.
Lack of training, education on how to provide new services to patients/people
Inertia; apathy; resistance to change
Lack of collaboration with other stakeholders
Barrier Group 5. Public Awareness Barriers
Lack of understanding of pharmacist profession: of what makes pharmacists unique, special, valuable
Low levels of COVID-19 related health literacy
Low levels of vaccine related health literacy: many types of vaccine; high vaccine hesitancy rates.
Lack of understanding of standards of practice, and pharmacists' professional obligations and capabilities
Lack of understanding of distinction between pharmacists (professionals) and pharmacies (organizations)
Lack of stakeholder awareness of pharmacy/pharmacists' value to the patients/people they serve; lack of knowledge about evidence-base demonstrating pharmacy/pharmacist value.
Barrier Group 6. Service Delivery Barriers Barriers Blocking Ability for the US Pharmacist and Pharmacy Sector to Provide Needed Health Services for Patient/People
Lack of pharmacist / pharmacy integration into care teams and the continuum of care
COVID-19 related services barriers: test and vaccine distribution challenges; pharmacies not prioritized at federal levels.
Lack of authorization for pharmacists/pharmacies to provide needed services in federal (CMS), State and Commercial contexts; high variation; includes lack of provider status.
Barrier Group 7. Lack of Collaboration
Lack of collaboration with physicians
Lack of collaboration with overall care teams
Barrier Group 8. Legacy Barriers
Workflow requirements: workflow does not support provision of services
Facility designs: facilities not set up to support services
Change management challenges
Legacy business models - product based structures
Pharmacy consolidation: disconnect between pharmacy and pharmacist interests

9 APPENDIX 3. TABLE OF STRATEGIES

The following list of strategy areas and strategies were developed through the following process. The list began with 196 strategies for overcoming barriers and meeting patient/peoples' needs provided by the panelists. These were reviewed, refined, standardized, and combined by the four researchers. Each strategy was analyzed looking at factors including: 1.) popularity (# times mentioned by the panel); 2.) estimated difficulty of implementing the strategy considering costs, barriers and other challenges; 3.) estimated US population size affected by the strategy, if implemented; 4.) estimated increase in health and wellbeing of that population if the strategy was implemented; and 5.) relevant insights from the literature related to the topic. The refined list was then sent to the panelists for a second round of feedback and discussed in a roundtable. Feedback was added into the spreadsheet. The refinement process was then repeated by the researchers to end up with the categories and needs shown.

Strategy Area A. Implement Value-Driven Pharmacist/Pharmacy Services
1.1. Develop, standardize, disseminate and deploy unique pharmacist-delivered services for high-impact use cases including: comprehensive medication management (CMM) and medication therapy management (MTM) (generally); COVID-19 (testing, vaccines, advice, messaging); Diabetes; Behavioral Health (depression, anxiety, substance use disorders); Care-coordination support services; Other chronic illnesses including CVD, Cancer; Maternal and Child Health; Vaccines generally (HIV, HEPC, Flu, Shingles, etc.); wellness and prevention services; public health services (education and guidance); Jail/prison transitions. Includes consideration of 1.8. (below): Position pharmacies as the "Service Hub" for services that support physicians and the healthcare ecosystem in the MAAPPIST areas: Medication-Management Services, Access services, Acute and Chronic Disease Management Support services, Prevention-and-Wellness Services Personalized Precision Medicine Support services, Immunizations for Adults, Screening for Adults, and Technology-driven apps, devices and monitoring. (MAAPPIST term coined by the UofL researchers to capture multiple types of services being proposed).
1.2 Develop, standardize, disseminate and deploy unique services and support for underserved and higher risk populations. Include: social determinants of health (SDOH) related services; filling gaps in care; patient education; affordability, insurance, transportation, culturally sensitive communications.
1.3 Pharmacies as "hub" for comprehensive management of vaccines (in alignment with CDC vaccine delivery guidelines) for adults (children continue to be supported primary through pediatricians, with pharmacies filling in access gaps in selected areas), including COVID-19.
1.4 Provide value-based care-oriented services for value-driven networks (ACOs, result-oriented plans, etc.)
1.5 Provide telehealth based telepharmacy services; virtual services; home health monitoring.
1.6 Digital Technology Driven Products and Services a. Technology driven consumer products/services sold through pharmacies. Alexa-type information services; data apps, wellness apps, devices, etc.

b. Best-in-class clinical decision support systems for pharmacists; include flagging, alerting about meds, vaccine challenges, healthy behaviors, other prompts;
c. Remote monitoring services and support, working in collaboration with physicians and other stakeholders to streamline processes. “pharmacies could capture this space” - simplifying processes for physicians as # of devices and measures increase. Could make a lot of money in this area.
d. Develop and offer person-centered “VISA-like” data sharing platform, providing individual, pharmacies and others access to data through linked payment cards, apps and services.

- VISA-like business model; pharmacies and others compete on shared platform; multi-billion dollar market opportunity for sector; individuals access their data using HIPAA “right of access” laws; own their data as their own "property right"; “share free or get-paid through your card”; card supports a variety of personalized pharmacy/pharmacist based services. UofL research team has a working paper with a more detailed approach. See also, Munger (2020).

