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# **Improving Patient and Health System Outcomes through Advanced Pharmacy Practice**

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**A Report to the U.S.  
Surgeon General 2011**

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**Office of the Chief Pharmacist**

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## RELEVANT ACRONYMS

AACP	American Association of Colleges of Pharmacy
AAFP	American Academy of Family Physicians
AAMC	Association of American Medical Colleges
ACA	Affordable Care Act
ACPE	Accreditation Council for Pharmacy Education
ADE	Adverse Drug Event
APhA	American Pharmacists Association
ASHP	American Society of Health-System Pharmacists
BOP	Federal Bureau of Prisons
BPS	Board of Pharmacy Specialties
CCP	Chronic Care Professional
CDTM	Collaborative Drug Therapy Management
CGP	Certified Geriatric Pharmacist
CMS	Centers for Medicare & Medicaid Services
CPA	Collaborative Practice Agreement
CPHIMS	Certified Professional in Healthcare Information and Management Systems
CPP	Clinical Pharmacist Practitioner
CPS	Clinical Pharmacy Specialist
DMAA	Disease Management Association of America
DOD	U.S. Department of Defense
HCFA	Health Care Financing Administration
HRSA	Health Resources and Services Administration
I/T/U	IHS, Tribal, and Urban
ICP	Infection Control Professional
IHS	Indian Health Service
IOM	Institute of Medicine
MedPAC	Medicare Payment Advisory Commission
MTM	Medication Therapy Management
MTMP	Medication Therapy Management Program
NAPLEX	North American Pharmacist Licensure Examination
NCCPC	North Carolina Center for Pharmaceutical Care
NCPS	National Clinical Pharmacy Specialist
NCPSC	National Clinical Pharmacy Specialist Committee
NP	Nurse Practitioner
NPP	Non-Physician Practitioners
OSG	U.S. Office of the Surgeon General
PA	Physician Assistant
PCMH	Patient-Centered Medical Home
PCP	Primary Care Provider
PDP	Prescription Drug Plan
PSPC	Patient Safety and Clinical Pharmacy Services Collaborative
VA	U.S. Department of Veterans Affairs

## EXECUTIVE SUMMARY

The 2011 Report to the U.S. Surgeon General is an update of a previously submitted Report in 2009 to then Acting Surgeon General, RADM Steven Galson. The 2011 Report provides health leadership with evidence-based discussion about improving patient and health system outcomes through an additional paradigm of health care delivery for expanded implementation in the United States. The 2011 Report provides rationale and compelling discussion to support health reform through pharmacists delivering expanded patient care services. In collaboration with other providers, this is an existing, accepted, and additional model of improved health care delivery that meets growing health care demands in the United States.

Health care delivery (including preventive or supportive care) in the United States is challenged by demands of access, safety, quality, and cost. These challenges are amplified by provider workforce shortages and dramatic increases in primary and chronic care visits. Projections suggest worsening of this situation. New or additional paradigms of care must be implemented to reduce these burdens. Current health care demands provide an opportunity for health leadership to recognize and adopt additional and successful health care deliver models.

Health reform has stimulated exploration of innovative care and payment reform models that can improve access to care, provide quality care, contain costs, and afford safe use of medications and other pertinent medication-related issues. The federal sector has already implemented and embraced such a health care delivery model through physician-pharmacist collaboration. This collaboration, through extensive performance data, has demonstrated that patient care services delivered by pharmacists can improve patient outcomes, promote patient involvement, increase cost-efficiency, and reduce demands affecting the health care system.

For over forty years, federal pharmacists have collaboratively managed disease through medication use, and other cognitive and clinical pharmacy services.<sup>1</sup> Although these models are accepted in the non-federal sector, utilization is often impeded due to policy, legislation, and compensation barriers that will be discussed in this Report.

The Report is framed around four focus points that clearly articulate and present evidence-based data that objectively illustrate improved health care delivery through the use of pharmacist-delivered patient care. A substantial amount of published literature from peer-reviewed journals has been collected and analyzed to support the discussion.

**Focus Point 1** discusses how pharmacists are already integrated into primary care as health care providers. Pharmacists unquestionably deliver patient care services in a variety of practice settings through collaborative practice with physicians or as part of a health care team. Definitions of primary care assist us to enumerate these integrated roles, and the long history of successful delivery demonstrates a level of interprofessional collaboration and support. After an initial diagnosis is made, pharmacists deliver many patient care services - and function as health care providers - in a variety of practice settings through collaborative practice

agreements (CPAs), to manage disease in patients (where medications are the primary mode of treatment). Pharmacists can:

- Perform patient assessment (subjective and objective data including physical assessment);
- Have prescriptive authority (initiate, adjust, or discontinue treatment) to manage disease through medication use and deliver collaborative drug therapy or medication management;
- Order, interpret and monitor laboratory tests;
- Formulate clinical assessments and develop therapeutic plans;
- Provide care coordination and other health services for wellness and prevention of disease;
- Develop partnerships with patients for ongoing (follow-up) care

The American Academy of Family Physicians, the Institute of Medicine, and the Care Continuum Alliance all describe the many facets of primary care. Once a diagnosis is made by the primary care provider, pharmacists do manage disease and provide patient care. Pharmacists that perform in these roles function as health care providers. Pharmacists are uniquely positioned (through their accessibility, expertise and experience) to play a much larger patient care role in the U.S. health care delivery system to meet these demands and improve the health of the nation. However, **pharmacists may be the only health professionals (who manage disease through medications and provide other patient care services) who are not recognized in national health policy as health care providers or practitioners.** Legislation, policy, and compensation mechanisms thus limit optimal patient outcomes and reduce the positive impact on the patient and the health care system.

**Focus Points 2 & 3** discuss how to sustain these value-added patient care services delivered by pharmacists. For pharmacists to continue to improve patient and health system outcomes as well as sustain various roles in the delivery of care, they must be recognized as health care providers by statute via legislation and policy, and be compensated through additional mechanisms commensurate with the level of services provided (and with other practitioners providing comparable services). Pharmacists with approved privileges, who currently perform in expanded clinical roles to manage disease and deliver other patient care functions, are not recognized by the Social Security Act<sup>2</sup> or Centers for Medicare & Medicaid Services (CMS) as health care providers or Non-Physician Practitioners (NPPs). The Social Security Act appropriately recognizes a number of other health care professionals as health care “providers or practitioners,” including physician assistants, nurse practitioners, certified nurse midwives, clinical social workers, clinical psychologists, and registered dietitians/nutrition professionals. These health professionals have multiple and varied areas of expertise and provide some facets of primary care, yet all deliver patient care services. Pharmacists provide expertise and health care delivery in a number of ways from primary prevention, to counseling and adherence programs, to comprehensive medication and chronic disease management - and are not yet recognized in this important piece of legislation. This omission is despite evidence that medications are involved in 80 percent of all treatments (and impact every aspect of a patient’s life), and drug-related morbidity and mortality cost this country almost \$200 billion annually.<sup>3</sup> Failure to recognize expanded roles of pharmacists limits the potential for patients and our health care system to benefit from access to additional quality primary care services. Exclusion



of pharmacists as health care providers also eliminates any subsequent service-sustaining compensation. Pharmacists are increasingly requested by many health systems, providers, and primary care teams to improve outcomes and delivery of care. However, in terms of pharmacist services, as the complexity or level of clinical service increases, the revenue generation potential is reduced. This is in stark contrast to the clinical services provided by other health professionals. In both the public and private sectors, health systems are fiscally challenged to sustain any clinical service without the ability to generate revenue.

**Focus Point 4** discusses and **collates the numerous articles, systematic reviews and meta-analyses of positive patient and health system outcomes that have been published** in peer-reviewed journals that validate this model as evidence-based. According to a recent comprehensive systematic review of 298 research studies, integrating pharmacists into direct patient care results in favorable outcomes across health care settings and disease states.<sup>4</sup> Pharmacists with larger roles in patient care improve outcomes, increase access to care (especially for medically underserved and vulnerable populations), shift time for physicians to focus on more critically ill patients in need of physician-based care, improve patient and provider satisfaction, assure patient safety, enhance cost-effectiveness, and clearly advance and improve health care delivery.

**An opportunity exists for health leadership and policy makers to support and implement additional, existing and evidence-based models of cost-effective pharmacist-delivered patient care as the following demands within our health system escalate:**

- **Chronic Care.** Chronic diseases are the leading causes of death and disability in the United States. Chronic diseases currently affect 45% of the population (133 million Americans), account for 81% of all hospital admissions, 91% of all prescriptions filled, 76% of physician visits, and continues to grow at dramatic rates.<sup>5</sup> Additionally, of all Medicare spending, 99% goes to beneficiaries with chronic disease.<sup>6</sup>
- **Access to care.** Medically underserved patients seeking a health care home and the growth of primary care visits are two components that lead to insufficient time for focused or comprehensive disease or medication management and other related health care issues.
- **Provider workforce.** The primary care workforce may not be able to meet the demands of increased access to care. Physician shortages and maldistribution of health care providers impact how we address this issue. The proportion of newly graduated U.S. medical students who choose primary care as a career has declined by 50% since 1997.<sup>7</sup> Currently, it is estimated that over 56 million Americans lack adequate access (not coverage) to primary health care because of shortages of primary care physicians in their communities.<sup>8</sup> As millions of new beneficiaries enter the health care system, the situation will most likely worsen.

Currently, the Affordable Care Act seeks to guarantee more health care choices and enhance the quality of health care for all Americans, while making health care affordable.<sup>9</sup> Innovative practice models need to be considered, especially with the current shortage of primary care providers and limited resources, in order to address these challenges. In medically underserved

and vulnerable populations and the federal health care settings, pharmacists have successfully functioned in interprofessional practice settings (e.g., IHS, VA, and DOD). Allowing pharmacists to function in these advanced models across more practice settings expands the health care infrastructure to meet demands for increased patient care services.

Pharmacists are remarkably underutilized in the U.S. health care delivery system given their level of education, training, and access to the community. Maximizing the roles and scope of pharmacists to deliver a variety of patient-centered primary care and public health, in collaboration with physicians, is a proven and existing paradigm of care that can be efficiently implemented.

During the April 11, 2011 launch of the Partnerships for Patients Initiative, Donald Berwick, CMS Administrator, stated, “America is facing a critical choice in health care. Either cut care or improve care. I don’t like to cut care, so the only right thing to do is improve care.”<sup>10</sup> The link between the impact of medications on the health system and the expertise of the pharmacist, coupled with the exponential growth in cost of care, draws a logical parallel to this model as a keystone of care. **One of the most evidence-based decisions to improve the health system is to maximize the expertise and scope of pharmacists and minimize expansion barriers of an already existing and successful health care delivery model.**

### Objectives

- Obtain advocacy from the U.S. Surgeon General to acknowledge pharmacists that manage disease through medication use and deliver patient care services, as an accepted and successful model of health care delivery in the United States, based on evidence-based outcomes, performance-based data and the benefits to patients and other health system consumers (physicians, administrators, payers, etc.).
- Obtain advocacy from the U.S. Surgeon General to recognize pharmacists, who manage disease and deliver many patient care services, as health care providers. One such action is advocate to amend the Social Security Act to include pharmacists among health care professionals classified as “health care providers.”
- Obtain advocacy from the U.S. Surgeon General to have pharmacists recognized by CMS as Non-Physician Practitioners in CMS documents, policies, and compensation tables commensurate with other providers, based on the level of care provided.
- Advance beyond *discussion* (and numerous demonstration projects) of the expanded roles of pharmacist-delivered patient care and move toward health system implementation.

## INTRODUCTION

The 2011 Report to the U.S. Surgeon General is an update of a previously submitted Report in 2009 to then Acting Surgeon General, RADM Steven Galson. The 2011 Report provides health leadership with evidence-based discussion about improving patient and health system outcomes through an additional paradigm of health care delivery for expanded implementation in the United States. The 2011 revision, herein referred to as the “Report,” provides a compelling discussion to support health reform through pharmacists that manage disease through medication use and deliver patient care services, in collaboration with other providers, as an accepted and additional model of health care delivery. Timing of this discussion is vital as health reform has stimulated exploration of innovative care and payment reform models that improve access to care, provide quality care, contain costs, and afford safe use of medications and other pertinent medication-related issues.

The Report discusses current and future demands on the health care system, including the challenge of aligning health care coverage with access to care, the increasing burden of chronic care needs, and primary care provider shortages. Current health care demands provide an opportunity to recognize successful and existing models of health care delivery. Within federal health care, utilizing pharmacists on the primary care team to prevent and manage disease, and provide patient care services has been one of the most evidence-based, proven, and time-tested strategies to mitigate similar demands. Federal pharmacy practice, over the past 40 years, has included expanded scopes within comprehensive disease management, health promotion, disease prevention, and other cognitive clinical services such as medication management.

Expanding the role of pharmacists is supported by evidence-based outcomes and existing innovative models. The benefits translate into improved consumer outcomes that support many tenets of health reform - enhanced access and quality of care, cost-effectiveness and patient safety. The Report is framed around four focus points that clearly articulate and present objective data that support the need for innovative practice models that include pharmacists as essential health care providers.

Based on current practice models, perceptions of pharmacists’ roles, specifically as a health professional exclusively associated with drug product and delivery, should now include many additional patient care, primary care, and public health services. It is essential to note that pharmacists currently provide multiple levels of direct and indirect patient care services in a variety of practice settings. Management of disease through medication use - inclusive of Collaborative Drug Therapy Management (CDTM), Comprehensive Medication Management (CMM) or Medication Therapy Management (MTM), health promotion, patient safety, disease prevention, care coordination, follow-up care and other primary patient care services - are performed by pharmacists in a similar manner as other health care providers. The rationale for this practice model is the fact that once a diagnosis is made, patient care services rely on pharmacologic interventions as the major form of therapy. Data clearly suggest that

medications are currently the cornerstone of chronic disease therapy, yet our health care system continues to fragment care and ‘reward’ reactive health care delivery models.

**Pharmacists’ formal education appropriately prepares them to successfully perform clinical services related to the prevention and control of disease through medications. Pharmacists are also well-positioned (through accessibility, expertise and experience) to play a much larger primary care role in the U.S. health care system to meet these demands and improve health care delivery (and the health) of the nation.**

Pharmacists’ current scope of practice positions them to provide these services through Collaborative Practice Agreements (CPAs) with physicians or within any coordinated patient care models - such as the Patient-Centered Medical Home (PCMH).

Pharmacists have functioned for decades to deliver expanded patient care services in many federal settings. More recently, non-federal pharmacists and health systems have also embraced expanded patient care roles through CDTM, medication management and other public health initiatives such as immunizations, emergency/disaster care, point-of-care testing, smoking cessation programs, etc. In 2002, the Medicare Payment Advisory Commission (MedPAC) stated that there was mounting evidence that clinical pharmacist involvement in managing drug treatment may reduce costs and improve the quality of care. The MedPAC voted unanimously that the Secretary of the Department of Health and Human Services should assess models for Collaborative Drug Therapy Management (CDTM) services in outpatient settings.<sup>11</sup> Progress has been made; however, eleven years later, the profession continues to perform requested clinical duties without appropriate service-sustaining recognition or compensation.

**While longevity of the physician-pharmacist collaborative practice model serves as an indicator of success, further support from key stakeholders is needed.** For system-wide improvement, mitigation of the barriers begins with the basic acknowledgement and support of these existing and successful models at the highest levels of health leadership. **A prime example of support to improve health care delivery would be recognition and definition of “Pharmacists; Pharmacist-Delivered Patient Care Services” in the Social Security Act under Title 18, Part E, Section 1861.** To continue to advance these value-added services, pharmacists must be recognized for their ability to provide these services. This includes statute through legislation, policy established by the administration, and commensurate compensation mechanisms similar to other billable practitioners that provide comparable services.

The role of federal and the U.S. Public Health Service (PHS) pharmacy is, and always has been, unique. There is a common acceptance and support structure within the federal system that recognizes pharmacists as essential members of the health care team that can provide specific patient care services, in addition to expertly managing disease through optimal medication use.

**Leveraging this unique and effective interprofessional practice environment, it is a PHS Pharmacy responsibility to recommend paradigms of care that will maximize use of our**

**profession to improve the health of the nation.** These models are not new in the federal sector, yet our non-federal colleagues and now even some federal partners, are challenged to sustain these pharmacist-delivered patient care services due to restrictive policy, legislation and compensation mechanisms. These persistent barriers arise during a time of heightened demand for access to care, cost-effective prevention and quality care. Coincidentally, it is also a time in which our health system needs innovation.

Pharmacists within the PHS, the Department of Veterans Affairs (VA), and the Department of Defense (DOD) have been and continue to be innovative in establishing successful models of pharmacist-delivered patient care. With support from physicians and other stakeholders, they continue to demonstrate positive outcomes. These models can be expanded to meet some of the demands on the current and future U.S. health care system. This Report will provide detailed discussion of advanced pharmacy practice through four focus points that offer objective findings to garner wider advocacy and acceptance for further implementation. As stated by the Patient-Centered Primary Care Collaborative, “Only with appropriate and optimal medication use will we see real quality of care improve and health care costs decrease...”<sup>3</sup>

## **APPENDICES**

- Appendix A: National Clinical Pharmacy Specialist (NCPS) Program - In 1997, the Indian Health Service (IHS) established a national credentialing system for IHS, Tribal, and Urban (I/T/U) pharmacists in an effort to assure advanced pharmacy practitioners in the IHS display a uniform level of competency.
- Appendix B: Outcomes Repository Spreadsheet - Evidence-based outcomes that support collaborative primary care. Both federal and non-federal sectors have numerous articles, systematic reviews and meta-analyses of positive patient outcomes that have been published in peer-reviewed journals. Format: Citation, Outcomes, Results/Conclusions.
- Appendix C: U.S. Collaborative Practice Map - Forty-four (44) of fifty (50) states<sup>12</sup> address or mention some form of collaborative practice and/or protocols between physicians and pharmacists.
- Appendix D: Physician Survey - Substantial PHS interprofessional and physician support currently exists for pharmacists practicing in advanced clinical and primary care roles.

## OBJECTIVES

- Obtain advocacy from the U.S. Surgeon General to acknowledge pharmacists that manage disease through medication use and deliver patient care services, as an accepted and successful model of health care delivery in the United States, based on evidence-based outcomes, performance-based data and the benefits to patients and other health system consumers (physicians, administrators, payers, etc.).
- Obtain advocacy from the U.S. Surgeon General to recognize pharmacists, who manage disease and deliver many patient care services, as health care providers. One such action is advocate to amend the Social Security Act to include pharmacists among health care professionals classified as “health care providers.”
- Obtain advocacy from the U.S. Surgeon General to have pharmacists recognized by CMS as Non-Physician Practitioners in CMS documents, policies, and compensation tables commensurate with other providers, based on the level of care provided.
- Advance beyond *discussion* (and numerous demonstration projects) of the expanded roles of pharmacist-delivered patient care and move toward health system implementation.

## DISCUSSION

### Focus Point 1: Pharmacists Integrated as Health Care Providers

Once a diagnosis is made, many pharmacists manage disease and deliver patient care services (inclusive of preventive and supportive care) as health care providers in the United States. Definitions of primary care characterize and affirm these integrated direct and indirect patient care roles. Successful delivery of these services demonstrates existing interprofessional collaboration and support.

#### *Definitions of Primary Care*

Current pharmacy practice is considerably more diverse than what has been previously reported in terms of scope of practice and practice setting. Traditional roles of the pharmacist tied solely to medication product and delivery have been greatly expanded. Pharmacists evaluate and counsel patients, provide health maintenance information, administer immunizations (as one of many public health functions), reduce drug misadventures through clinical interventions, respond to disaster needs, assume regulatory roles in drug delivery to assure safety, assess patients who access the health system through community pharmacies, and perform point-of-care testing. In more advanced practice settings, pharmacists are involved with provision of more expanded direct patient care through comprehensive disease management, CDTM, medication management, health promotion/disease prevention, care coordination and follow-up patient care. Many of these services are similar in scope and complexity to other primary care services delivered in our health care system.

Following diagnosis, maximizing the expertise of the pharmacist is both logical and critical considering that the majority of patient care - and demand on the health care system - involves the treatment or maintenance of the diagnosed condition through use of medications. Medications are involved in 80 percent of all treatments and impact every aspect of a patient's life.<sup>3</sup> An inordinate amount of time and resources are spent within the health system delivering disease management and monitoring of disease through selected therapy. Even through collaborative practice, pharmacists with a formal education that focus on therapeutics and management of disease through medication use are widely underutilized. **Once a diagnosis is made**, it is undeniable that physicians, physician assistants, nurse practitioners *and* pharmacists assume direct patient care roles. Definitions of primary care help clarify and confirm the provision of similar patient care services by pharmacists.

**The American Academy of Family Physicians (AAFP)** defines primary care as "health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment of acute and chronic illnesses in a variety of health care settings."<sup>13</sup> The definition also states the provision of primary care is often given by a physician in collaboration with other health care professionals in an atmosphere where consultation and referrals are utilized. Primary care also promotes patient involvement and cost-efficiency. The primary care provider is often the patient's first point of contact when seeking medical care, and is the

service that then takes responsibility for each patient's comprehensive continuing health care. Structurally, primary care "teams" often include physicians and non-physician health care professionals. AAFP lists nurse practitioners, physician assistants, and "some other health care providers," under the umbrella of non-physician primary care providers or Non-Physician Practitioners (NPPs), but it does not specifically include pharmacists. Yet pharmacists are continually requested and utilized in provision of patient care services and patient-centered health care homes. AAFP does state that these non-physician providers work in collaborative teams with the primary care physician toward the ultimate goal of optimal patient health.<sup>13</sup>

Pharmacists in advanced practice models with physician-driven privileges have been successful in many of these roles as defined by the AAFP.

**The Institute of Medicine (IOM)** defines primary care as "integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs," but it does not specifically state what type of clinicians provide this care. It goes on to discuss that services include developing a sustained partnership with patients, and practicing in the context of family and community.<sup>14</sup> More concisely, primary care can be described as consisting of four basic attributes: access, longitudinality, comprehensiveness of care, and care coordination.<sup>15</sup> It further explains primary care has been shown to provide benefits such as greater access, better quality of care, greater focus on prevention, early management of health issues, and reduction of unnecessary specialist care, which can be a strategy to achieve cost-effectiveness.

Pharmacists collaborate as part of this primary care team to achieve the aforementioned benefits and coordinate with primary care providers to minimize unnecessary care and utilize each team member to their utmost ability.<sup>15</sup> Pharmacists in many settings provide additional access to direct patient care, care coordination, comprehensive care through disease management (where medications are the primary method of treatment), and improved quality of care.

**The Care Continuum Alliance** - formerly the Disease Management Association of America (DMAA) - defines primary care through disease management as "a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant."<sup>16</sup> Disease management also includes prevention of exacerbations and complications, with the ultimate goal of improving the overall health of the patient. Components of disease management include identifying eligible patients, following evidence-based guidelines, utilizing collaborative practice models, encouraging patient self-management of chronic conditions, assessing, evaluating, and managing outcomes, and promoting continual feedback with stakeholders. Stakeholders include the patient, physician, health plan, and other care providers. The Care Continuum Alliance definitively recommends the following to prevent the complications of multiple uncoordinated providers: "all the diseases a patient has are managed by a single disease management program." For the purpose of this Report, the PHS Pharmacy program implies a definition of disease management that is



consistent with primary care models and clinical management of disease (inclusive of medication use and management) with less focus on individual case management services.

**According to all cited definitions from the AAFP, IOM, and the Care Continuum Alliance, and similar to other health care providers, many of these patient care services are delivered by pharmacists.** Pharmacists have been collaboratively managing disease and providing patient care in this manner. However, pharmacists are the only health professionals providing this level of care who are not recognized in national health policy as health care providers.

The federal sector has supported physician-pharmacist collaboration and demonstrated that these direct patient care services delivered by pharmacists can improve patient outcomes as well as promote patient involvement and cost-efficiency. For over forty years, pharmacists have practiced primary care through disease management and other cognitive and clinical services.<sup>1</sup> In the federal sector, this is not a new model of health delivery. These models are accepted in the non-federal sector; however uptake and growth are slowed due to inherent policy, legislation and compensation barriers discussed later in the Report.

### ***Pharmacist Roles***

In some settings, through CPAs, the pharmacist serves as the clinical chronic disease manager (inclusive of customary privileges of similar health care providers) and can refer back to the physician at scheduled intervals for review. This can take place whether the pharmacist is part of a primary care team or as an individual provider of care in collaboration with the physician. Pharmacist-delivered patient care is based upon an effective, sustained relationship between patients, physicians, and other health care practitioners. This integrated team approach also inherently allows for pharmacists to function within the patient-centered medical home (PCMH) or any other patient-centered health care home model.

*Currently*, pharmacists deliver patient care services in a variety of practice settings through CPAs to manage disease whereby they:

- Perform patient assessment (subjective and objective data including physical assessment);
- Have prescriptive authority (initiate, adjust, or discontinue treatment) to manage disease through medication use and deliver collaborative drug therapy or medication management;
- Order, interpret, and monitor laboratory tests;
- Formulate clinical assessments and develop therapeutic plans;
- Provide care coordination and other health services for wellness and prevention of disease;
- Develop partnerships with patients for ongoing (follow-up) care.

Delivery of comprehensive care requires collaboration and communication of all health care providers. This emphasizes the importance of patient education, follow-up, and individual patient ownership. Although appropriately initiated by a physician as the diagnostician, referral to a collaborating pharmacist to deliver patient care services for provision of ongoing or chronic

care, prevention of exacerbation, and improvement of clinical outcomes is accepted practice in many clinical settings. In this collaborative practice, communication is ongoing between the physician (or another primary care provider) and the pharmacist - functioning as a health care provider that can manage disease through medication use.

**The federal infrastructure has provided pharmacy practice a progressive environment, producing some of the oldest documented examples of successful interprofessional practice through expanded roles in direct patient care, disease management, and public health.**

Pharmacists in the IHS, VA, and the DOD have long been recognized as leaders in innovative pharmacy practice. Their enduring history of physician-supported collaborative pharmacy practice models clearly validates and confirms these models' provision of positive patient-focused quality care. Pioneers like Dr. Allen Brands (Chief Pharmacist for IHS from 1955-1981 and Chief Professional Officer of the U.S. Public Health Service from 1967-1981) recognized the need for expanded pharmacy services as early as the 1960s. During that time frame, the pharmacist's role began to shift from a distributive function of medications to a more clinical role. From the 1960s forward, the IHS led a national effort toward improving patient-pharmacist interaction and education.<sup>17</sup> By 1974, over 90 percent of the IHS sites had one or more pharmacist-run disease management programs in place.<sup>18</sup>

This IHS patient-centered and collaborative approach facilitated the evolution and development of the IHS Pharmacy Standards of Practice, which were developed in the mid-80s, formalized and published in 1989, and continue to this day.<sup>1,19</sup> The IHS Standards of Practice were in use before Hepler and Strand's 1990 article on Pharmaceutical Care that popularized many of these clinical concepts.<sup>20</sup> These six Standards of Practice include:

1. Assure Appropriateness of Drug Therapy
2. Verification of Understanding
3. Assure Availability, Preparation and Control of Medications
4. Provide Drug Information and Staff Education
5. Provide Health Promotion and Disease Prevention
6. Manage Therapy/Care for Selected Patients in Whom Drugs are the Principal Method of Treatment (inclusive of disease management)

The first five standards of practice - basic IHS pharmacy services - already includes non-compensated clinical and cognitive services; for example, completion of all treatment plan elements of current visit (dose, interactions, adverse events, lab values, etc.), current status of health maintenance and wellness parameters, and appropriateness of follow-up for current health problems. Utilizing the full medical record (or electronic health record), pharmacists integrate care coordination and provide comprehensive services. These services optimize therapeutic outcomes and fit well within the core concepts of Medication Therapy Management (MTM) under Medicare Part D discussed later. The sixth standard of practice was developed to encompass expanded patient care services delivered by pharmacists - and truly represents an advanced practice commensurate with many services from other non-physician practitioners.

The evolution of pharmacists' clinical roles in federal pharmacy programs was made possible by certain practice setting variables including full access to medical records, interprofessional support and in most cases, the principle focus on health outcomes. Historically, there was less focus on revenue generation capacity of the practicing pharmacist in these roles. The focus was (and is) improved health care delivery and outcomes. However, because of the demand for services, acceptance of pharmacists in prescriptive roles by physicians, willingness of the entire system to work collaboratively with pharmacists in these innovative roles, and positive patient outcomes, programs were continued. It is not surprising that expanded clinical practice roles occurred first in federal agencies like the IHS, VA, and the DOD due to these and other variables that supported innovation. In fact, in the 1970's, the IHS had already developed and implemented what the IOM proposed in its consensus report from 2009 regarding national directives to deliver interdisciplinary health care.<sup>14</sup> Additional examples of clinical pharmacy practice in the VA date back to 1995 and can be discussed in similar contexts.<sup>21</sup> Through the 1980s and 1990s, IHS pharmacists continued to provide American Indians and Alaska Natives, primarily located in rural and underserved communities, with advanced pharmacy practices that improved patient care and increased access to vital primary care services, disease management, and prevention services. Implementing a similar paradigm of health care delivery utilizing pharmacists may lessen the impending challenges of health reform - such as access to care, particularly with medically underserved and vulnerable populations.

### ***Interprofessional Collaboration and Support***

**Substantial interprofessional support (from physicians, other NPPs, and administrators) exists for pharmacists practicing as providers in expanded clinical roles.** George Halvorson, chairman and **CEO of Kaiser Foundation Health Plan, Inc.** and author of *Health Care Reform Now!: A Prescription for Change*, gave the keynote address at the 2009 Healthcare Information and Management Systems Society (HIMSS) Annual Conference and Exhibition. While speaking on the subject of much needed health reform, Halvorson declared that **"clinical pharmacists are the most underutilized members of the health care team."**<sup>22</sup> Expanded pharmacist-delivered patient care can be an essential component of any collaborative care model. The various services are easily integrated into CPAs that further define pharmacists' clinical privileges and patient care services. These services can be delivered via the PCMH model, disease management, CDTM, or any other type of patient care service.

Health reform calls for an integrated workforce that utilizes the skill sets of health care professionals across disciplines.<sup>22,23</sup> **Turf issues are age-old barriers to interprofessional practice that do not support any type of successful health reform. However, in many practice settings, the 'turf' issue is more a myth that needs to be dispelled than an actual barrier.** Collaborative practice currently exists internal and external to the federal pharmacy sector. In addition to the federal practice setting, **CPAs between physicians and pharmacists are directly authorized by 44 state pharmacy boards.**<sup>12</sup>

Appendix C displays a map of states that legislatively support collaborative practice between pharmacists and physicians. It is important to note, however, that because nuances exist between the terms "CDTM" and "CPA", interpretations can vary. CDTM tends to define the process by which a pharmacist may adjust therapy and manage medication use. CDTM and CPA agreements are specific to medication use and management. However, CPAs may allow additional flexibility for both the physician and pharmacist to provide more comprehensive primary care and patient services, such as care coordination, disease management, disease prevention, and follow-up care. This added flexibility helps physicians to better meet the diverse and wide-ranging needs of individual patients and practice settings.

As discussed, 44 states allow for some form of collaborative practice, which means that the individual state pharmacy laws allow pharmacists to "initiate, modify, and/or discontinue drug therapy pursuant to a collaborative practice agreement or protocol".<sup>12</sup> While this definition is very close to the pharmacy associations' consensual term "CDTM",<sup>24</sup> some states specifically address CDTM in their state practice acts and others do not. As a matter of fact, a few states address collaborative privileges to pharmacists under their medical acts. Another example of such inconsistency is when one state allows collaborative practice, but it is "limited" by restricting drug therapy management to a setting (e.g., hospitals only) or a drug class (e.g., oral contraceptives only in Maine). In May 2011, the governors of New York signed legislation to expand CDTM to teaching hospitals, moving the Empire state from a "Pending" status with the National Association of Boards of Pharmacy to "Yes" with regards to CDTM. This legislation increased the number of collaborative practice states to 44 in 2011 even though CDTM was already approved at non-teaching hospitals in New York.<sup>12</sup> These statistics, however, don't truly represent the extent of CDTM since the remaining six states do not address collaborative practice but documentation in pharmacy journals shows that it exists. This ambiguity has pros and cons. Without specific regulations or guidance, state pharmacy boards can have more flexibility to regulate CDTM, prohibit the practice completely, or allow collaboration de facto if no one objects.

In 2008, a pioneering effort was undertaken by the National Clinical Pharmacy Specialist (NCPS) Program within the U.S. Public Health Service to illuminate physician-pharmacist collaboration through a respondent-driven survey and help dispel some of the myths of non-support. The NCPS Program, which now extends beyond the IHS and into the Bureau of Prisons (BOP), has been successful with physicians, medical staffs, and other stakeholder collaborations for 13 years. The program ensures consistency and quality of primary care for patients treated and managed by NCPS pharmacists. Within most literature reviews, the customary approach is to have pharmacists attest to the support they have received from physician. However, attestation and data collected from physician-only perspectives is much less common. To overcome this data gap, the NCPS Program developed a respondent-driven survey to seek the input of IHS physicians on the clinical and administrative impact of pharmacists delivering primary care services including disease management. **Physician-respondent support of this paradigm of health care delivery was decisive:**

- Demographics
  - 117 Physicians representing 13 states and 33 IHS and Tribal facilities responded.
  - 100% of the data collected came from physicians in facilities that have pharmacists practicing under collaborative practice agreements (CPAs).
  - 87.2% of the providers surveyed have worked or are currently working with a pharmacist who was recognized as a NCPS. As discussed, the NCPS Program helps to assure a standardized scope that includes specific prescriptive authority, laboratory authority and some physical assessment privileges.
- Results
  - **96% of physicians who responded reported some benefits, including improved disease management outcomes, increased return on investment, allowing the physician to shift their workload to more critical patients, increased patient access to care and more.**
  - 76.8% of physicians surveyed “agreed” or “strongly agreed” that from their experiences, the services provided by pharmacists provide adequate evidence to recognize them as billable non-physician practitioners.
  - 85.2% of physicians surveyed “agreed” or “strongly agreed” that NCPS certified pharmacists have adequate knowledge/training to provide clinical services.
  - 71.6% of physicians felt that clinical services such as disease management provided by pharmacists are necessary to optimize patient care.
  - 88% of physicians felt this collaborative practice with pharmacists in their facilities has improved overall primary patient care.