1.7 Psychosocially informed education and communications services.
Provide methods, tools and materials based on motivational interviewing, behavioral change techniques, and other psychosocial methods; work to demonstrate impact on adherence, healthy behaviors and other measures; look at potential to reduce ADEs, non-optimized medication protocols; scale with what works.

1.8 "More than Just Medications" Suite of Services." Define and provide the MAAPPIST Suite of Services*: position pharmacies as a "**Service Hub**" for services that support physicians and the healthcare ecosystem in the MAAPPIST areas: **Medication-Management** Services, **Access** services, **Acute and Chronic Disease** Management Support services, Prevention-and-Wellness Services **Personalized Precision Medicine** Support services, **Immunizations** for Adults, **Screening** for Adults, and **Technology-driven apps, devices and monitoring**. (MAAPPIST term coined by the UofL researchers to capture multiple types of services being proposed).

Strategy Area 2. Policy Reform

2.1 Pharmacists recognized as providers by CMS. Advocate for and achieve pharmacy provider status with Medicare Part B and other contexts; increased payment for extended services at every level (federal, state, commercial); use COVID-19 to "open this door"; work with Joint Commission of Pharmacy Practitioners.

2.2 All states allow pharmacists to practice at the “top of their professional abilities” (e.g. “ top of license”). Advocate for and achieve changes in state level scope of practice laws to allow pharmacies to operate at "top of professional abilities"; consider Idaho model

2.3 Advocate for CMS, CMMI, Medicaid, Commercial plans, others to provide new mechanisms to pay for value.

a. Advocate for and achieve comprehensive medication management (CMM) as new billable service at every level; consider tiered levels of CMM service authorized based on patient profiles.

b. Advocate for and achieve Commercial Payment Reform: work with AHIP; payer adoption of

pharmacy/pharmacist inclusion in medical networks; adoption of CPT/billing codes for defined services; reimbursement commensurate with physicians.

c. CMMI pilots to demonstrate value of new services models

d. Obtain CMMI waiver; other mechanisms.

2.4 Advocate for and establish telehealth and telepharmacy: permanent rights to deliver pharmacy/pharmacist related services such as CMM via telehealth (assuming payment reform)

2.5 Advocate for and establish emergency pharmacist provider status, so that pharmacists can use their expertise to test, treat, and bill for services related to COVID-19.

2.6. Permanent Vaccine Authority. Advocate for and achieve Federal policies similar to recent HHS advisory and guidance, to permanently expand pharmacist authority to provide accessible services including COVID-19 tests and vaccines and all other FDA authorized vaccines; remove pharmacy scope of practice restrictions.

2.7 Advocate for and achieve sustainable margins on product; reduce margin compression; realign how pharmacies, PBMs and Pharma interact to continually maximize patient value.

Strategy Area 3. Strategically Position Pharmacists/Pharmacies for the Future

Includes Public Awareness Campaigns; Public Education activities; and Stakeholder Education activities

3.1. Develop/implement evidence-driven “One Voice for Patients” Campaign(s) and Messaging Strategies across Sector – these should bring the entire sector together to speak with a unified voice about the value of pharmacists and pharmacy in the US. This may include leveraging existing strategies like Pharmacist for Healthier Lives.

a. Entire sector needs to speak with a unified voice: align to single, defined message of pharmacist provided care that is endorsed by all; launch united public awareness campaign about past successes during COVID-19 pandemic.

b. Strategically position pharmacists/pharmacies as essential, important, unique, irreplaceable, highly educated, trustworthy: “you are at risk without advanced pharmacy services supporting you”; pharmacists must focus on quality, objectivity, value, error-free delivery.

Educate the public about the Pharmacists Oath:
● "I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow: ... I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct. I will embrace and advocate changes that improve patient care.
Make the case that pharmacists are to medicines and vaccines what physicians are to overall health: essential. People in the 21st century are at risk without pharmacists and the valuable services they provide. Why? Medicine and vaccines are getting more and more complex; you are at risk without advanced pharmacist services supporting you and your family.