A more comprehensive summary of findings can be found in Appendix D. Given these results, **it is the perspective of physician respondents within this survey that the positive outcomes of pharmacists delivering primary care services - with appropriate privileges from the physician or medical staff - are undeniable.** Federal and PHS Pharmacy have been aware of this support for many years. Collecting data from physicians directly involved in this model of health care delivery should help dispel some of the misperceptions of collaboration and demonstrate the substantial amount of positive patient and health system outcomes.

Collaboration between the pharmacist and physician also provides the patient with higher quality, safer, and more comprehensive health care via the team approach. Pharmacists are uniquely qualified to provide additional patient care services through these collaborative and synergistic efforts that compliment physician services. Advanced practice pharmacy models benefit many consumers, including other primary care providers, patients, and administrators. The models also provide benefit to third-party payers in the form of preventive care, quality care, patient safety and cost-containment. Other countries are also working toward integrating the pharmacist into the primary care setting. In Canada, the IMPACT study has placed pharmacists at primary care sites in Ontario, Canada with promising results.<sup>25</sup> In the United Kingdom, “Pharmacy in England: building on strengths – delivering the future,” proposes a model that involves the pharmacist in the community setting, as well as schools, care homes, prisons, health centers, and general practice settings.<sup>26</sup> In the United States, specifically in federal pharmacy, this integration has been in place for decades.

In 1997, conclusions reached by the MedPAC stated that “in general, physicians support the concept of collaborative drug management,”<sup>11</sup> suggesting that ongoing involvement would need to be clearly defined. During this discussion, the American College of Clinical Pharmacy (ACCP) offered that in these relationships, the physician would diagnose the patient and decide upon initial treatment. The physician would then authorize the pharmacist to select, monitor, modify and discontinue medications as necessary.<sup>11</sup> In the federal pharmacy sector, both concepts were already applied in practice. As seen over the last decade, support was evident in the non-federal sector, yet less than optimal. More recently, however, an editorial in the AJHP noted that a number of medical society groups have concluded having pharmacists working directly with them is critical. Examples cited included The Society of Critical Care Medicine, the Infectious Diseases Society of America, and the National Association of Epilepsy Centers.<sup>27</sup>

From an academic perspective, the American Association of Colleges of Pharmacy (AACCP) annually convenes an Argus Commission comprised of the five immediate past AACCP presidents. The 2009-2010 Commission examined the pharmacist’s contribution to primary health care delivery in the context of national health care reform. The Commission’s President subsequently invited representatives from education associations of various disciplines recognized as primary health care providers. This included providers and representatives from:

- American Dental Education Association
- Association of American Medical Colleges
- Physician Assistant Education Association
- Emory University School of Medicine
- American Association of Colleges of Nursing
- School of Medicine and Health Sciences, The George Washington University
- Association of Schools of Public Health
- Association of American Colleges of Osteopathic Medicine

Two distinct findings resulted: 1) All participants agreed that medication use factors were important elements of quality primary care, including patient education, monitoring, and safety considerations, and 2) All of the disciplines represented embraced interprofessional education (IPE) and practice, and specifically recognized the importance of IPE in addressing deficiencies in the chronic care patient management model.<sup>28</sup>

More recently, an editorial was released from the Chair of the American Medical Association Board of Trustees, Dr. Ardis Dee Hoven. The editorial discussed ‘Doctor-pharmacist teamwork’ that can apply to many settings. It recognized that collaborative drug therapy management can be a positive and powerful way to enhance patient care and reduce costs. It also noted that successful collaborations already exist.<sup>29</sup> This was a positive step in the right direction with our largest and most renowned medical society. This discussion continues and has involved the pharmacy profession’s largest organization, the American Pharmacists Association (APhA).

## Focus Point 2: Recognition as Health Care Providers

Pharmacists that deliver patient care services, including management of disease through medication use, should be recognized as health care providers and practitioners as defined in the Social Security Act and other health legislation and policy.

### *Advanced Pharmacy Practice Models*

In some states, pharmacists are recognized for their expanded services, in policy and privileging, through CPAs, or other collaborative practice arrangements - and in rare cases, through licensure as clinicians. **Although separate licensure for pharmacists in these roles is not necessarily needed, current recognition by some states reflects a precedent that primary care services (post-diagnosis) are successfully delivered within the current scope of pharmacy practice through CPAs.** With this level of state recognition, pharmacist-delivered patient care has the potential to be sustained through commensurate compensation and support. For example, some progressive state Medicaid programs (New Mexico, Arizona, South Dakota, and Minnesota) have recognized the benefits of these pharmacist services and already compensate pharmacists for health care services more commensurate with other non-physician practitioners via fee-for-service or more frequently as a flat-rate fee. Even in practice environments without fiscal barriers, this type of recognition and scope, reflective of pharmacist-delivered direct patient care, allows for advanced practice models to flourish and obtain greater support from colleagues and administrators.

Discussion of the IHS pharmacy practice model offers an appropriate example. In response to years (1970-1995) of IHS medical staff support of advanced pharmacy practice, **former IHS Director Michael Trujillo, MD, MS, MPH released a Special General Memorandum (SGM 96-2) in 1996. This groundbreaking document recognized Clinical Pharmacy Specialists (CPSs) as primary care providers with prescribing authority.**<sup>30</sup> In 1997, representatives from the IHS pharmacy program and leaders from the Health Care Financing Administration (HCFA), renamed Centers for Medicare & Medicaid Services (CMS) in 2001, discussed the recognition of pharmacists as primary care providers.<sup>31</sup> There was little disagreement about the expanded scopes and levels of service provided. However, a recommendation was made by CMS to develop a uniform and national credentialing program that would assure consistency and quality of care for patients treated or managed by pharmacists in the IHS. The IHS promptly responded to the recommendation made by CMS with the development of the NCPS in 1997.<sup>31</sup>

Through CPAs, many IHS pharmacists deliver direct patient care through disease management including, but not limited to, anticoagulation, dyslipidemia, congestive heart failure, coronary artery disease, diabetes, asthma, hypertension, end-stage renal disease, pain management, and tobacco cessation.<sup>31</sup> They are uniquely qualified as experts in drug therapy and currently function with expanded scopes in many settings where they perform physical assessment, have prescriptive and laboratory authority, formulate clinical assessments, develop therapeutic plans, provide patient education, care coordination, and follow-up care, manage both acute and chronic disease, and provide many other cognitive clinical services.

These patient care services are delivered by pharmacists once an initial diagnosis is made, which is similar to those services provided by other primary care providers and non-physician practitioners. Over the last 13 years, 278 IHS pharmacists have been certified by the NCPS Program. Currently, there are 179 actively practicing NPCPS pharmacists that are increasing access to care and improving quality of care in over 41 sites and 16 states. To become privileged at a particular site within the IHS, a local medical staff and physician must observe and attest that the pharmacist is a competent health care provider. This assures oversight and is a physician-driven and local privileging mechanism. A CPA is developed between the medical staff and the NCPS pharmacist. The CPA identifies the scope of medical conditions the NCPS pharmacist is privileged to manage once the diagnosis is made. Pharmacists, as demonstrated later in this Report, have been able to improve consumer outcomes including clinical, administrative (i.e., increase physician time for more critical care and increased patient access to care), and cost-effectiveness. **Thus, pharmacists in these clinics perform direct patient care services and document the findings similar to any other health care provider, but with recognition and revenue generation capacity only in a limited number of states.**

Administrative barriers increase the potential that patients will not be able to access primary care services. For example, access to health care delivery for a medically underserved population may be directly impacted. In some practice settings, pharmacist-delivered care may be the only care available - aside from waiting lists for appointments with overburdened primary care staff.

The Health Resources and Services Administration (HRSA) also strongly supports the role of the pharmacist and the provision of pharmacy services to patients with multiple chronic conditions through an interprofessional team. In 2008, the Senate Appropriations Committee Report “encourages HRSA to establish a pharmacy collaborative to identify and implement best practices, which may improve patient care by establishing the pharmacist as an integral part of a patient-centered, interprofessional health care team.”<sup>32</sup> HRSA began its work by studying the leading practices in patient safety, clinical pharmacy services and health outcomes identified in organizations found to be “early adapters” across the nation.<sup>33</sup> In addition to many of the high performing sites in the safety net setting, HRSA also utilized and compiled the decades of experience and leading practices established by the IHS advanced pharmacy practice models. These IHS models can assist health systems, clinics, and communities learn, replicate, test, and adopt these practices to improve health outcomes and reduce adverse drug events. In October 2007, HRSA planned and implemented the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC), where teams of health care providers, including HRSA supported entities and their partners from communities across the nation, are working to transform the delivery of patient care. Using a patient-centered approach, the teams integrated evidence-based clinical pharmacy services into the care and management of high-risk, high-cost, complex patients. Currently, the most successful teams involve clinicians from multiple disciplines, together with their organizations’ leaders, understanding, growing, and tracking the impacts of clinical pharmacy services. This integrated interprofessional approach is revising traditional health care team roles and both maximizes and leverages the expertise of the entire team so the patient receives the best quality care. Based on data collected from PSPC teams, 54 percent of patients once identified as “out of control” or not optimally medically managed, are now



“under control” across a range of chronic conditions using standardized measures. Also, adverse drug events (ADEs) or actual events that cause patient harm have fallen by an average of 49 percent for this high-risk patient population. In its third year, the PSPC has expanded to 127 community-based teams in 43 states.<sup>33</sup> Teams continue the rapid spread of leading practices found to improve patient safety and health outcomes most effectively in a health home model. Year three will work to expand and spread to larger patient populations that need this transformation delivery system.

Outside the federal sector, there are some progressive models that have developed, as noted in New Mexico and North Carolina. In both states, pharmacists practicing in advanced clinical scopes are recognized more broadly through policy, legislation, and even licensure. Additionally, both states have identified an advanced scope of practice through CPAs and compensate similarly for a primary care visit. New Mexico’s Pharmacist Clinician (PhC) program has developed an appropriate compensation mechanism through its state Medicaid process. This will be discussed in more detail within Focus Point 3.

In North Carolina, the Clinical Pharmacist Practitioner Act became effective July 1, 2000 and opened the door for collaborative practice opportunities. This successful implementation of legislation acknowledged the importance of pharmacists and collaborative practice. The state of North Carolina has offered credentials to pharmacists who wish to become a Clinical Pharmacist Practitioner (CPP). In this model, if the pharmacist meets certain qualifications, he or she is approved by the Medical and Pharmacy Boards of North Carolina as a CPP, and is assigned a provider identification number.<sup>34</sup> Required credentials, in addition to a North Carolina pharmacist license and agreement with supervising physician, include one of the following: 1) certification (either from the Board of Pharmacy Specialties, or is a Certified Geriatric Pharmacist) or an American Society of Health-System Pharmacists (ASHP) Residency including two years of clinical experience, or 2) a Doctor of Pharmacy (PharmD) degree with three years of experience, plus completion of one North Carolina Center for Pharmaceutical Care (NCCPC) or Accreditation Council for Pharmacy Education (ACPE)-approved Certificate Programs, or 3) a Bachelor of Science (BS) degree with five years of experience, plus completion of two certificate programs from NCCPC or ACPE.<sup>34,35</sup> North Carolina’s example of certification qualifications offers needed flexibility within the profession. This is important because many different paths arrive at the same place - clinical competence. This flexibility is also seen in the New Mexico PhC program. Once credentialed, a North Carolina CPP is able to order, change, or substitute therapies, and order laboratory tests, while under the purview of a CPA with a licensed physician.<sup>36</sup> CPAs are kept “broad and generalized” to allow choice of therapy based on individual patients, and also include a plan for a weekly “quality control” meeting between the CPP and supervising physician. In these meetings, the physician reviews the pharmacist’s orders.<sup>35</sup>

## ***Pharmacy Education and Training***

Because pharmacy practice has already shifted to allow more clinical services, the nation's colleges and schools of pharmacy have followed suit with appropriate education and training to support these roles. The entry-level degree, which has been elevated from a BS in Pharmacy to a Doctor of Pharmacy, requires additional years of training. This has increased over the years from four years of training to five, and now to a minimum of six years. The core curriculum includes pathophysiology, pharmacology, therapeutics, clinical problem solving, laboratory monitoring, and physical assessment skills for many diseases. Student pharmacists are required to complete hospital rounds with medical students and physicians. The latest curricular guidelines from the Accreditation Council for Pharmacy Education (ACPE) also mandate early pharmacy practice experience training/shadowing in a physician's office and clinical hospital setting in order to expose student pharmacists to a collaborative practice environment and give them insight into the responsibilities and decision-making skills that physicians perform daily.<sup>37</sup> Most universities that have both medical and pharmacy colleges have built interprofessional practice into the curriculum and teach both professions' students together to provide patient care. Pharmacists' years of education and level of training is aligned with that of dentists and surpasses, in many examples, the amount of education and training required of other non-physician practitioners.

All pharmacy school graduates are required to take the North American Pharmacist Licensure Examination (NAPLEX), a national, comprehensive, and standardized board exam. Having a standardized licensing exam ensures that all pharmacy graduates are held to high and uniform expectations.

Post-graduate training is encouraged throughout the profession, including first and second year residencies, fellowships, Master, and Doctoral-level training. Residencies are one to two years in length and are accredited by the American Society of Health-System Pharmacists (ASHP). Pharmacy residency programs, both in hospitals and in the community, serve to focus a new pharmacist's skills for specialization in the management of a specific or multiple disease states. Residency training is hands-on, multi-disciplinary, and clinically comprehensive. The VA has a robust residency program with approximately 159 sites. The IHS offers 18 progressive practice residency sites and is currently graduating approximately twenty-two resident pharmacists a year. The Bureau of Prisons currently has one residency site.

Clinical specialty certifications are widely available for pharmacists. Pharmacists may become board certified by the Board of Pharmacy Specialties (BPS) as a pharmacotherapy specialist (BCPS), nuclear pharmacist (BCNP), nutrition support pharmacist (BCNSP), oncology pharmacist (BCOP), psychiatric pharmacist (BCPP), or ambulatory care pharmacist (BCACP). BPS regulates applicant eligibility and content of the examination.<sup>38</sup> Although BPS designations are granted to individuals who pass the examination, this board certification is not required of pharmacists. These designations are not analogous to the board specialty examinations that physicians are required to pass for specialty licensure.

Another specialty certification available to pharmacists is the Certified Geriatric Pharmacist (CGP), established by the American Society of Consultant Pharmacists.<sup>31</sup> Additional certifications that pharmacists may pursue include Certified Diabetes Educator (CDE), Board Certified Advanced Diabetes Management (BC-ADM), Infection Control Professional (ICP), a Certified Professional in Healthcare Quality (CPHQ), a Certified Professional in Healthcare Information and Management Systems (CPHIMS) and a Chronic Care Professional (CCP).<sup>39</sup>

This Report, while supportive of the BPS and other credentials, recognizes that certain types of credentials beyond the NAPLEX should not limit the professional scope of pharmacy. The Report also communicates (as discussed under the New Mexico and North Carolina models) that with the exception of the NAPLEX, flexibility of advanced practice pharmacist qualifications is necessary to ensure competence. The BPS and other credentialing programs require satisfactory completion of a thorough exam; they do not require direct observation of competence by medical personnel. Direct observation of competence however, can be required within a collaborative practice agreement (CPA) in order to gain local medical privileges. **Each practice environment should consider what combination of credentials, training, and experience is most appropriate, yet remain flexible to allow for all qualified and competent pharmacists the opportunity to improve outcomes.** Current training and education after six years of focused study on therapeutics and related topics, the subsequent NAPLEX exam, and competency-based experience have proven to be both adequate and successful, and are supported through decades of collaborative physician-pharmacist practice.

Pharmacists undergo a very similar level of education compared to other non-physician practitioners. In all pharmacy school curricula, a pharmacist will need a minimum of six years to complete the didactic education portion, not including a residency. Physician Assistants' (PA) educational programs consist of either a five-year combination bachelor's/master's degree, or a full-time two-year professional program after the completion of a bachelor's degree with appropriate prerequisites.<sup>40</sup> Nurse Practitioners (NP) must first become a registered nurse (through a bachelor's, associate's, or diploma program), which can be accomplished in under four years, and then complete a master's program to obtain practitioner certification, including a two-year course of full-time study.<sup>41</sup> Both PAs and NPs are trained to perform physical examination, diagnose medical conditions, and in most states, prescribe medications to treat their patients. Both of these professional types also focus on patient education and disease prevention.<sup>40,41</sup> In both cases, these highly skilled, recognized, and appropriately compensated health care providers have the same amount and similar type of education as pharmacists.