Develop a powerful story explaining why relaxed regulations should be made permanent because of how pharmacies and pharmacists improved care and reduced risks to patients during the COVID era.
3.2 Extend existing campaigns and efforts such as Pharmacists for Healthier Lives; keep doing what is working.
3.3 Explore new campaigns and messages for different contexts and groups.
3.4 Educate and engage all other health stakeholders (including physicians and plans) directly and as part of collaborative action activities. Educate stakeholders (physicians, hospitals, nurses, plans and others) about growing value of pharmacies/pharmacists in today's environment: highlight COVID-19 contributions; highlight role of pharmacists as front-line responders during COVID-19; how pharmacists have worked across practices settings /continuum of care.
Strategy Area 4. Collaborative Action In recent years, academics have identified multi-organizational collaborations as an increasingly effective way of enabling change beyond the organizational level. Use of new collaboration technologies, including virtual meetings tools, are making it feasible to administer such collaboratives with increasing levels of efficiency and effectiveness.
4.1 Develop collaboration plan and priorities for US Pharmacist/Pharmacy Sector
A. Form formal collaborations with US physician groups: identify areas of shared opportunity to improve health and wellbeing for patients and generate new value for physician community and pharmacy sector: consider CMM, care coordination, tests, vaccines, health data sharing. Consider: AMA, AAFP, Specialty Associations.
. Form formal collaborations with US stakeholders representing the "spectrum of care" (all types of care activities): identify shared opportunities to improve health and wellbeing for patients and create new value for the stakeholders through care coordination; consider CMM, tests, vaccines and data sharing; include major associations for each sector.
C. Form formal collaborations with value-based care networks: CMS, CMMI, Commercial; Medicaid; ACOs.
D. Form formal collaborations with public health: data sharing; prevention; surveillance; emergency response; CDC, State/Local Health Departments, RWJF, VA, Others.
E. Form formal collaborations with the Pharma sector: to help drive change at scale: Sanofi, Pharma Foundation, others.
F. Form Collaborative Research Networks: work collaboratively to demonstrate value of new pharmacy/pharmacist services: include Pharma, Academia, Associations, Federal government agencies like CMS, NSF, NIH; form research collaborative(s)
G. Form State-Level Pharmacy Transformation Collaboratives: focus on driving state level change; support from national associations, federal agencies, large stakeholders.

H. Form “Pharmacy Sector Change Messaging Collaboratives”: engage Fortune 100 pharmacy companies, big pharma, plans, major associations to advance the narrative of pharmacists as unique and trustworthy sources of guidance.

I. Form collaboratives with Schools of Pharmacy and State Pharmacy Associations; create assistance in implementation of services and education on different billing/payment pathways at state and local levels.

J. Form formal collaboratives with in-patient providers: hospitals, health systems and aging care systems; focus on reducing burden of non-optimized medication protocols through CMM.
Consider focus on reducing $528B of excess costs associated with medication misadventures leading to treatment failure (TF) and new medical problems (NMP);focus on high-value use cases including transitions of care, care coordination and 30 day readmits; do related research; AHA; Aging Care Associations; large national systems.

Strategy Area 5. Health IT / HIE Innovation and Implementation

Health information technology (Health IT) refers to any form of information and communications technology (ICT) that is used in healthcare and health related services. Health IT may include hardware (computers, smartphones, tablets); communications platforms (telecom, platforms, social media); big data and analytics engines; genomics and proteomics storage and analysis engines; and many types of software (apps, electronic health records, billing systems, research systems, etc.). Health Information Exchange (HIE) refers to the ability to exchange health information of many kinds between disparate systems in a way that preserves data integrity, provenance, and meaning.

Goal is to enable data sharing with pharmacists across the continuum of care. Strengthen ability for pharmacies and pharmacists to access and share unified personal health data, including: medications, immunizations, test results, wellness and fitness information, over the counter purchases, social determinants data, maternal and child health data, and chronic illness data.

5.1 Stay the course – stay aligned with current status quo

a Support relevant infrastructure projects and groups including Pharmacy Health IT Collaborative, Pharmacy Quality Initiative, NCPDP, HL7 and other groups.

b. Support existing initiatives like the NCPDP Pharmacists eCare Plan,

5.2. Create the future – support high-risk high-return transformational innovation focused on person-centered, personally-owned data platforms and connected services.

a. Strengthen pharmacy innovation ecosystem

b. Support Research on LIFE Platform and related concepts, e.g. person-centered, personally owned, pharmacy linked, decentralized, “VISA-like” data sharing platforms able to support a competitive ecosystem of apps and services distributed through pharmacists and pharmacies;

c. Develop, source, sell new pharmacy-connected digital products/services

Strategy Area 6. Strengthen and Disseminate Evidence Base

6.1 Develop/strengthen research infrastructure through collaboration with academic institutions, the Pharmacy Quality Alliance (PQA) and others to:

a. Define measurement strategies for how pharmacist and pharmacy services are evaluated;

b. Raise the research bar: interdisciplinary research partnerships should feature high levels of rigor in study design and methodologies; publish in non-Rx, highly esteemed journals;

c. Drive increases in priority research projects;

d. Develop infrastructure to support shared data collection and reporting for research and benchmarking to demonstrate outcomes and successes.

6.2. Demonstrate value in value-based care contexts.

a. Document the value of pharmacist/ physician partnerships;

b. Work with CMS and CMMI;

c. Work with commercial payers, ACOs, PCMHs;

d. Work with Medicaid networks;

e. Work with Pharma;

f. Measure the value of COVID-19 work and use that to educate influence leaders;

g. Consider the "quadruple aim": better quality, outcomes, satisfaction and cost measures;

h. Show impact of pharmacy services on total cost of care; i. Develop evidence of value by use case/disease state: e.g. COVID-19, diabetes; behavioral health (depression, anxiety, substance use disorders); maternal and child health; vaccines generally (HIV, HEPC, Flu, Shingles, etc.); wellness and prevention services; public health services (education and guidance); care-coordination support services; jail/prison transitions; j. Demonstrate value of pharmacy and pharmacist-based Health IT / HIE data sharing services.