Compared to PAs and NPs, the educational preparation of pharmacists emphasizes patient assessment and therapeutic monitoring, which establishes pharmacists' expertise in the comprehensive management of disease through medication use. The emphasis on drug therapy in the pharmacy curriculum is inextricably linked to providing quality care subsequent to a diagnosis. Pharmacy school curricula also include diagnostic and physical assessment coursework as well. As discussed in Focus Point 1, once a diagnosis is made, especially in the case of chronic disease, most of patient care (up to 80 percent) is geared to management of disease through drug therapy. Considering these patient care needs, the pharmacist is uniquely

qualified to compliment the diagnosticians, such as physicians, to provide comprehensive care. Other NPPs similarly take on roles that provide value related to their expertise. It is also a good example of how health reform implementation can maximize the skill sets of health care professionals across disciplines.<sup>23</sup> The amount of education or training a pharmacist completes should not be challenged in this discussion. Rather, the most pressing challenge is to facilitate consumer understanding of the proven advantage of having pharmacists involved in the delivery of health care - including provision of quality primary care to meet health system demand. Those consumers include legislators, administrators, health leadership, insurers, and other third party payers.

The federal sector is not the only system that supports pharmacists in advanced practices. Although New Mexico and North Carolina were mentioned as having specific programs with advanced practices, forty-four (44) states (as of May 2011) across the United States support collaborative drug therapy management (CDTM) in their Board of Pharmacy policy or by-laws.<sup>12,42</sup> This is encouraging as it demonstrates that pharmacists are supported by their state boards and that performing these expanded clinical duties (respective of each state policy) is within their legal scope of practice. These collaborative practices range from immunizations, to medication therapy management, to disease management with privileges including prescriptive and laboratory authority.

As another example, “health care providers” are generally seen as having prescriptive authority. Much like pharmacists in the IHS and VA, a growing number of states (such as New Mexico, North Carolina, and Massachusetts) already allow for prescriptive authority to pharmacists through collaborative practice. In February 2011, the Drug Enforcement Administration (DEA) granted prescriber numbers to pharmacists in Massachusetts (1 of 7 states).<sup>43</sup> This important recognition of pharmacists as mid-level practitioners allows pharmacists working under CDTM agreements to prescribe controlled substances.

The existing roles of pharmacists and their current delivery of patient care in multiple settings based on health system demands necessitates further evolution of legislation and policy.

**Recognition of pharmacists’ provision of additional levels of patient care through legislation and policy will promote the support needed (increased private sector response and adequate compensation mechanisms) to fully sustain these value-added services that are proven to improve patient outcomes and health care delivery.**

In the Affordable Care Act (ACA), there are several references to pharmacists as “part of a health team” (Section 3502), and “pharmacist-delivered and pharmacist-provided services” (Section 3503). In addition, Section 3503 authorizes Medication Management Services in Treatment of Chronic Disease to be provided by licensed pharmacists as a collaborative, multidisciplinary, interprofessional approach.<sup>23</sup> **Recognizing “Pharmacists (Pharmacist-Delivered Patient Care Services)” in the Social Security Act as health care providers is the appropriate evolution of legislation that will expand the utility and eligibility of pharmacists to better address the nation’s health care demands, and improve patient and health system outcomes.**

### **Focus Point 3: Compensation Mechanisms**

Current compensation mechanisms for pharmacists in advanced practice roles need to expand and reflect the level of patient care services provided. The lack of compensation mechanisms is a current barrier for optimal health system outcomes, and the expansion and sustainability of pharmacist involvement.

#### ***Essential for Sustainability***

Snella, et al. suggests that compensation, rather than reimbursement, is the proper term to apply to the payment of pharmacists who are recognized as health care providers. Compensation refers to “payment for a service that reflects both reimbursement for the cost of an item or service and the value added by the provider.”<sup>44</sup> Pharmacists functioning as health care providers perform cognitive patient care services that add value to the patient’s care. The current reimbursement model indicates that pharmacists should only be paid for a drug product or device, with little or no payment for the cognitive and value-added portion of the service.

At the 2008 World Health Care Congress, health stakeholders recognized that aligning reimbursement with the quality of care is expected to drastically improve the health care system as a whole.<sup>45</sup> This suggests a performance-based compensation. Focus Point 4 illustrates hundreds of evidence-based outcomes within many different advanced pharmacy practice models. These models demonstrate that after rigorous collection and analysis of data within the appropriate practice environment, including expanded pharmacist privileges, outcomes improve. Pharmacists who demonstrate positive patient and health system outcomes, and perform a level of care with similar impact to Nurse Practitioners, Physician Assistants, or Physicians need to be equally compensated. Improved parity in compensation for pharmacists providing similar levels of care through disease management or other patient care services is imperative if these valuable and sought-after resources are to continue.

In both the public and private sectors, health systems are challenged to sustain any clinical service without the ability to generate revenue from the service provided. Although pharmacists do play a larger patient care role in many federal settings, sustainability is threatened by the lack of commensurate compensation.

As an example, federal funding for the IHS falls below the mainstream health plan annually. Because of this continual resource disparity gap, fiscal appropriation for the IHS now necessitates revenue generation from Medicaid, Medicare, and other third party payers. Consequently, many progressive practice settings are fast approaching a crossroads and must decide whether to continue value added services that have been provided without compensation and potential revenue generation, or discontinue them, further escalating problems with access, quality, and cost-effectiveness. The IHS continues to demonstrate successful advanced pharmacy practice models in many states. However, states where pharmacists can generate additional revenue through Medicaid programs greatly assist in

sustaining these services. These states either recognize pharmacists as health care providers for clinical services to Medicaid recipients (New Mexico and North Carolina) or provide additional compensation for cognitive pharmacist services (Arizona, Minnesota, South Dakota). **However, the level and consistency of compensation vary greatly. These variations may be significant enough to create a disparity of health care services offered to certain state populations with a need for a health care home or with other health inequities.**

HRSA funded a study to collect clinical pharmacy services outcomes data from one of its networks of HRSA-supported health centers. The study was conducted by an impartial, objective, non-pharmacy, research corporation: Mathematica Policy Research, Inc. Mathematica noted that, “The current financing environment creates a major challenge to sustainability of these services.”<sup>46</sup> Clinical pharmacy services could feasibly assist both patients (through clinical outcomes) and providers (by reducing time constraints). However, Mathematica suggested that reconsideration of payment policies are needed to recognize these pharmacy services as a legitimate approach to care.<sup>46</sup> These conclusions suggest that clinical pharmacy could play a more substantial role in the delivery of care if supported by appropriate compensation mechanisms.

In March 2011, the Patient-Centered Primary Care Collaborative (PCPCC) released *Better to Best: Value-Driving Elements of the Patient Centered Medical Home and Accountable Care Organizations*. This consensus report presents four themes or “value-driving elements” that either require urgent overhaul (enhanced access, care coordination) or are essential tools (health information technology, payment reform) to optimize value in health care.<sup>47</sup> Regarding payment reform, the report reviews the leading proposed models:

- Fee-for-service + management fee + performance model
- Episode of care (case rate model)
- Risk-adjusted comprehensive payment and bonus
- Accountable care organization

Pharmacists with physician-approved patient care privileges, performing in expanded clinical roles of disease management, and other patient care functions could seamlessly be a value-added piece to any of these models. **One advantage of the decades of evidence-based performance is that our work is currently built around demonstrating positive outcomes that subsequently decrease overall health care costs.** The pharmacy profession has frequently been called upon to “prove” its capacity in demonstrating outcomes. This Report collates some (but not all) of the success. Thus, pharmacists could be compensated appropriately within any one of these models based on the level of service provided.

The most significant and influential payer for these services is the CMS. Many additional third party payers follow the CMS compensation structures and guidance. Pharmacists are not currently recognized by CMS as health care providers, potentially impeding some private and federal sector patients from receiving optimal quality patient care services. As a point of comparison, the Social Security Act appropriately recognizes a number of other health care

professionals as “providers or practitioners,” including physician assistants, nurse practitioners, certified nurse midwives, clinical social workers, clinical psychologists, and registered dietitians or nutrition professionals. Recognition of pharmacists as health care providers in the Social Security Act under Title 18, Part E, Section 1861 is a critical addition of language needed to sustain these services to meet the growing demands of access to care as well as serving vulnerable and rural populations. CMS payment policies and definitions can then parallel pharmacists’ current and critical role to improve health care delivery.

### ***Legislation History***

In May 2001, Senator Tim Johnson (D-SD) introduced the Medicare Pharmacist Services Coverage Act of 2001 into the Senate. The bill proposed changes to the Social Security Act to provide for coverage of pharmacist services under Part B of the Medicare program. Senator Johnson expressed that the Act will “reform Medicare by recognizing qualified pharmacists as health care providers within the Medicare program and make available to beneficiaries important drug therapy management services that these valuable health professionals can and do provide. These services, which are coordinated in direct collaboration with physicians and other health care professionals as authorized by State law, help patients make the best possible use of their medications.”<sup>48</sup> This legislative motion demonstrated recognition, at the lawmaking level, of the value of pharmacists as health care providers. The bill was referred to the Committee on Finance, only to be cleared from the books at the end of the session.<sup>49</sup>

In August 2001, the Medicare Pharmacist Services Coverage Act of 2001 was introduced into the House of Representatives. After being referred to the Subcommittee on Health, it remained there until cleared from the books at the end of the session.<sup>50</sup>

In 2004, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2004 was introduced to propose changes to the Social Security Act to provide for coverage of clinical pharmacist practitioner services under Part B of the Medicare Program. This was the first time that legislation appropriately addressed a change to the Social Security Act that would add the definition of Clinical Pharmacist Practitioner to the list of non-physician practitioners already being reimbursed for their services through Medicare. A month later, the bill was referred to the House Subcommittee on Health, and no further action was taken.<sup>51</sup>

In 2008, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2008 was introduced to propose changes to the Social Security Act to provide for coverage of clinical pharmacist practitioner services under Part B of the Medicare Program.<sup>52</sup> The bill was referred to the House Subcommittee on Health, and no further action was taken. Again, this bill demonstrated that expanding compensation through Medicare Part B for the cognitive pharmacy services these clinicians provide is the next logical step.

In 2010, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2010 was introduced to propose changes to the Social Security Act to provide for coverage of clinical pharmacist practitioner services under Part B of the Medicare Program. This bill was assigned to

the Subcommittee on Health on May 27, 2010, but no further action was taken.<sup>53</sup> It was cleared from the books with the convening of the 111<sup>th</sup> Congress in December 2010.

As of July 2011, there have been three pharmacy-related bills that have been introduced into the 112th Congress, 1st Session.

- H.R. 891 – The Medication Management Therapy Benefits Act of 2011 proposes to amend Part D of title XVIII of the Social Security Act to promote medication therapy management under the Medicare part D prescription drug program.<sup>54</sup>
- S. 48 – The Pharmacist Student Loan Repayment Eligibility Act of 2011 proposes to amend the Public Health Service Act to provide for the participation of pharmacists in National Health Services Corps programs, and for other purposes.<sup>55</sup>
- S.274 – The Medication Therapy Management Empowerment Act of 2011 proposes to amend title XVIII of the Social Security Act to expand access to medication therapy management services under the Medicare prescription drug program.<sup>56</sup>

Multiple attempts to change national legislation through bills have been proposed in the last 10 years. It appears state-specific bills may contain nomenclature that is limited in such a way that documentation, support, or explanations are insufficient to justify the change. **Attempts have been made to consult the most experienced, evidence-based and innovative federal pharmacy systems (that have advanced the profession for the last half-century); however process barriers have prevented further discussion. This Report collates many of these data points for the first time and can be utilized by health leadership to advance this discussion.**

On a state level, New Mexico Medicaid pioneered a pharmacist-directed compensation mechanism that has experienced success for a number of years. In the mid-1990s, pharmacists worked with the State of New Mexico Board of Pharmacy and Medical Examiners to develop an advanced practice license designated as a Pharmacist Clinician (PhC).<sup>57</sup> New Mexico legislation has recognized Ph.Cs, along with Physician's Assistants and Nurse Practitioners, as mid-level providers with prescriptive authority. As a licensed New Mexico provider, the Pharmacist Clinician can apply to become a Medicaid provider, and is therefore eligible for Medicaid reimbursement.<sup>58</sup> This program offers an appropriate level of compensation for eligible pharmacists providing an advanced level of care. This state recognition demonstrates that pharmacists can be recognized successfully with regards to receiving an appropriate level of compensation, and with experience and local privileging (including some level of physician supervision). Although the delineation of scope is through separate licensure in the state of New Mexico, it is not necessarily needed as new models of credentialing and privileging are considered. With additional competency training and assessment by physician supervisors, a pharmacist can be privileged through a CPA and still remains within the current scope of state licensure.



Another example of a state-level attempt took place in Minnesota. In 2001, Minnesota Medicaid policy recognized “Physician Extenders” as primary care providers, making anyone falling into their classification system eligible for reimbursement. The clause listed examples of Physician Extenders and did not specifically name pharmacists. Details of the definition were questioned. State officials, although supportive of the perspective, were unable to determine whether this list was all-inclusive or merely listing examples of “Physician Extenders” based on the level of care provided was sufficient. If the latter, pharmacists providing and documenting a similar level of care could be considered physician extenders. A final determination was not made at that time. Since then, Minnesota has been innovative in their advancement of payment mechanisms for pharmacists providing clinical patient care.

One key point to consider with these programs and any others that may develop from the concepts of this Report is that not all pharmacists will be eligible for this level of compensation. **Pharmacist’s eligibility for higher levels of compensation commensurate with other primary care providers should be based upon the level of service provided.**

### ***Medication Therapy Management (MTM) under Medicare Part D***

Currently, pharmacists are eligible to receive some compensation for Medication Therapy Management (MTM) through Medicare Part D. CMS designed these programs (MTMP) to ensure optimal therapeutic outcomes for targeted beneficiaries through improved medication use and reduce the risk of adverse events.<sup>59</sup> MTM programs are administered by Prescription Drug Plans (PDPs) and are required to be developed in cooperation with licensed and practicing pharmacists and physicians. However, numerous policy constraints limit patient participation in these programs even with the 2010 CMS enhancements.

- Medicare Part D restricts patient eligibility: Currently, only senior age, disabled, and low-income patients are eligible for prescription benefits and MTM services via Part D. However, disease management and all other patient care services occur at any age within our U.S. health system as both a preventive measure for progression or exacerbation of chronic disease, and as a treatment measure.
- Patients must be a Medicare Part D participant: For those patients meeting the Medicare Part D eligibility criteria, monthly premiums payable directly by participants are required. In the current IHS system for example, where 100% of health care expenses for eligible patients are covered, the patient-perceived benefit of paying monthly premiums possibly reduces participation in MTM services.
- Eligibility for MTM services varies among the PDPs: Patients who suffer from co-morbid chronic diseases like diabetes, hypertension, dyslipidemia, must take multiple Medicare Part D-covered prescription medications, and must incur at least \$3,000 in Medicare Part D drug expenses annually in order to qualify for MTM services.<sup>59</sup> CMS allows the PDP to define certain eligibility parameters: number of medications a patient must be taking, number of chronic conditions the patient must have, and specific diseases covered. The PDP also defines whether all drugs are covered, only disease-specific drugs are included, or only specific drug classes are included. Because of specific targeting

criteria, patients who may need MTM services but do not meet the plan's criteria will not be able to participate. MTM compensates pharmacists for a subset of cognitive services they can provide in only some of our sickest patients.

- Enrollment has been historically low: In 2006, approximately 10% of Medicare Part D-enrolled participants met the criteria for MTM services. More recent program years show a slight increase to 12%.<sup>60</sup>
- MTM under Part D does not incentivize the health system to focus on prevention: The growing incidence of various complex disease states such as cardiovascular diseases, heart failure and hypertension are affecting patients at earlier stages of their lives.<sup>61</sup> These younger patients require pharmacists to spend significant amounts of time and resources managing their health care needs, but without a compensatory mechanism for the pharmacist's cognitive services. This delay of care seems to go against current medical practice and withholds value-added, preventive, cost-effective, and patient-centered services until the customer has progressed to a more critical state of health.
- Part D Sponsors can determine which discipline of provider to deliver their MTM services: Although pharmacists are specifically named by CMS for MTM delivery, and currently provide 99.9% of services, other qualified providers such as nurses, physicians, and other Non-Physician Practitioners represent health care alternatives for utilization in MTM programs.<sup>59</sup>

This Report recognizes ongoing and expanded Medicare Part D reimbursement for MTM services is critical for the advancement of the pharmacy profession in multiple settings. Many MTM advocates are aware that expansion of eligible beneficiaries, as well as potential increases in levels of compensation, will need to take place in order to make MTM more applicable in a wider variety of pharmacy practice settings. **This Report supports expanded MTM programs and other pragmatic solutions to the barriers of eligibility requirements.**

From PHS's ongoing pharmacy experiences, MTM Part D is utilized when patients fit the restrictive criteria and pharmacists have the time to complete additional paperwork needed to obtain limited reimbursement. The medication therapy management model improves outcomes; however, eligibility restrictions neither foster cost-effective or efficient care nor promote comprehensive health, disease management, nor prevention of progression of disease or primary prevention. Although rates and frequency of compensation for MTM services are well defined in most Medicare Part D plans, they may not be adequate to support or sustain provision of these services. Also, MTM service opportunities are offered only periodically and appear primarily targeted toward expanded patient medication profile reviews and/or physician intervention, including identification of drug-related problems, generic conversion potential, and medication adherence. While patient medication reviews clearly reduce and avoid medication-related adverse effects, it is only one component in the potential array of patient care provided by pharmacists. Furthermore, the rate of compensation offered by most Part D sponsors does not equate to the degree and complexity of care delivered in pharmacist-delivered patient care visits. As described above, the breadth of knowledge and skill required by any physician, NPP, or pharmacist to deliver primary care is not reflected with current MTM Part D compensatory rates. While periodic, limited cognitive compensation is openly offered

through MTM, there remains apprehension within the PHS Pharmacy program to contract with PDPs offering MTM Programs due to questionable cost-effectiveness and resources to implement on a national basis. In the private sector, MTM has improved the utilization of clinical pharmacists; however growth is slow, in part because of patient restrictions and inadequate compensation.

Restrictions, eligibility constraints, and fiscal considerations limit the feasibility of MTM Part D becoming a central (or substantial) source of compensation or revenue for services for any health professional. Upon literature review, no studies of other NPPs (eligible for MTM compensation) have been found to utilize MTM as their primary source (or even an adequate source) of compensation. Yet, at this time, it is basically the sole mechanism for compensating pharmacists for cognitive and/or primary care services.

Even the largest of industry giants can identify a potential barrier in the utility of MTM. Walgreen's Chief Executive, Greg Wesson, wished to have his "army of coaches" take on a greater role for President Barack Obama as the White House and Congress came together to expand health insurance coverage to the nation's uninsured. Wesson says his "company's efforts go beyond just filling prescriptions" as part of a solution he calls medication therapy management, where "helping patients stick to taking their medications and making better and more cost-effective choices...could help save billions of dollars in medical care costs." But Wesson also says that "to make MTM work, pharmacies would need to be paid more, and the payments would need to include the time to provide patient consultations, plus wellness advice and other tips."<sup>62</sup>

As noted, pharmacists practice in many different settings. The provision and core concepts of MTM, under Medicare Part D, are not intended to parallel the comprehensiveness of a primary care practice or visit to a health care provider. In a 2011 published study by Kucukarslan et al., evidence suggests MTM services are capable of providing measurable improvements in two areas: patients who are newly diagnosed with a chronic condition and patients who have not yet achieved their therapeutic goal.<sup>63</sup> However, pharmacy practice settings best suited for MTM services with regard to the Medicare Part D model often lack access to a full patient health record, adequate staffing and guidance, and the prescriptive or laboratory privileges usually needed for comprehensive pharmacist-delivered patient care. MTM services in all practice settings need to continue in order to improve health system and patient outcomes; however, changes in eligibility, compensation mechanisms, and barriers to implementation need ongoing advancement and support.

## **Focus Point 4: Evidence-Based Alignment with Health Reform**

Through the delivery of patient care services, pharmacists improve outcomes, increase access to services for medically underserved and vulnerable populations, improve patient safety, shift time for physicians to focus on diagnosis and more critically ill patients, improve patient and provider satisfaction, enhance cost-effectiveness, and demonstrably improve the overall quality of health care through evidence-based practice.

### ***Quality of Care and Patient Outcomes***

Pharmacists involved in the delivery of patient care services with appropriate privileges across many practice settings have been successful at improving patient outcomes. The implementation of more expanded pharmacy practice models demonstrates improved performance measures through evidence-based outcomes. Hundreds of peer-reviewed publications and sustained interprofessional support indicate that this successful practice is both evidence-based and accepted as an additional model of health care delivery with improved access to patient care services. As presented below through large database reviews, pharmacist-delivered patient care services clearly have a positive impact on disease outcomes (prevention and management), quality care, access to care, cost-containment, patient safety, and overall health system efficiency.

- Diabetes: Machado et al. reviewed and identified 302 articles, including 108 pharmacists' interventions encompassing 2,247 patients in 16 studies. They found a significant reduction in hemoglobin A1C levels in diabetic patients in the pharmacist intervention group.<sup>64</sup>
- Hypertension: Machado et al. performed a literature-based meta-analysis that involved 203 articles, 2,246 patients in 13 studies. They found pharmacists' interventions significantly reduced systolic blood pressure.<sup>65</sup>
- Dyslipidemia: Machado et al. found 48 studies, of which 23 met inclusion criteria, that demonstrated a significant reduction in both total and LDL cholesterol in the pharmacist intervention group.<sup>66</sup>
- Congestive heart failure: Two systematic reviews of the literature concluded that pharmacists can improve patient care and reduce the rate of hospitalization, particularly in heart failure patients.<sup>67,68</sup>
- Cost-containment and health system efficiency: A Cochrane database review of 25 studies involving more than 40 pharmacists and 16,000 patients found expanded pharmacist services led to a decrease in the number of non-scheduled health services, as well as a decrease in specialty visits and the number and cost of drugs.<sup>69</sup>
- Quality care and patient safety: University of Arizona researchers conducted a comprehensive systematic review with focused meta-analysis to explore the effects of pharmacist-provided direct care on therapeutics, safety, and humanistic outcomes. A total of 298 studies were included and the researchers found favorable therapeutic and safety outcomes. Additionally, they conducted a meta-analysis study of specific quality care

indicators (HgA1c, LDL, blood pressure, etc.) and the results were significantly in favor of pharmacist-delivered care over comparative services.<sup>4</sup>

Because the quantity, depth, and variety of these clinical studies are far too numerous to detail in this Report, a partial summary of published outcomes has been provided in Appendix B. Nearly 60 studies have been cited from various peer-reviewed publications. In some cases, as denoted above, a published study may be a meta-analysis of many additional studies yielding a substantial amount of documented outcomes. These published outcomes are collected from various practice settings to include community, hospital, and federal facilities, and demonstrate improved outcomes (patient, administrative, economic, etc.) among pharmacist-managed clinics and programs.<sup>25,70-104</sup>

Although discussion in this Report focuses on improving health care delivery through utilization of the pharmacist, a pivotal piece to successful implementation also hinges on continued efforts to leverage health information technology (HIT). HIT has long been recognized as a key means for supporting improvements in health care quality, safety, and efficiency. With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, many health care collaborations were formed to support and advance HIT to the fullest extent. According to the Patient-Centered Primary Care Collaborative (PCPCC), health IT “can provide critical information about the patient to the entire care coordination team across all stages of care, support physician-patient communication, enable more timely and accurate performance measurement and improvement, and improve accessibility of the physician practice to the patient.”<sup>105</sup>

The pharmacy profession has traditionally been an early adopter of HIT and recognizes the benefits of HIT to optimizing patient care and outcomes-based measurement. In 2010, nine national pharmacist associations formed the Pharmacy e-Health Information Technology Collaborative (e-HIT Collaborative) to focus on and ensure the technology needs of the pharmacy profession advance with the federally-incentivized progression of HIT infrastructure in the United States. The goal of this collaborative was to define a common vision for HIT to improve patient care quality and outcomes through the integration of pharmacists’ patient care services into the national electronic health records (EHR) infrastructure. The focus of the e-HIT Collaborative is to “assure the meaningful use (MU) of standardized EHR to support safe, efficient, and effective medication use, continuity of care, and provide access to the patient-care services of pharmacists with other members of the interdisciplinary patient care team. The e-HIT Collaborative assures the pharmacist’s role of providing patient-care services is integrated into the National health IT interoperable framework.”<sup>106</sup> The e-HIT Collaborative is pursuing EHR standards that support the delivery, documentation, quality measures, and billing for pharmacist-provided patient care services across all care settings. Thus, the pharmacy profession has already realized the clinical utility of electronic health data and has positioned itself well ahead of the curve for standardized outcomes-related data collection and enhanced electronic data accessibility for delivering quality patient care services.

## ***Disease Prevention and Management***

Disease prevention, or progression of chronic disease, directly alleviates the disproportionate amount of chronic care needs and demands on the health system. Approximately 125 million Americans (45 percent of the U.S. population) had one or more chronic conditions in 2000 and 61 million (21 percent of the U.S. population) had multiple chronic conditions. It is estimated the population of people with chronic conditions will increase steadily, and that by 2020, 164 million people (almost 50 percent of the U.S. population) will have a chronic condition and 81 million (24 percent) of them will have two or more conditions.<sup>107,108</sup> Inpatient admissions for ambulatory care sensitive conditions and hospitalizations with preventable complications increased with the number of chronic conditions. As an example, Medicare beneficiaries with four or more chronic conditions were 99 times more likely than a beneficiary without any chronic conditions to have an admission for an ambulatory care sensitive condition (95% confidence interval, 86-113). Per capita Medicare expenditures increased with the number of types of chronic conditions from \$211 among beneficiaries without a chronic condition to \$13,973 among beneficiaries with four or more types of chronic conditions.<sup>109</sup> The number of people with chronic conditions is projected to increase steadily for the next 30 years. While current health care financing and delivery systems are designed primarily to treat acute conditions, 78 percent of health spending in the United States is devoted to people with chronic conditions.<sup>110</sup>

Chronic diseases are the leading causes of death and disability in the United States. Chronic diseases currently affect 45 percent of the population (133 million Americans), account for 81 percent of all hospital admissions, 91 percent of all prescriptions filled, 76 percent of physician visits, and continues to grow at dramatic rates.<sup>111</sup> These numbers are daunting. Quality medical care for people with chronic conditions requires a new orientation toward prevention of multiple chronic disease conditions, and provision of ongoing care and care management to maintain their health status and functioning.

It has been stated that specific focus should be applied to people with multiple chronic conditions.<sup>107,108</sup> However, a single chronic condition (for example, hypertension) causes many other potential co-morbidities and negative health outcomes. Any chronic condition, even without co-morbidities would benefit from prevention of disease progression. This must be realized in discussion and applied to legislation involving health care delivery paradigms in order to provide the highest quality and most cost-effective care (both short and long term). This perspective must also be evident in legislation to minimize any restrictions placed on eligibility for these types of services whether they are delivered by pharmacists or not. As a reminder, in some MTM Part D cases, the pharmacist is not eligible to practice MTM unless the patient has more than one chronic disease. The health system would not restrict primary care delivered by a physician or other care provider simply because a patient has only one chronic disease. Why would it do so in the case of pharmacist-delivered services? Why would it do so in a system that is attempting to prevent further progression of disease or development of new co-morbid conditions? Pharmacists are uniquely qualified to work within this scope, with

extensive formal education on therapy and management of chronic disease (single or multiple) through the safe use of pharmacologic interventions.

The Diabetes Ten City Challenge (DTCC) was a multi-site community pharmacy health management program for patients with diabetes. It was an employer-funded, collaborative health management program using community-based pharmacist coaching, evidenced-based diabetes care guidelines, and self-management strategies. DTCC successfully implemented the program and demonstrated positive clinical and economic outcomes for 573 patients who participated in the program for at least one year, compared with baseline data. However, in addition to the clinical and economic benefits, many preventive measures showed substantial improvement demonstrating the value of pharmacists in preventive care. Between the initial visit and the end of the evaluation period, influenza vaccination rate more than doubled from 32 percent to 65 percent, eye examination rate increased from 57 percent to 81 percent, and foot examination rate increased from 34 percent to 74 percent.<sup>70</sup>

The Asheville Project is yet another widely-known example of successful pharmacist-delivered patient care in the non-federal sector. It began in 1995 as a result of a strategic planning committee held by state pharmacy leaders. The idea was to sponsor a pharmaceutical care demonstration project in the state of North Carolina. The Asheville project utilized advanced practice pharmacists, in coordination with the Diabetes Education Center and physicians to provide Disease State Management (DSM) services to people with diabetes.<sup>112</sup> The outcomes were extremely positive in terms of both fiscal and clinical outcomes. The Asheville Project demonstrated that patients, providers, and managers believed aligned incentives and community-based resources (i.e., pharmacists) providing health care services to patients offer a practical, patient-empowering, and cost-effective solution to escalating health care costs.<sup>113</sup>

More recently, a collaborative project in Connecticut (Connecticut Medicaid Program; the Connecticut Pharmacists Association; and the University of Connecticut School of Pharmacy) tested a pharmacist practice model in patients with chronic conditions and complex medication regimens. Although small sample limitation and generalizability were addressed, the study demonstrated that pharmacists are crucial for optimizing patient outcomes with regards to disease management. There were 369 face-to-face encounters, and pharmacists identified 917 drug therapy problems. Pharmacists resolved 78 percent of these problems without the patient having to be referred back to their primary care provider. Additionally, 82 percent of prescribers made changes in their patients' therapies based on the pharmacists' recommendations.<sup>114</sup>

With a projected shortage of general primary care practitioners and a growing mass of eligible consumers, the Report strongly encourages health leadership to consider pharmacists as providers that can assist to reduce the burden of chronic disease on the health care system, especially in cases where further progression of disease or development of co-morbid conditions can be prevented.

## ***Cost-Effectiveness and Cost-Containment***

In addition to pharmacists' ability to improve clinical outcomes for patients through disease management or other advanced clinical roles, pharmacists have contained or reduced health care costs, whether associated with reduced adverse clinical events (hospitalizations, emergency room visits, etc.),<sup>115,116</sup> reduced outpatient visits, cost savings to a health care institution or health insurance plan,<sup>93,95,112,116-123</sup> direct cost savings to the patient,<sup>124,125</sup> or less missed/non-productive workdays.<sup>112,115</sup> Bond and Raehl have shown on a macro-level that advanced patient care services delivered by pharmacists reduce drug-related morbidity and mortality, and lower the overall cost of care.<sup>126</sup>

Utilizing pharmacists as drug therapy experts will maximize resources, contain or reduce costs and improve care. Significant reductions in drug misadventures could be potentiated by allowing pharmacists greater clinical intervention and comprehensive medication management authorities. By selecting and monitoring therapeutic and patient care regimens through focused disease management, pharmacists can improve the overall quality of the health care system.

Pharmacists have been shown to produce annual health care savings of:

- \$3.5 billion in hospital costs by coordinating medications from multiple providers.<sup>127</sup>
- More than \$1,600 in direct health care costs per patient at a pharmacist-run anticoagulation clinic, compared with usual medical costs.<sup>93</sup>
- \$1,200 to \$1,872 per patient in direct health care costs for patients with diabetes enrolled in the Asheville Project for up to five years.<sup>112</sup>
- \$918 per patient in direct health care costs for patients with diabetes enrolled in the Patient Self-Management Program for Diabetes for one year.<sup>113</sup>
- \$1,230 per patient in indirect costs for those with asthma and direct cost savings of \$725 average per patient.<sup>115</sup>
- \$1,123 per patient on medication claims and \$472 per patient on medical, hospital, and emergency department expenses at five primary care sites in Connecticut.<sup>114</sup> (The pharmacists in this study provided comprehensive evaluation of multiple medical conditions.)

The Asheville Project, in which more than 50 percent of patients in the study improved clinically, also demonstrated notable administrative and fiscal benefits:

- Patient and physician satisfaction increased and health care costs were reduced.
- Direct medical costs decreased by \$1,200 per patient per year and an estimated annual increase in productivity of \$18,000 due to reduction of sick time were reported.<sup>115</sup> Even after paying the pharmacists to provide these services, net costs were lower.<sup>112</sup>



Schumock et al.<sup>123,128</sup> and Perez et al.<sup>129</sup> conducted multiple ACCP-funded studies across two decades that evaluated the economic value of clinical pharmacy services. Collective research supported significant economic savings in a broad range of clinical categories among multiple care settings (See Table 1: Benefit to Cost Ratio). The categories included disease management, general pharmacotherapeutic monitoring, pharmacokinetic monitoring, targeted drug programs, patient education program, and cognitive service. The table below represents economic value of clinical pharmacy services in the form of benefit to cost ratio (financial benefit/dollar invested to provide the service) for the periods shown. The benefit to cost ratio was calculated by dividing the reported gross economic benefits derived from the service, by reported total costs to provide the clinical pharmacy service described for the same time period.

**Table 1: Benefit to Cost Ratio**

<b>Benefit to Cost Ratio</b>	<b>1988-1995</b>	<b>1996-2000</b>	<b>2001-2005</b>
Lowest	\$1.08 : \$1	\$1.70 : \$1	\$1.02 : \$1
Highest	\$75.84 : \$1	\$17.01 : \$1	\$34.61 : \$1
Median	\$4.09 : \$1	\$4.68 : \$1	\$4.81 : \$1
Mean	\$16.70 : \$1	\$5.54 : \$1	\$7.98 : \$1

Even at the ratios' lowest level, clinical pharmacy services benefit is still higher than the cost. The average benefit gained in each of the time periods shown was between 5.5 and 16.7 times greater than cost. **Consequently, for each dollar invested in the clinical pharmacy service over the period from 1988 to 2005 (nearly two decades), the overall average benefit gained was \$10.07 per \$1 of allocated funds.**

One final way to measure the cost-efficiencies of pharmacist-delivered patient care is to consider the calculated return on investment (ROI). This ROI reflects the value of the service based on the cost of delivering the service. The data collected from medication management services demonstrated an ROI of as high as 12:1 and an average of 3:1 to 5:1. This value is based on the ability of medication management services to reduce hospital admissions, reduce the use of unnecessary or inappropriate medications, and reduce emergency room admissions and overall physician visits.<sup>130 131</sup>

Thus, effective patient care services related to medication management can lower total health care costs. Although initial medication costs may rise due to improved medication adherence, it has been shown that hospital and emergency room visits are reduced.<sup>3</sup> Given the significance of this calculation and the challenging economic environment, the ROI of medication management services can be seen as a legitimate cost-containment and cost-effective strategy for health plans, employers and other third party payers.