6.3 Aggregate and disseminate pharmacy related innovations more effectively; get the word out about existing evidence of pharmacy value: “the evidence is there, it's compelling, it needs to be more effectively shared."

6.4 Develop, strengthen and disseminate standards including:

a. Unified standards of care, competency, practice and services including Pharmacist Patient Care Process Model (2014);

b. Advance standards for services including minor medical ailment triage; collaborative drug therapy agreements; population health management; social determinants informed support;

c. "Top of license" (top of professional abilities) model based on Idaho Model for pharmacist/pharmacy practice.

Strategy Area 7. Advance Profession

7.1 Professional Development / New Competencies

a. Increase systematic training of pharmacists and technicians to provide "More than just Medications" services and support

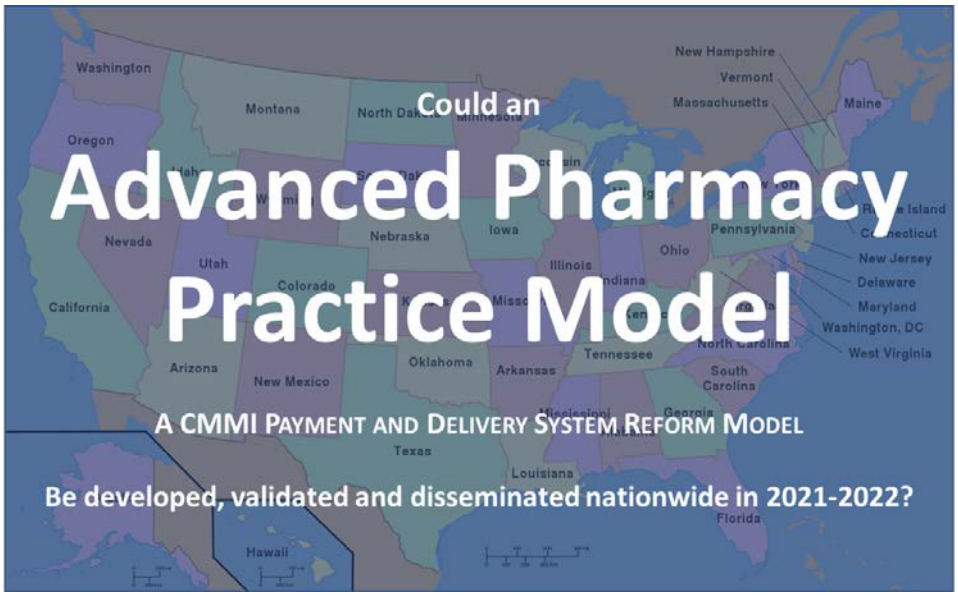
b. Enable pharmacists to work at top of their professional abilities (e.g. top of license) by offering advanced licenses and certifications as rules change

c. Strengthen training on high-impact communications skills, including motivational interviewing, culturally responsive communications, behavioral change techniques, and other psychosocial methods. This area offers significant potential to improve adherence and healthy behaviors; potential to reduce ADEs, non-optimized medication protocols. Should also consider advances in behavioral psychology, cognitive biases, behavioral economics, and related areas of research.

APPENDIX 4. TRANSFORMATIONAL STRATEGIES (DETAILS)

10 DEVELOP TRANSFORMATIONAL PRACTICE/PAYMENT MODELS

The first transformational strategy is to bring many parties in the sector together in a research context to generate substantial grant and payor support for developing, piloting and disseminating *sustainable, scalable value-driven practice and payment models*. The goal is to provide pharmacists across the US with increased financial support to provide value-driven medication management services, cognitive services and the like to patients who need the services. It would support value-driven services in in-patient, ambulatory, assisted living and skilled nursing environments.

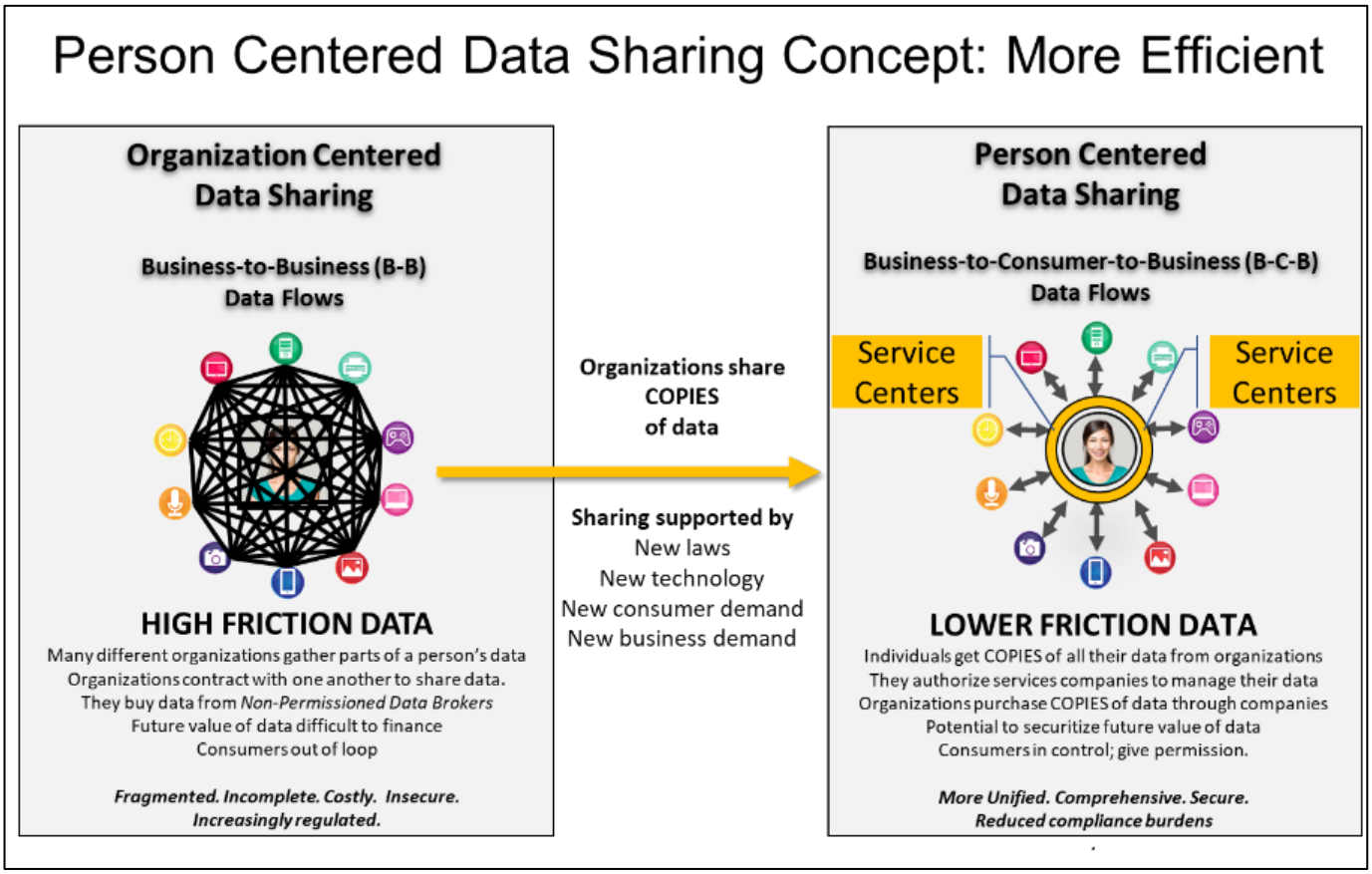


Collaboration with CMMI and private plans to develop and support these kinds of models is a potential mechanism for moving this agenda forward, although there are many other avenues to explore as well.

11 Develop Person-Centered, Pharmacy-Distributed "VISA-Like" Data Sharing Platform(s)

The second transformational strategy is to support development of one or more person-centered, pharmacy-distributed "VISA-like" data sharing platforms, designed so that pharmacies and pharmacists can get paid, and generate increased revenues, for their work distributing and using the new technologies to improve care for patients. A quick background on developments in this space can provide context for this strategy.

In the digital health information space, a paradigm shift is underway worldwide. Data architectures are moving from organization-centered to person-centered ones.[47] Organization-centered models are ones in which organizations aggregate partial data about individuals and share it with one-another, often with limited on no consent. Person-centered models are ones in which more complete data about a person is gathered under their control, and shared with their informed consent. Recent changes in US Federal law, new technologies like APIs[48] and stronger interoperability standards are leading to strengthening capabilities for creating person-centered health data sharing models in the US.



However, several challenges to developing such platforms have limited progress to date. One is growing concerns about very large companies controlling too much data or enabling misuse and abuse of that data. One solution identified for this is to construct a platform using a VISA-like model, in which a number of large companies collaborate to develop, invest in and support a co-branded model. This would allow multiple "service companies" to compete for business on a collaborative, scalable platform.

A second challenge is how to create a safe, secure interoperable technology platform that can support growth to potentially billions of people. A solution is a decentralized personally-owned and controlled architecture, in which data is stored in the cloud, and is controlled by and moves with the person. This architecture means there is no master data store which can ever be hacked.[49] A third challenge has been interoperability. Development of FHIR and APIs, encouraged through 21st Century Cures and other activities, are helping lower these barriers.[50] A fourth barrier has been the policy and regulatory environment. These barriers are also dropping as 21st Century Cures rules are being instantiated by HHS. In recent years, versions of these person-centered models have been advanced by senior US technology leaders including William Yasnoff, Aneesh Chopra and David Blumenthal, using terms like health record banks, and personal data fiduciaries.[51,52]

Data from Munger, and other studies, suggest that the US Pharmacist/Pharmacy space may be a niche market that is well suited to start the build-out of such a platform.[53,54] The value of access to medications data to improve health and care is high. Pharmacists and pharmacies have high trust with consumers, and low costs of distribution of a new service like this. Data connections to pharmacy systems are feasible. Many pharmacy consumers will be willing to pay for advanced pharmacy services enabled by such technologies.