## **Primary Care Workforce**

In recent years, many reports have identified an imminent shortage of primary care physicians.<sup>132-135</sup> As health reform presses forward, trends in health care workforce capacity may become the critical issue. Solutions are minimal, yet current data shows the number of graduating physicians entering primary care is decreasing, due in part to high patient loads and declining revenue when compared to specialists, among other reasons.<sup>135-137</sup> The “backbone of the American medical system” is threatened by this severe shortage of primary care physicians, which could lead to fragmented health care.<sup>135</sup>

Providing affordable and accessible insurance to all Americans does not solve the problem of access *to services* of those insured. Those gaining insurance benefits as a result of health reform are part of the medically disenfranchised population in the United States. According to “Access Denied,” most people living in these disenfranchised areas have health insurance.<sup>134</sup> It has been said that “having insurance coverage without a source of care is like having currency without a marketplace.”<sup>132</sup> A recent and comprehensive report from the Association of American Medical Colleges (AAMC) Center for Workforce Studies enumerated roughly 26 reference documents and articles that all speak to current and future physician shortages. Some of the studies projected a physician shortage anywhere from 85,000 to 200,000 by 2020,<sup>138</sup> and a 38 percent increase in demand for general internists is projected by the year 2020.<sup>136</sup> These are not predictions. These projections indicate if current physician utilization and work patterns continue, a physician shortage is imminent – if it is not already here. The report also hypothesized non-static models that demonstrate:

- Growth in future demand could double if visit rates by age continue to increase at the same pace they have in recent years;
- Universal health care coverage could add 4% to demand for physicians; this would increase the projected physician shortfall by 25% to nearly 155,000 physicians; and
- If the relationship between economic growth and physician demand holds true – a demand for physicians will occur that is likely beyond what supply could meet. If younger physicians continue working fewer hours than their predecessors, which seems probable, then any and all shortages will be amplified.

Even a modest increase in physician productivity could alleviate some of the projected gap, but productivity improvements in health care have been hard to achieve as care has become more complex. An increase in health care coverage would introduce millions of patients into an already stressed system, further increasing the number of medically disenfranchised. At least 12 states have already reported current or projected physician shortages (AZ, CA, FL, GA, KY, MA, MI, MS, NC, TX, OR, and WI).<sup>133</sup> The current supply of physicians would simply be unable to provide primary care to the increased population of insured individuals.

This Report supports maximizing the utility of the current health care workforce. There is an identifiable and projected need whereby pharmacists, through advanced pharmacy practice models, can contribute.<sup>139</sup> Current health systems utilize other non-physician providers.

Physicians work alongside PAs, NPs, and other health professionals who increase the productivity of physicians both by assisting with patient care and providing patient care (i.e., providing comprehensive assessment for a primary care visit) under the direction of a physician. The AAMC report cites “of particular importance are clinicians who can provide some of the services usually provided by physicians.”<sup>140</sup> These Non-Physician Practitioners listed include PAs, NPs and “others.” To parallel current pharmacy practice, this Report clearly articulates that pharmacists can function as health care providers and provide direct patient care services. Increasing the capacity of pharmacists to provide these services (through recommendations in this Report) will provide one existing solution to address some of the growing shortages and demand for primary care services.

The AAMC report also considers two scenarios to assist with the demand for primary care services in which NPs and PAs: 1) increase their growth beyond baseline or 2) provide more primary care services. While these two scenarios project future demand under what may be attractive policy goals, current infrastructure might be insufficient to produce the virtual doubling of PA and NP supply that these hypothetical scenarios would require. The report suggests that PA and NP numbers will not be sufficient to eliminate the physician shortage likely to come. Nonetheless, it appears evident that an increased role in the provision of care is just one part of the solution to the projected shortage. The AAMC report proposes to reduce physician demand based on an increased role for PAs and NPs in primary care. However, PAs are increasingly moving into non-primary care specialties. Thus, trends in PA and NP specialty choice may also require as close a watch as those for physicians.<sup>133</sup> Adding pharmacists into the models of this particular report will substantially boost access and distribution of providers that provide primary care services. Much like current roles in the Indian Health Service, PAs, NPs and pharmacists play a larger role in rural and medically underserved areas as well as offering services to those without a medical home. The health system will better utilize pharmacists across the United States if they are given similar patient care roles that leverage their expertise in focused or comprehensive disease management. This provides more opportunity to improve patient and health system outcomes.

There are other benefits of involving a pharmacist in primary care settings. In the UK, a database has estimated there are about 57 million primary care physician consultations per year. About 51.4 million out of those are for minor ailments alone, which also could be handled by a pharmacist.<sup>141</sup> A similar model has been in place in the IHS from the early 1970s with the initial Pharmacy Practitioner Program. Much of this model dissipated as a result of growth in the dispensary role of the pharmacist as well as the lack of appropriate compensation. The detrimental combination of the number of patients that need primary/chronic care, high use of medications, provider shortages, and shortened appointments, does not provide adequate time to focus on comprehensive disease management or other important health issues. These factors create a strained practice environment with the potential for multiple liability issues and sub-optimal outcomes.

Pharmacists have demonstrated their competence as health care providers in the delivery of patient care services. Additionally, it has also been said the presence of pharmacists embedded within the community allows pharmacists to play the role of “gatekeeper” to the health care system.<sup>142</sup> This supports the notion that pharmacists also provide primary care through care coordination. As previously discussed, pharmacists are equipped to provide complementary clinical services to supplement physician care with expertise in managing disease outcomes through medication use. Healthy People 2020 states “as one approaches health equity, health disparities become smaller.”<sup>143</sup> As public health professionals, through interprofessional practice, pharmacists can directly affect health determinants in each of the levels provided by the Healthy People 2020 Action Model.

### ***Access to Care***

A report from the National Association of Community Health Centers states 56 million Americans are medically disenfranchised: they do not have a health care home.<sup>93,132,134</sup> One of the most common problems of our health system is that even if patients have health care coverage, it may not translate equally as access to care. Thus, increasing access to quality care for those Americans necessitates discussion on how to alleviate additional burden on the health system and providers. Another report states “hospitalization rates and expenditures are higher in areas with fewer primary care physicians and limited access to primary care.”<sup>144</sup> Rural areas attract fewer doctors, and thus become overburdened more easily.

**A significant contribution to health reform by the pharmacy profession may be to increase access to patient care services, in collaboration with other primary care providers, particularly to the underserved or medically disenfranchised populations.**

Pharmacists are the most accessible health care professionals in the United States and have always been one of the most trusted professions.<sup>145</sup> **A 2000 estimate of pharmacy patronage showed that the equivalent of the entire U.S. population (approximately 275 million people at the time of publication) visited pharmacies each week.**<sup>146</sup> **This statistic alone is remarkable and suggests, as a profession, pharmacists are underutilized in addressing the health care needs of the nation.** As noted, physicians are currently overburdened, and the problem is only going to worsen as the first of the baby-boomer generation turns 65 in 2011. The U.S. population as a whole is aging; it is projected by 2030, one in five Americans will be over the age of 65.<sup>136 147</sup> Older Americans require more health care, including office visits, hospital visits, and prescriptions.

Physicians in the NCPS survey in Focus Point 1 (Interprofessional Collaboration and Support) affirm that pharmacists offer increased access to care for underserved populations where other primary care providers are in limited number or distribution. Pharmacists can decrease physicians’ routine or “chronic” workloads, potentially increasing the amount of time physicians can spend with their more complex patients providing increased revenues per physician-unit time. Generally the physician initially diagnoses the patient, sends them for disease management with the pharmacist for continued regular follow-up, laboratory monitoring, and

some level of prescriptive authority, but the physician remains as the driver behind the system. The pharmacist provides primary care collaboratively, managing the patient for optimal disease outcomes through medication use and preventing disease progression or exacerbation. Pharmacists that deliver direct patient care services can reduce physician time spent on these patients by eliminating multiple follow-up visits with the physician and increases focused disease management by the pharmacist: creating a “win-win” (non-zero sum gain) situation.

The U.S. health care system is transforming to include increased health coverage, where access to primary care and access to quality care will become paramount for the projected millions of new beneficiaries. **With increased demand for services, it will be essential to consider all populations, including racial and ethnic minorities, medically underserved, and vulnerable populations with additional health disparities.** Primary care health services are now a focus of a larger health care strategy in which a great need for these services will evolve. De Maeseneer et al. argued primary care contributes to public health by improving access; however they added that primary care also contributes to social cohesion and empowerment of people so that they become less vulnerable.<sup>148</sup> This only occurs when quality of care and health care delivery is optimized. **Coverage without access, coupled with accessibility without quality, could develop into a perilous public health situation. Pharmacists may be in the best position of any health professional to effectively meet the demands and address the changing needs of the health care system.**

Pharmacists are the most accessible cadre of health professionals in the United States and are remarkably underutilized in our health care system. The pharmacy profession is uniquely situated to expand to help meet our health care system’s changing needs. Pharmacists have the appropriate education, training, scope, and support (as providers of patient care complimentary to existing providers) to deliver quality care. Pharmacists already perform as health care providers in the PHS and federal pharmacy settings, and some non-federal health systems as well. These pharmacists are trained to handle this type of role and can rapidly expand to meet some of the demand for access to care across the nation – especially if appropriate policy structures are in place. The cost to the system to implement this change is minimal as it is more a change in policy and perception than it is a change in fiscal resources. **The American Pharmacists Association (APhA) states that “by expanding the use of pharmacists’ expertise in the treatment of chronic diseases, monetary savings and patient care improvements can help solve many challenges facing the U.S. health care system.”<sup>149</sup>**

Dramatic changes are needed to fix our health care system: expanding coverage and access to all; reforming compensation to promote value; supporting clinicians’ efforts to reengineer care; and engaging patients in making better choices and managing their health conditions. The burden of health care in the United States will likely broaden to create an even greater need through increasing workload and plans of more universal insurance coverage. Truly better quality of care - care that is more effective, safe, and efficient - is imperative for aiding our nation’s economic recovery and making good on our commitment to cover the uninsured.<sup>150</sup>

## CONCLUSION

Multiple bills and committee briefings have been submitted to Congress from leading pharmacy and non-pharmacy organizations that would fully support, utilize, and advance the pharmacy profession by maximizing pharmacists' value within current health delivery structures.<sup>31, 11,48,111,151-153</sup>

Implementation of these pharmacy practice models require strong and urgent consideration as partial solutions to the demand for health care in the United States. **Existing pharmacy practice models can rapidly relieve some of the projected burden of access to quality care, reduce health disparities, and improve overall health care delivery.** Pharmacists are integral to the provision of and access to quality patient care. Maximizing the expertise of the pharmacist, pharmacy profession, and each pharmacy practice is critical to advance our nation's health.

Physicians, administrators and patients *that have worked within this paradigm* of collaborative patient care delivered by pharmacists have supported and continue to support this model.

**What has occurred over time within this paradigm is somewhat analogous to "common law."**

In common law, decisions are based on past precedent in lieu of specific policy or statute.

Federal pharmacy systems have developed a "common pharmacy practice" across decades of implementation where it has become common and accepted for pharmacists to function as health care providers and deliver direct patient care services in collaboration with physicians based on positive outcomes. **Although this collaborative practice is implemented as a pragmatic solution to meet some of the health care demands and improve delivery of care, it is not clearly discussed at the highest levels of health leadership or correctly articulated in current pharmacy legislation or compensation structures.** This Report includes objectives that would acknowledge and advance this "common pharmacy practice" in the form of advocacy, policy, and legislation.

**The Partnership to Fight Chronic Disease (PFCD) briefed the Senate Finance Committee (SFC) regarding the SFC's health reform paper, *Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs*.** In the letter dated May 15, 2009, the PFCD stated, **"Without changes in Medicare payments and delivery models that emphasize chronic disease prevention and control, we will fail in our efforts to control Medicare costs and improve the health of our population."** Also in the letter, **the PFCD recognized and exemplified pharmacists as one of "our nation's primary health care providers."**<sup>111</sup>

Throughout the Report, a rational and logical justification has been made for pharmacists to help bridge some of the gaps and needs of our primary care and health care systems. It has been exhaustively demonstrated through evidence-based data that pharmacists within these models of care improve outcomes and contain costs. Organizations, academia, industry, community, hospital, and federal pharmacy can and will continue to demonstrate the positive outcomes of its pharmacists. Pharmacists have evolved as providers of care because it is the right thing to do for patient care and the nation's health.

It is essential that additional fiscal and policy support exist for this paradigm shift to allow pharmacists to continue to sustain these expanded services and improve outcomes. **It is time to enact legislation to recognize and compensate pharmacists - reflecting a change in the pharmacy practice that has *already* occurred.** These changes will rapidly answer a need to improve the cost-effectiveness, quality, and access to primary care and further advance the health of the nation.

Given the practice environment and innovative care models of federal pharmacy, the non-federal sector has historically looked to federal pharmacy to assist in advancing the profession. Federal pharmacy has pioneered many facets of service delivery utilizing pharmacists to the maximum extent of their licensure and education. During this era of health reform, it is once again necessary for PHS and federal pharmacy to advance these successful and existing health care delivery models past exploration and into implementation. **PHS Pharmacy is poised and capable to assist the nation toward the overall goal of improved health care delivery.**

Those in decision-making positions (in the face of decades of proven performance, interprofessional support and evidence-based outcomes) may need to consider expanded implementation of the full spectrum of pharmacist-delivered patient care services with appropriate policy and compensatory mechanisms - or clearly state the barriers of this paradigm change - that has demonstrated improved health care delivery.

During the April 11, 2011 launch of the Partnerships for Patients Initiative, Donald Berwick, CMS Administrator, stated, "America is facing a critical choice in health care. Either cut care or improve care. I don't like to cut care, so the only right thing to do is improve care."<sup>10</sup> One of the most logical, evidence-based decisions that can be made to improve care is to maximize the expertise and scope of pharmacists, and minimize expansion barriers of an already existing and successful health care delivery model.

**If the objectives of this paper are actualized, the U.S. Public Health Service, in partnership with federal pharmacy leadership and the Office of the U.S. Surgeon General, will directly support health care delivery improvement and advance the health of the nation with a new paradigm for care.**

## **APPENDICES**

- A. National Clinical Pharmacy Specialist (NCPS) Program
- B. Outcomes Repository Spreadsheet
- C. U.S. Collaborative Practice Map
- D. Physician Survey



## **Appendix A: National Clinical Pharmacy Specialist (NCPS) Program**

### **Issue**

For decades, Indian Health Service (IHS) pharmacists have practiced in a variety of expanded and advanced clinical roles to provide patient care. IHS pharmacy is widely known (in the federal sector, private sector and academia) for its innovative pharmacy practice, which includes privileges in disease management. In many IHS facilities, it is common for patients to have pharmacists providing focused medical care through clinic visits very similar to that of other primary care providers. With this advanced level of clinical care provided by pharmacists (through expanded scopes of practice agreements approved by local facilities), it is important to establish best practices, promote uniformity among credentials and competencies, and explore appropriate reimbursement for services. As of December 2008, this uniformity extends beyond the IHS into the Bureau of Prisons (BOP) as a Memorandum of Understanding was signed between the IHS and the BOP to expand the NCPS Program into the BOP.

### **Purpose**

The IHS established a national credentialing system for IHS, Tribal, and Urban (I/T/U) pharmacists in an effort to promote enhanced patient outcomes and address the following:

- Promote uniform clinical competency among I/T/U and BOP pharmacists;
- Define and recognize advanced scopes of practice for I/T/U and BOP pharmacists;
- Establish critical elements for developing collaborative practice agreements (CPAs);
- Develop a review process to approve CPAs and clinical pharmacy specialists by a national group of subject matter experts to help ensure uniformity of scope and competency both locally and nationally;
- Review credentials, protocols, training, education and experience of I/T/U and BOP pharmacists, and grant NCPS certification to recognize a pharmacist's local privileges that meet the specified national standards for credentialing;
- Establish these elements to help promote universal recognition of NCPS pharmacists as billable providers.

### **Background**

The October 18, 1996 memorandum from the IHS Director established IHS pharmacists as primary care providers (PCPs) and allows for privileges to include prescriptive authority. In response to a growing interest in clinical practice nationwide, and meetings with key stakeholders such as the Health Care Financing Administration (HCFA), the NCPS Program and NCPS Committee (NCPSC) were established by the Chief Pharmacy Officer in 1997 and 1998 to provide a mechanism to assure all Clinical Pharmacy Specialists in the IHS display a uniform level of competency. The provision of advanced pharmacy care follows the IHS Pharmacy Standards of Practice as outlined in Chapter 7 of the Indian Health Manual. With this official charge and history of advanced clinical care spanning over 30 years, the scope of NCPS care includes all criteria and responsibilities covered in the IHS Standards of Practice, as well as focused management of disease states for selected patients in whom medications are the principle method of treatment. Patient care may include a patient interview, chart review,

ordering and interpretation of laboratory tests, physical assessment, prescriptive authority, formulation of clinical assessments, and development of therapeutic plans, patient education, and patient follow-up. Treatment and management are performed through a collaborative practice agreement (CPA) that has been approved by the local medical staff. If the pharmacist is a credentialed NCPS, the CPA has also been approved by the NCPSC. NCPS certification is intended to uniformly recognize an advanced scope of practice locally aimed at managing one or more diseases and/or optimizing specific pharmacologic therapy. Pharmacists may practice disease management at a facility after completing local requirements, however NCPS certification will only be granted after submission of an appropriate application and fulfillment of all national requirements. In order to promote uniform competency and consistency in the credentialing process, it is now also strongly recommended that all facilities adopt, at a minimum, the NCPS standards for local credentialing of pharmacists in advanced scopes of practice.