The researchers have developed a *LIFE Platform Research Proposal* as one way to advance this opportunity. Other avenues for exploring this strategy, or related ones, will also be worthy of consideration.

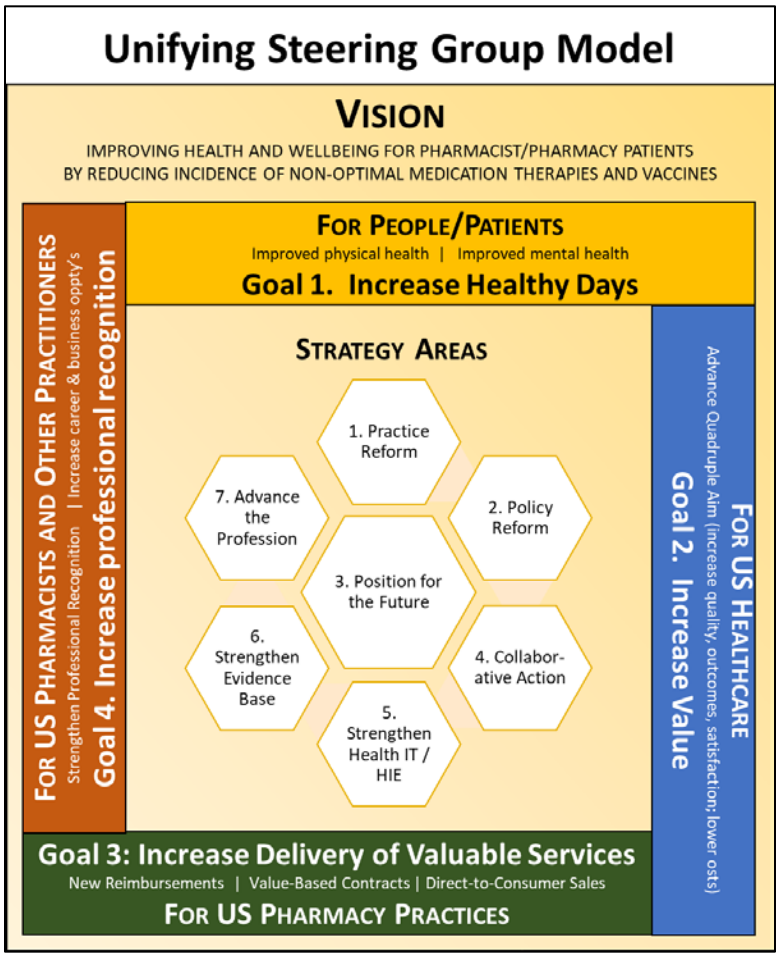
12 Form Unifying Steering Group

The third transformational strategy is for pharmacist and pharmacy sector leaders to explore formation of a unifying steering group or body that *advocates for and supports action by the entire pharmacist and pharmacy sector*, focused on measuring and managing progress for a small set of high-level measurable goals.

The vision of such an initiative, if it made sense to key parties to support it, could be to develop and support a more unified approach to reducing incidence of non-optimal medication therapies across the sector (e.g. Watanabe 2018). Such an effort could be organized around a few high-level measurable goals that bring everyone together and strengthen ability to community about the unique value provided by pharmacists and pharmacies.

The researchers' spent some time thinking about a set of higher-level unifying goals that the entire sector could unify around, in accordance with best practices for strategic planning.[43,44]

Four potentially measurable goals, one for each of four major stakeholder groups, were identified for consideration. Each of the strategies identified in the report have potential to be mapped to goals along these lines.



Goal 1. Increase "Healthy Days" for US Populations

Goal 1 is to engage the US pharmacist and pharmacy sector everywhere to increase "healthy days" for the 330 million US residents. Healthy Days is an established proxy measure for population health and wellbeing developed by the CDC, and widely used in public health.[46] In recent years, it has been adopted by major companies, including Humana, to help drive corporate strategy.[45]

This goal is aligned with the focus on serving the patient/person identified by panelists reflected in a consensus vision statement published by the Joint Commission of Pharmacy Practitioners: *Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.*

- **2025 Goal:** Increase Healthy Days of People Served by Pharmacists/Pharmacies by ____% by 2025 (compared to baseline)

- **Measurement:** Healthy Days could be measured at national, state, local, and pharmacy levels using existing data, complemented by randomized surveys. A baseline could be developed in 2020 or 2021, and progress measured over time.
- **Action:** Each pharmacy organization, in collaboration with others, could focus on action to increase healthy days measures for their customers, and/or their communities.
- **Strategies:** Implementation of many of the strategies identified would drive measurable improvements in Healthy Days.
- **Publicity:** Publicity announcements touting pharmacist/pharmacy contributions to increased healthy days could help strengthen public perceptions about the role and value of pharmacists/pharmacies.

Goal 2. Increase Quadruple Aims; reduce Healthcare Industry Spending.