**Activity**

After 13 years, the program has reviewed the credentials and certified 279 I/T/U pharmacists from 18 states (approximately 20 percent of IHS pharmacists); directly increased the access to and quality of primary care through collaborative practice and disease management.

**Appendix B: Outcomes Repository Spreadsheet**

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<b>Improved Clinical Outcomes</b>		
<p>Barbanel D, Eldridge S, et al. (2003). Can a self-management program delivered by a community pharmacist improve asthma control? A randomized trial. <i>Thorax</i> 58(10):851-4. (YES)</p>	<p>A randomized controlled study was undertaken to determine whether a community pharmacist could improve asthma control using self-management advice for individuals recruited during attendance at a community pharmacy. Methods: Twenty four adults attending a community pharmacy in Tower Hamlets, east London for routine asthma medication were randomized into two groups: the intervention group received self-management advice from the pharmacist with weekly telephone follow-up for three months and the control group received no input from the pharmacist. Participants self-completed the North of England asthma symptom scale at baseline and three months later.</p>	<p>Results: Symptom scores improved in the intervention group and marginally worsened in the control group to 20.3 (4.2) and 28.1 (3.5), respectively. Conclusions: A self-management program delivered by a community pharmacist can improve asthma control in individuals recruited at a community pharmacy. Further studies should attempt to confirm these findings using larger samples and a wider range of outcome measures.</p>
<p>Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilization, costs, and patient outcomes. <i>Cochrane Database Syst Rev</i> 2000(3):CD000336</p>	<p>Cochrane Review of articles discussing pharmacists with expanded roles</p>	<p>Twenty-five studies included &gt;40 pharmacists and 16,000 patients. Scheduled service utilization was slightly increased, and hospital admissions and ER admissions were decreased. Pharmacist services decreased the use of non-scheduled health services, the number of specialty physician visits, or the number and costs of drugs, compared to control patients (six studies). Improvements in targeted patient condition were reported in 10 of 13 studies that measured patient outcomes, but patients' quality of life did not seem to change. All studies demonstrated that pharmacist interventions produced the intended effects on physicians' prescribing practices.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Bluml BM, McKenney JM, Cziraky MJ. (2000). Pharmaceutical care services and results in project ImPACT: hyperlipidemia. <i>J Am Pharm Assoc</i> 40(2):157-65. (YES)</p>	<p>Objective: To demonstrate that pharmacists, working collaboratively with patients and physicians and having immediate access to objective point-of-care patient data, promote patient persistence and compliance with prescribed dyslipidemic therapy that enables patients to achieve their National Cholesterol Education Program (NCEP) goals. Participants: 26 community-based ambulatory care pharmacies: independent, chain-professional, chain-grocery store, home health/home infusion, clinic, health maintenance organization/managed care. Outcome measures: Rates of patient persistence and compliance with medication therapy and achievement of target therapeutic goals.</p>	<p>Over an average period of 24.6 months and in 397 patients, observed rates for persistence and compliance with medication therapy were 93.6% and 90.1% respectively, and 62.5% of patients had reached and were maintained at their NCEP lipid goal at the end of the project. Conclusion: Working collaboratively with patients, physicians, and other health care providers, pharmacists who have ready access to objective clinical data, and who have the necessary knowledge, skills and resources, can provide an advanced level of care that results in successful management of dyslipidemia.</p>
<p>Bogden PE, Koontz LM, et al. The physician and pharmacist team. An effective approach to cholesterol reduction. <i>J Gen Intern Med</i> 1997;12(3):158-64.</p>	<p>Objective: To assess the effect of a program that encourages teamwork between physicians and pharmacists on attempts to lower total cholesterol levels and to meet recommended goals proposed by the National Cholesterol Education Program (NCEP). Design: Single-blind, randomized, controlled trial lasting six months. Setting: An ambulatory primary care center. Patients: A sample of 94 patients with total cholesterol levels of 240 mg/dL or higher. Intervention: Equal numbers of patients were randomly assigned to a control arm in which standard medical care was received, and an intervention arm which implemented close interaction between physicians and pharmacists.</p>	<p>Results: The rate of success in achieving NCEP goals in the intervention arm was double the rate in the control arm (43% vs 21%, P &lt; .05). Total cholesterol levels in the intervention arm declined 44 +/- 47 mg/dL versus 13 +/- 51 mg/dL in the control arm (p &lt; .01). An effect of intervention was absent in patients without coronary heart disease and with fewer than two risk factors. Conclusions: Attempts to lower total cholesterol levels and achieve NCEP goals are likely to be more successful when combined with programs that include teamwork between physicians and pharmacists. Some programs, however, may be more successful for high-risk patients, for whom it is often easier to provide more aggressive therapies. Although altering adverse lipid profiles in lower-risk patients may be difficult, achieving optimal cholesterol levels could have an important impact on preventing movement to higher risk strata.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Bozovich M, Rubino CM, Edmunds J. Effect of a Clinical Pharmacist-Managed Lipid Clinic on Achieving National Cholesterol Education Program Low-Density Lipoprotein Goals. <i>Pharmacotherapy</i> 2000;20(11):1375-1383. (YES)</p>	<p>Patients in each arm were followed for a minimum of six months. A protocol for therapy changes in clinic patients was developed by the clinical pharmacist and approved by the cardiologist.</p>	<p>At the end of six months, 69% of patients in the pharmacist-managed clinic achieved their LDL goal, compared with 50% of controls. Compliance with laboratory tests and drug regimens also improved in clinic patients. Compliance with lipid panels went from 8% two months before to 89% two months after the start of the study. At the end of six months, compliance with laboratory work and refills was 80%. Thus the clinical pharmacist-managed clinic was highly successful in achieving NCEP goals for secondary prevention.</p>
<p>Carson, J. J. Pharmacist-coordinated program to improve use of pharmacotherapy for reducing risk of coronary artery disease in low-income adults. <i>Am J Health Syst Pharm</i> 1999;56(22):2319-24. (YES)</p>	<p>Patients were categorized as secondary prevention, or high-risk primary prevention of cardiovascular disease. Intervention: The pharmacist made pharmacotherapy recommendations based on guidelines. Patients' use of aspirin, lipid-lowering therapy, and HRT was noted before program entry. Use of these pharmacotherapeutic modalities was then tracked through subsequent visits. In addition, the patient's baseline serum lipid values were recorded and tracked.</p>	<p>Results: In secondary-prevention group, mean LDL fell by 26% (<math>p &lt; 0.0001</math>), and 24 (73%) of the patients had a reduction in LDL concentration. Mean total cholesterol concentration among secondary-prevention patients decreased by 11% (<math>p = 0.007</math>), and the mean HDL concentration increased by 19% (<math>p &lt; 0.0001</math>). The percentage of secondary-prevention patients achieving their NCEP LDL goal of <math>&lt;100</math> mg/dL increased from 6% to 27% (<math>p &lt; 0.04</math>). In the primary-prevention group, the mean LDL concentration fell by 27% (<math>p &lt; 0.0001</math>), and 29 (71%) of the patients had a reduction in LDL concentration after entry into the program. The mean total cholesterol concentration fell by 15% (<math>p = 0.0002</math>), and the mean HDL concentration increased by 12% (<math>p = 0.009</math>). The percentage of patients achieving their NCEP-recommended LDL goal of <math>&lt;130</math> mg/dL increased from 20% to 51% (<math>p = 0.006</math>). Conclusion: A program in which a pharmacist estimated patients' risks for coronary artery disease and recommended pharmacotherapeutic interventions improved the use of these pharmacotherapeutic modalities by low-income adults.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Carter BL, Barnette DJ, et al. (1997). Evaluation of hypertensive patients after care provided by community pharmacists in a rural setting. <i>Pharmacotherapy</i> 1997;17(6):1274-85. (YES)</p>	<p>Blood pressure control, quality of life, quality of care, and satisfaction of patients who were monitored by specially trained community pharmacists in a group medical practice was evaluated. After participating in an intensive skill development program, pharmacists performed in an interdisciplinary team in a rural clinic. The primary objective was assessed by evaluating outcome variables at six months compared with baseline in 25 patients randomly assigned to a study group. A control group of 26 patients was also evaluated to determine if outcome variables remained constant from baseline to six months.</p>	<p>Results: Systolic blood pressure was reduced in the study group (151 mmHg baseline, 140 mmHg at 6 mo., <math>p &lt; 0.001</math>) and diastolic blood pressure was significantly lower at 2, 4, and 5 months compared with baseline. Ratings from a blinded peer review panel indicated significant improvement in the appropriateness of the blood pressure regimen, going from 8.7 +/- 4.7 to 10.9 +/- 4.5 in the study group, but they did not change in the control group. Several quality of life scores improved significantly in the study group after six months. There were no significant changes in the control group. Patient satisfaction scores were consistently higher in the study group at the end of the study. Results indicate that when community pharmacists in a clinic setting are trained and included as members of the primary care team, significant improvements in blood pressure control, quality of life, and patient satisfaction can be achieved.</p>
<p>Coast-Senior EA, Kroner BA, Kelley CL, et al. Management of patients with type 2 diabetes by pharmacists in primary care clinics. <i>Ann Pharmacother</i> 1998 Jun;32(6):636-41.</p>	<p>The objective of this study was to determine the impact of clinical pharmacists involved in direct patient care on the glycemic control of patients with type 2 diabetes mellitus in two primary care clinics in a university-affiliated Veterans Affairs Medical Center. The pharmacists provided diabetes education, medication counseling, monitoring, and insulin initiation and/or adjustments. All initial patient interactions with the pharmacists were face-to-face. Thereafter, patient-pharmacist interactions were either face-to-face or telephone contacts. Study subjects were patients with type 2 diabetes who were referred to the pharmacists by their primary care providers for better glycemic control. Primary outcome variables were changes from baseline in glycosylated hemoglobin,</p>	<p>Twenty-three veterans aged 65-94 years completed the study. Fifteen (65%) patients were initiated on insulin by the pharmacists eight (35%) were already using insulin. Patients were followed for a mean-SD of 27-10 weeks. Glycosylated hemoglobin, fasting blood glucose concentrations, and random blood glucose concentrations significantly decreased from baseline by 2.2% (<math>p = 0.00004</math>), 65 mg/dL (<math>p &lt; 0.01</math>), and 82 mg/dL (<math>p = 0.00001</math>) respectively. Symptomatic hypoglycemic episodes occurred in 35% of patients. None of these episodes required physician intervention. Conclusion: This study demonstrated that pharmacists working as members of interdisciplinary primary care teams can positively impact glycemic control in patients with type 2 diabetes requiring insulin.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
	fasting blood glucose, and random blood glucose measurements. Secondary outcomes were the number and severity of symptomatic episodes of hypoglycemia, and the number of emergency room visits or hospitalizations related to diabetes.	
Dolovich L, Pottie K, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. <i>Clin Pharmacol Ther</i> 2008;83(6):913-7. (YES)	Pharmacists placed in seven family practice sites in Ontario, Canada. Physicians reviewed advice provided by the pharmacists and determined a management approach.	Pharmacists evaluated 969 patients over a 24 month period. Pharmacists identified an average of 4.4 drug related problems per patient (3974 total). Pharmacists identified adverse drug reactions in 241 patients.
Ellis SL, Carter BL, Malone DC, et al. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study. Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. <i>Pharmacotherapy</i> 2000 Dec;20(12):1508-16.	This study examined the impact of ambulatory care clinical pharmacist interventions on clinical and economic outcomes of 208 patients with dyslipidemia and 229 controls treated at nine Veterans Affairs medical centers. This was a randomized, controlled trial involving patients at high risk of drug-related problems, though only those with dyslipidemia are reported here. In addition to usual medical care, clinical pharmacists were responsible for providing pharmaceutical care for patients in the intervention group. The control group did not receive pharmaceutical care. Seventy-two percent of the intervention group and 70% of controls required secondary prevention according to the National Cholesterol Education Program guidelines.	Significantly more patients in the intervention group had an improved fasting lipid profile compared with controls. The absolute change in total cholesterol (17.7 vs 7.4 mg/dl, p = 0.028) and low-density lipoprotein (23.4 vs 12.8 mg/dl, p=0.042) was greater in the intervention than in the control group. There were no differences in patients achieving target lipid values or in overall costs despite increased visits to pharmacists. Ambulatory care clinical pharmacists can significantly improve dyslipidemia in a practice setting designed to manage many medical and drug-related problems.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Erhun WO, Agbani EO, et al. Positive benefits of a pharmacist-managed hypertension clinic in Nigeria. <i>Public Health</i> 2005;119(9):792-8. (YES)</p>	<p>Design: One-year prospective, randomized cohort study of the outpatients of a state comprehensive health centre in South-western Nigeria. Free primary health services including free drugs were provided for all patients. Methods: 51 Nigerian patients with uncomplicated hypertension aged 45 years or more were included. Participating pharmacists counseled on current medication, personalized goals of lifestyle modification stressing weight loss and/or increased activity, increased patient awareness by providing relevant education about hypertension and associated/related diseases, adjusted drug therapy to optimize effectiveness and minimize adverse events, utilized treatment schedules that enhanced patients' adherence to therapy, and monitored treatment outcomes between enrollment and return visits. Patient satisfaction and the number of treatment failures within six months post enrollment were compared with retrospective data from an earlier study involving physician-managed patients under a similar setting.</p>	<p>Results: Uncontrolled BP reduced from 92% to 36.2% by 10.15+/-5.02 days after enrollment. Treatment failures were observed at 5.9% of the total return visits (n=184) within six months. Conclusion: Pharmacist-managed hypertension clinics can improve BP control, reduce treatment failure and increase patient satisfaction.</p>
<p>Gattis WA, Hasselblad V, et al. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure management team: results of the Pharmacist in Heart Failure Assessment Recommendation and Monitoring (PHARM) Study. <i>Arch Intern Med</i> 1999;159(16): 1939-45. (YES)</p>	<p>181 patients with heart failure and left ventricular dysfunction (ejection fraction &lt;45) undergoing evaluation in clinic were randomized to an intervention or a control group. Patients in the intervention group received clinical pharmacist evaluation, which included medication evaluation, therapeutic recommendations to the attending physician, patient education, and follow-up telemonitoring. The control group received usual care. The primary end point was combined all-cause mortality and heart failure clinical events.</p>	<p>Results: Median follow-up was six months. All-cause mortality and heart failure events were significantly lower in the intervention group compared with the control group (4 vs 16; P = 0.005). In addition, patients in the intervention group received higher angiotensin-converting enzyme (ACE) inhibitor doses as reflected by the median fraction of target reached (25th and 75th percentiles), 1.0 (0.5 and 1) and 0.5 (0.1875 and 1) in the intervention and control groups, respectively (P &lt; 0.001). The use of other vasodilators in ACE inhibitor-intolerant patients was higher in the intervention group (75% vs 26%; P = 0.02). Conclusions: Outcomes in heart failure can be improved with a clinical pharmacist as a member of the</p>



CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
		multidisciplinary heart failure team. This observation may be due to higher doses of ACE inhibitors and/or closer follow-up.
<p>Goode JV, Swiger K, et al. Regional osteoporosis screening, referral, and monitoring program in community pharmacies: findings from Project ImPACT: Osteoporosis. <i>J Am Pharm Assoc</i> (2003) 2004;44(2):152-60. (YES)</p>	<p>Design: Single-cohort observational study in a 29-store pharmacy chain in Richmond, VA. Participants were 532 consumers with one or more known risk factors for osteoporosis in the chain's customer service area. Intervention: During the initial phase (health promotion and disease prevention) of the project, pharmacy-based osteoporosis screening with referral and follow-up was provided to consumers who responded to the chain's screening promotions. The second phase – provision of collaborative community health management services focused on osteoporosis monitoring and management – is ongoing and includes patients who are at risk for or diagnosed with osteoporosis and are covered by a regional payer. Outcome measures: Results of screenings; responses of patients and physicians to notifications; and long-term results during collaborative care.</p>	<p>Results: 305 patients were available for follow-up interviews three to six months later. The stratification for risk of fracture was 37%, high risk; 33%, moderate risk; and 30%, low risk. A total of 78% of patients indicated they had no prior knowledge of their risk for future fracture. In the moderate- and high-risk categories, 37% of patients scheduled and completed a physician visit, 19% had a diagnostic scan, and 24% of those patients were initiated on osteoporosis therapy subsequent to the screening. Participating pharmacies received payment for both the osteoporosis screening and the collaborative health management services. Conclusion: Pharmacists can play a useful role in the identification, education, and referral of patients at risk for osteoporosis through pharmacy-based BMD screening. Patients are willing to pay for pharmacy-based osteoporosis screening services. Third-party payers are willing to compensate pharmacists for collaborative community health management services.</p>
<p>Hanlon JT, Weinberger M, Samsa GP, et al. A randomized, controlled trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy. <i>Am J Med</i> 1996 Apr;100(4):428-37.</p>	<p>The purpose was to evaluate the effect of sustained clinical pharmacist interventions involving elderly outpatients with polypharmacy and their primary physicians. Methods: Randomized, controlled trial of 208 patients aged 65 years or older with polypharmacy (&gt; or = 5 chronic medications) from a general medicine clinic of a Veterans Affairs Medical Center. A clinical pharmacist met with intervention group patients during all scheduled visits to evaluate their drug regimens and make recommendations to them and their physicians. Outcome</p>	<p>Results: Inappropriate prescribing scores declined significantly more in the intervention group than in the control group by three months and was sustained at 12 months. Fewer intervention than control patients experienced adverse drug events. Measures for most other outcomes remained unchanged in both groups. Physicians were receptive to the intervention and enacted changes recommended by the clinical pharmacist more frequently than they enacted changes independently for control patients (55.1% versus 19.8%; P &lt; 0.001). Conclusion: A clinical pharmacist providing pharmaceutical care for</p>