Goal 2 is focused on helping the US healthcare sector measurably increase quality, outcome and satisfaction measures while reducing could help simplify the strategic approach in accordance with best practices for strategic planning.[43,44] (e.g. the quadruple aims) as measured by CMS and others. US healthcare spending is approaching $4 trillion annually ($12,000 per person per year), nearly twice that of many other advanced economies. Yet US healthcare quality, outcomes and patient satisfaction measures lag well behind those of most other advanced economies. The US Pharmacist/Pharmacy sector has an opportunity to be recognized for meaningfully impacting these measures by continuing to focus efforts on reducing excess spending estimated at $528B per year associated with sub-optimal medication use.[7]

- **2025 Goal:** Reduce addressable US healthcare spending by $_____ by 2025
- **Measurement:** Use established measurement methods[7] to assess results annually. A baseline could be developed in 2020 or 2021, and progress measured over time.
- **Action:** Each pharmacy could focus on action (e.g. CMM and other value-driven services) to advance quadruple aims and reducing medication related spending for care-team partners and consumers.
- **Strategies:** Implementation of many of the strategies identified would drive measurable improvements in the quadruple aims.
- **Publicity:** Publicity announcements touting pharmacist/pharmacy contributions to the quadruple aims could help strengthen perceptions about the role and value of pharmacists/pharmacies.

Goal 3. Increase Delivery of and Payment for Valuable Products and Services by Pharmacies

Goal 3 is focused on increasing delivery of and payment for valuable products and services by pharmacies to purchasers, healthcare stakeholders and patients/people. Three areas of opportunity are identified.

1. Area 1 is ***increase reimbursements*** from Medicare, Medicaid, Commercial Insurers, and others for valuable services. Some of these reimbursements will require policy changes (as noted above). However, there are many emerging opportunities for new kind of reimbursement from plans that could be explored. As a recent opinion piece on the "optimal community pharmacy" stated: "*Two-thirds of payers were very likely or likely to reimburse for the optimal pharmacy service*."[55]

2. Area 2 is ***Direct-to-Consumer sales*** of value-added products and services. Opportunities may exist to "upsell" new value-added products and services of up to $15.00 per retail visit to consumers.[54] There is also rapid growth in new retail services offerings emphasizing convenience and lower prices. These may include remote monitoring and concierge services.

3. Area 3 is ***Value-Driven Contracts*** with US purchasers, plans and providers. This is a rich, rapidly developing area as value-based care continues to progress. One subset of this area, which could help drive new value, is delivery of new kinds of data, analytics and sharing related services.

- **2025 Goal:** Increase delivery of new pharmacy sector services by $_____ Billion by 2025. Includes $____B in new reimbursements; $_____B in new direct-to-consumer sales; and $____B in new value-driven contracts.
- **Measurement:** Existing and new methods for measuring delivery of these kinds of services could be considered. A baseline could be developed in 2020 or 2021 and progress measured over time. Development of new billing codes and quality measures will be important to put in place to support attribution to pharmacists/pharmacy services.
- **Action:** Each pharmacy and the sector as a whole could focus on accelerating innovation to speed up sales of new value-added products and services.
- **Strategies:** Implementation of many of the strategies identified would drive increases in this area
- **Publicity:** Publicity announcements touting new, valuable products and services developed and offered by the US pharmacist and pharmacy sector could help improve perceptions about the role and value of the sector, while also driving increases in delivery of valuable health improving services to patients/people..

Goal 4. Increase Recognition of the "Unique, Indispensable Value Offered by Pharmacists"

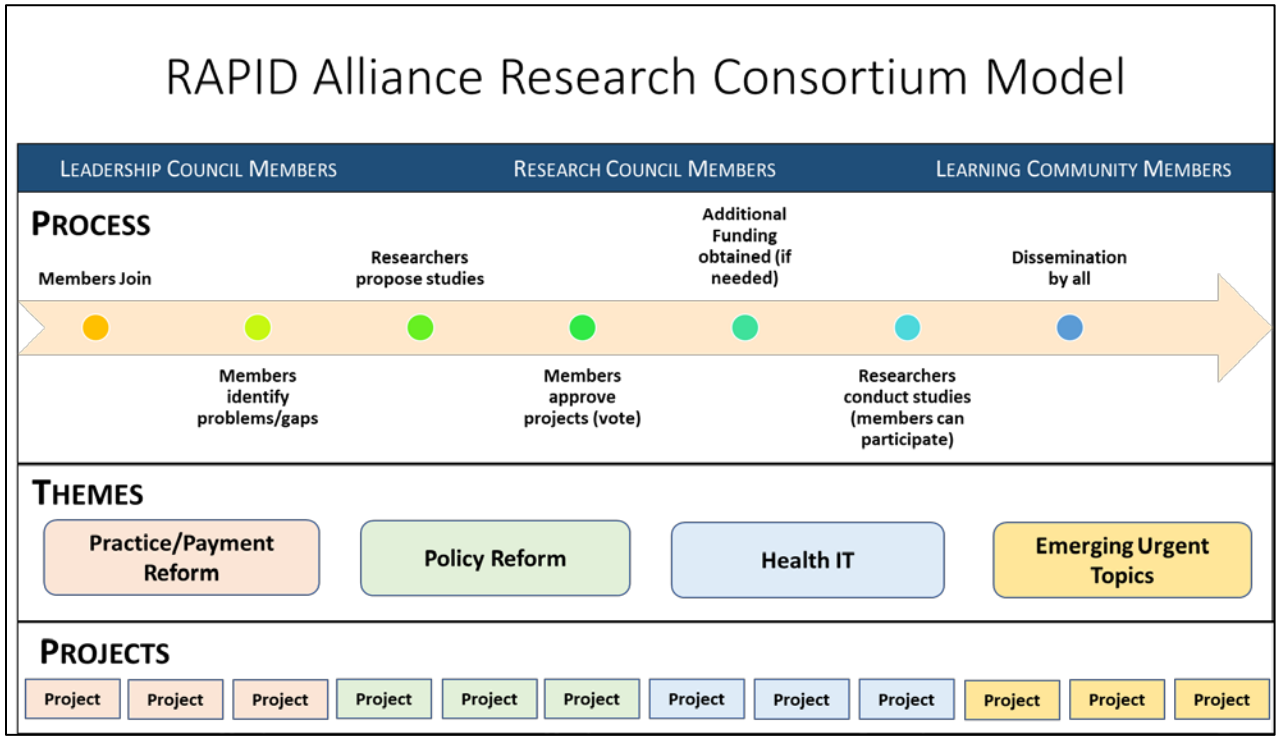
Pharmacists are uniquely trained, qualified and licensed to provide and guide many of the valuable services identified in this report. Yet, the public and other healthcare stakeholders are not as aware as they might be of the unique and indispensable value offered by pharmacists. The fourth goal is to strengthen public and stakeholder recognition of this unique value. Benefits of such an approach for pharmacists could include new career and earning opportunities based on the added value they uniquely offer.

- **2025 Goal:** Increase pharmacist positive recognition scores by _____ % [100%?] by 2025 compared to 2020 baseline.
    - Possible survey question 1: I see my local pharmacist as an "indispensable resource for improving my health and wellbeing"
        - 1=strongly disagree to 5=strongly agree
    - Possible survey question 2: Net promotor score.
        - On a scale of 1-10, how likely are you to recommend this pharmacist/pharmacy to a friend?
        - Baselines may already exist on this measure.

- **Measurement:** National, state and local surveys, possibly done in tandem with Healthy Days surveys, could be conducted to gather this data. Baselines could be developed in 2020 or 2021 and progress measured over time.
- **Action:** Each pharmacist and pharmacy and the sector as a whole should focus on actions to strengthen the reputations of pharmacists everywhere.
- **Strategies:** Implementation of many of the strategies identified would drive increases in this area.
- **Publicity:** Publicity announcements touting accomplishments of pharmacists everywhere in helping drive improvements in Goal 1. Healthy Days, Goal 2. The Quadruple Aim, and Goal 3. Distribution of Valuable New Products and Services should be considered.

13 FORM RESEARCH CONSORTIA

The fourth transformational strategy is to form one or more sector-wide research consortia to conduct *university-based research and disseminate results* in accordance with priorities identified in this report or by future members. A "big-tent" model, with a place at the table for all stakeholders touched by pharmacist and pharmacies is recommended. Leading researchers from multiple schools of pharmacy and other spaces should be invited to participate, propose and complete studies. Priority research projects, and supporting funding, should be collaboratively developed.



Participants in the model include *Leadership Council Members* willing and able to make a financial or in-kind investment and help guide decision-making about research priorities, university based r*esearchers* who propose and conduct research and help disseminate the results, and *Learning Community Members* who join free, participate in webinars and events, learn and help disseminate results. A "big tent" membership model provides a "seat at the table" for leading organizations across the US pharmacist/pharmacy ecosystem. Details about who should be invited are available separately.

The ***process*** is driven through collaboration among participants, supported by the principal investigators. Leadership Council Members *Join*. They participate in virtual meetings and brainstorming processes to *identify problems and gaps*. *Researchers propose studies* to address the problems and fill gaps. Council members then *vote to approve* priority projects. Members and researchers may work together to *generate additional funding* – such as grants or donations – if needed. The researchers *conduct the research* and present the results. Other members can participate in the research if and as appropriate. Finally, everyone works together to *disseminate the results* of the research through academic papers, trade channels, webinars, and other methods.

Four ***themes***, identified in this study, are identified to start the process. These are practice/payment reform, policy reform, Health IT innovation, and emerging urgent topics, such as topics related to COVID-19.

Multiple ***projects*** are implemented linked to the themes. Projects may range in size from quite small and time limited (e.g. a $25,000 6-month study) to quite large (e.g. a 2-year, $2 million dollar pilot study of a new value-driven practice model. Each project has a "project group" comprised of participants who are involved with it, who may also support and collaborate on it as the project progresses.

All activities would be conducted virtually, on a fast-cycle, supported through videoconferences, online surveys, webinars and other methods.

This model is offered as one example of a consortium model that could be developed. The researchers plan to move forward with organizing one along these lines but are also open to collaborating with and supporting other consortia that may be developed.