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	measures were prescribing appropriateness, health-related quality of life, adverse drug events, medication compliance and knowledge, number of medications, patient satisfaction, and physician receptivity.	elderly primary care patients can reduce inappropriate prescribing and possibly adverse drug effects without adversely affecting health-related quality of life.
Jaber LA, Halapy H, et al. Evaluation of a pharmaceutical care model on diabetes management. <i>Ann Pharmacother</i> 1996;30(3):238-43. (YES)	Patients were randomized to either a pharmacist intervention (diabetes education, medication counseling, instructions on dietary regulation, exercise, and home blood glucose monitoring, and evaluation and adjustment of their hypoglycemic regimen) or control group (standard medical care provided by their physicians) and followed over a 4-month period. Primary outcome measures: fasting plasma glucose and HbA1c. Secondary outcomes: blood pressure, serum creatinine, creatinine clearance, microalbumin to creatinine ratio, total cholesterol, triglycerides, HDL, and LDL.	In the 39 patients who completed the study, significant improvement in glycated hemoglobin and fasting plasma glucose was achieved in the intervention group. No change in glycemia was observed in the control subjects. Statistically significant differences in the final glycated hemoglobin and fasting plasma glucose concentrations were noted between groups. Conclusion: This study demonstrates the effectiveness of pharmaceutical care in the reduction of hyperglycemia associated with non-insulin-dependent diabetes mellitus (NIDDM) in a group of urban African-American patients.
Jackson SL, Peterson GM, et al. Improving the outcomes of anticoagulation: an evaluation of home follow-up of warfarin initiation. <i>J Intern Med</i> 2004;256(2): 137-44. (YES)	A number of studies have reported the risk of bleeding associated with warfarin is highest early in the course of therapy. This study examined the effect of a program focused on the transition of newly anticoagulated patients from hospital to the community. Design: Open-label randomized controlled trial. Setting: Home-based follow-up of patients discharged from acute care hospital in southern Tasmania, Australia. Subjects: 128 patients initiated on warfarin in hospital and subsequently discharged to general practitioner (GP) care were enrolled in the study. Sixty were randomized to home monitoring (HM) and 68 received usual care (UC). Interventions: HM patients received a home-visit by the project pharmacist and point-of-care international normalized ratio (INR) testing	Results: At discharge, 42% of the HM group and 45% of the UC group had a therapeutic INR. At day eight, 67% of the HM patients had a therapeutic INR, compared with 42% of UC patients (P < 0.002). In addition, 26% of UC patients had a high INR, compared with only 4% of HM patients. Bleeding events were assessed three months after discharge and occurred in 15% of HM patients, compared with 36% of the UC group (P < 0.01). Conclusion: This program improved the initiation of warfarin therapy and resulted in a significant decrease in hemorrhagic complications in the first three months of therapy.

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	<p>on alternate days on four occasions, with the initial visit two days after discharge. The UC group was solely managed by the GP and only received a visit eight days after discharge to determine anticoagulant control.</p>	
<p>Kaboli PJ, Hoth AB, et al. Clinical pharmacists and inpatient medical care: a systematic review. <i>Arch Intern Med</i> 2006;166(9):955-64. (YES)</p>	<p>Purpose: to evaluate published literature on the effects of interventions by clinical pharmacists on processes and outcomes of care in hospitalized adults. Methods: Peer-reviewed, English-language articles were identified from January 1, 1985 through April 30, 2005. Three independent assessors evaluated 343 citations. Inpatient pharmacist interventions selected if they included control group and objective patient-specific health outcomes; type of intervention, study design, and outcomes such as adverse drug events, medication appropriateness, and resource use were abstracted.</p>	<p>Results: Thirty-six studies met inclusion criteria, including 10 evaluating pharmacists' participation on rounds, 11 medication reconciliation studies, and 15 on drug-specific pharmacist services. Adverse drug events, adverse drug reactions, or medication errors were reduced in 7 of 12 trials that included these outcomes. Medication adherence, knowledge, and appropriateness improved in 7 of 11 studies, while there was shortened hospital length of stay in nine of 17 trials. No intervention led to worse clinical outcomes and only one reported higher health care use. Improvements in both inpatient and outpatient outcome measurements were observed. Conclusions: The addition of clinical pharmacist services in the care of inpatients generally resulted in improved care, with no evidence of harm. Interacting with the health care team on patient rounds, interviewing patients, reconciling medications, and providing patient discharge counseling and follow-up all resulted in improved outcomes. Future studies should include multiple sites, larger sample sizes, reproducible interventions, and identification of patient-specific factors that lead to improved outcomes.</p>

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<p>Koshman SL, Charrois TL, et al. Pharmacist care of patients with heart failure: a systematic review of randomized trials. <i>Arch Intern Med</i> 2008;168(7):687-94. (YES)</p>	<p>To clarify the role of pharmacists in the care of patients with heart failure (HF), a systematic review was performed evaluating the effect of pharmacist care on patient outcomes in HF. Methods: A search was conducted on PubMed, MEDLINE, EMBASE, International Pharmaceutical Abstracts, Web of Science, Scopus, Dissertation Abstracts, CINAHL, Pascal, and Cochrane Central Register of Controlled Trials for controlled studies from database inception to August 2007. Randomized controlled trials that evaluated the impact of pharmacist care activities on patients with HF (in both Inpatient and outpatient settings) were included. Summary odds ratios (ORs) with 95% confidence intervals (CIs) were calculated using a random-effects model for rates of all-cause hospitalization, HF hospitalization, and mortality.</p>	<p>Results: A total of 12 randomized controlled trials (2060 patients) were identified. Extent of pharmacist involvement varied among studies, and each study intervention was categorized as pharmacist-directed care or pharmacist collaborative care using a priori definitions and feedback from primary study authors. Pharmacist care was associated with significant reductions in the rate of all-cause hospitalizations (11 studies [2026 patients]) and HF hospitalizations (11 studies [1977 patients]), and a non-significant reduction in mortality (12 studies [2060 patients]). Pharmacist collaborative care led to greater reductions in the rate of HF hospitalizations than pharmacist-directed care. Conclusions: Pharmacist care in the treatment of patients with HF greatly reduces the risk of all-cause and HF hospitalizations. Since hospitalizations associated with HF are a major public health problem, the incorporation of pharmacists into HF care teams should be strongly considered.</p>
<p>Leal S, Herrier RN, Glover JJ, Felix A. Improving quality of care in diabetes through a comprehensive pharmacist-based disease management program. <i>Diabetes Care</i> 2004;27(12):2983-84. (YES)</p>	<p>Pharmacist worked under a collaborative practice agreement as the PCP for a diabetic population; collaboration also included HTN and lipid management in 199 patients</p>	<p>Significant decreases in HbA1c, LDL, total cholesterol, triglycerides, SBP, DBP, and blood glucose; "pts managed by pharmacist were more likely to have attained treatment goals and had recommended examinations, medications, and tests"</p>
<p>Lee J, McPherson ML. Outcomes of recommendations by hospice pharmacists. <i>Am J Health Syst Pharm</i> 2006;63(22): 2235-9. (YES)</p>	<p>Purpose: The value of pharmaceutical care recommendations made by consultant pharmacists and the outcomes of these recommendations were studied. Methods: The study was conducted at three hospice programs, and the investigators were</p>	<p>Ninety-eight interventions were collected and evaluated. Eighty-seven of the 98 interventions were classified as clinical interventions with specific therapeutic goals established. Of these 87 interventions, 73 (84%) were accepted by the prescriber and 56</p>

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	<p>consultant pharmacists who shared the responsibility of providing drug therapy recommendations to the three programs. A literature search was conducted to determine if any tools had been developed to evaluate recommendations made by pharmacists in clinical practice settings. One tool was identified and adapted for use in a hospice clinical setting. Drug-related problems (DRPs) (n = 98), clinical interventions (n = 87), and outcomes data were collected by two hospice consultant pharmacists and evaluated by a panel of experts using the assessment tool.</p>	<p>(77%) out of the 73 helped achieve the therapeutic goals. An additional six (8%) interventions partially achieved the therapeutic goals. Over 75% of all of the pharmacists' recommendations achieved their intended therapeutic effect, which resulted in better management of the patients' physical symptoms. None of the accepted recommendations resulted in the patient coming to harm or having an adverse effect. Overall agreement between raters for severity and value was moderately high, 60-70% and 63-80%, respectively. Kappa scores were low. Conclusion: Hospice-based clinical pharmacists influenced patient outcomes positively by identifying DRPs and recommending appropriate drug therapy.</p>
<p>Lipton HL, Bero LA, et al. The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing. A randomized controlled trial. <i>Med Care</i> 1992;30(7):646-58. (YES)</p>	<p>The impact of clinical pharmacists' consultations on geriatric drug prescribing was studied in a prospective randomized controlled trial of patients 65 years of age and over discharged on three or more medications for chronic conditions from a 450-bed community hospital. The pharmacists provided consultation to experimental patients and their physicians at hospital discharge and at periodic intervals for three months post discharge. Using a standardized tool, a physician-pharmacist panel, blinded to study group assignment of patients, evaluated the appropriateness of prescribing for a random sample of 236 patients.</p>	<p>88% had at least one or more clinically significant drug problems, and 22% had at least one potentially serious and life-threatening problem. Drug-therapy problems were divided into six categories: 1) inappropriate choice of therapy; 2) dosage; 3) schedule; 4) drug-drug interactions; 5) therapeutic duplication; and 6) allergy. Experimental patients were less likely to have one or more prescribing problems in any of the categories (P = 0.05) or in the appropriateness (P = 0.02) or dosage (P = 0.05) categories. A summary score, measuring the appropriateness of the patient's total drug regimen, indicated that experimental patients' regimens were more appropriate than those of controls (P = 0.01). Results of this trial reveal that clinical pharmacists can improve the appropriateness of geriatric drug prescribing in outpatient settings.</p>
<p>Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to</p>	<p>Meta-analysis of pharmacist intervention in diabetes management</p>	<p>Diabetes education and medication management were the most frequently utilized interventions. Significant reduction in HbA1c in pharmacist intervention</p>

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<p>pharmacist interventions. Part I: systematic review and meta-analysis in diabetes management. <i>Ann Pharmacother</i> 2007;41:1569-82. (YES)</p>		
<p>Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part II: systematic review and meta-analysis in hypertension management. <i>Ann Pharmacother</i> 2007;41:1770-81. (YES)</p>	<p>Meta-analysis of pharmacist intervention in hypertension management</p>	<p>Hypertension education and medication management were the most frequently utilized interventions. Significant reduction in systolic blood pressure (BP) in pharmacist intervention</p>
<p>McKenney JM, Slining JM, Henderson HR, et al. The effect of clinical pharmacy services on patients with essential hypertension. <i>Circulation</i> 1973 Nov;48(5):1104-11.</p>	<p>Compared clinical pharmacy services provided to 25 study patients vs. 25 control patients with regard to essential hypertension.</p>	<p>Results: Significant improvement in number of study patients whose blood pressure (BP) was kept within the normal range during the study period. Conclusion: Pharmacy clinical services are beneficial and pharmacists should become more involved in the long term care given to hypertensive patients.</p>
<p>Radley AS, Hall J, et al. Evaluation of anticoagulant control in a pharmacist operated anti-coagulant clinic. <i>J Clin Pathol</i> 1995;48(6):545-7. (YES)</p>	<p>Compared pharmacist-run anticoagulation to rotation medical senior staff-run clinic. Switched from medical staff to senior staff in April 1992 – retrospective study of the four months before and four months after the switch</p>	<p>No clear difference between pharmacist-run and medical staff-run clinics in the 382 patients who were analyzed. Patients with an INR result "out" of control limits were more likely to be returned "in" to control at their next visit by the pharmacists than by the physicians.</p>

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<p>Reeder TA, Mutnick A. Pharmacist- versus physician-obtained medication histories. <i>Am J Health Syst Pharm</i> 2008;65(9):857-60. (YES)</p>	<p>Physician-obtained medication histories were compared to those obtained by a pharmacist. Methods: Patients whose medication histories were obtained were included in the evaluation if they were at least 18 years old and admitted to an internal medicine service at the University of Virginia Medical Center. Data were collected in two phases. The first 20 patients identified for inclusion were asked to provide an accurate medication history to pilot test the medication history form used by the pharmacist and received no pharmacist follow-up or interventions. In the second phase, patients were asked to provide an accurate medication history, and a pharmacist intervened when discrepancies in the pharmacist-obtained medication history were identified.</p>	<p>Results: A total of 55 patients were included in the study. The pharmacists identified 614 medications for these patients, compared with 556 identified by the physicians (<math>p &lt; \text{or} = 0.001</math>). The pharmacist documented significantly more medication doses and dosage schedules than did physicians (614 versus 446 and 614 versus 404, respectively) (<math>p &lt; \text{or} = 0.001</math> for both comparisons). The pharmacist identified 353 discrepancies, including 58 medications not initially identified from the physician-obtained histories. The pharmacist intervened for 161 discrepancies, correcting 142 after contacting the respective physician; 19 medication discrepancies could not be justified by the physician. Conclusion: A total of 353 discrepancies were identified when medication histories obtained by physicians were compared with those obtained by a pharmacist during the study. During the intervention phase, the majority of discrepancies identified were either corrected by the pharmacist after contacting the respective physician or justified by the physician.</p>
<p>Rosen CE, Copp WM, Holmes S. Effectiveness of a specially trained pharmacist in a rural community mental health center. <i>Public Health Rep</i> 1978;93(5);464-7. (YES)</p>	<p>Compared pharmacist-provided care with psychiatrist-provided care to mental health patients in eight clinics over a three year period.</p>	<p>Patients in the pharmacist group reported being significantly healthier since coming to the clinic than did other patients; also reported needing significantly less additional help than did the other patients.</p>

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<p>Rothman R, Malone R, et al. Pharmacist-led, primary care-based disease management improves hemoglobin A1c in high-risk patients with diabetes. <i>Am J Med Qual</i> 2003;18(2):51-8. (YES)</p>	<p>Primary care-based diabetes disease management program for patients with type 2 diabetes and poor glucose control. Pharmacists offered support to patients with diabetes through direct teaching about diabetes, frequent phone follow-up, medication algorithms, and use of a database that tracked patient outcomes and actively identified opportunities to improve care.</p>	<p>After an average of six months of intervention, the mean reduction in HbA1c was 1.9 percentage points in the 138 patients who completed the study. In conclusion, a pharmacist-based diabetes care program integrated into primary care practice significantly reduced HbA1c among patients with diabetes and poor glucose control.</p>
<p>Sadik A, Yousif M, et al. Pharmaceutical care of patients with heart failure. <i>Br J Clin Pharmacol</i> 2005;60(2):183-93. (YES)</p>	<p>Objective: Investigate the impact of a pharmacist-led pharmaceutical care program, involving optimization of drug treatment and intensive education and self-monitoring of patients with heart failure (HF) within the United Arab Emirates (UAE), on a range of clinical and humanistic outcome measures. Methods: Randomized, controlled, longitudinal, prospective clinical trial of HF patients. Intervention patients received a structured pharmaceutical care service while control patients received traditional services. Patient follow-up took place when patients attended scheduled outpatient clinics (every three months). A total of 104 patients in each group completed the trial (12 months). The patients were generally suffering from mild to moderate HF (NYHA Class 1, 29.5%; Class 2, 50.5%; Class 3, 16%; and Class 4, 4%).</p>	<p>Results: Intervention patients showed significant improvements in a range of summary outcome measures including exercise tolerance, forced vital capacity, health-related quality of life, as measured by the Minnesota living with heart failure questionnaire. The number of individual patients who reported adherence to prescribed medications was higher in the intervention group (85 vs. 35), as was adherence to lifestyle advice (75 vs. 29) at the final assessment (12 months). There was a tendency to have a higher incidence of casualty department visits by intervention patients, but a lower rate of hospitalization. Conclusion: The research provides clear evidence that the delivery of pharmaceutical care to patients with HF can lead to significant clinical and humanistic benefits.</p>



CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Scott DM, Boyd ST, et al. Outcomes of pharmacist-managed diabetes care services in a community health center. <i>Am J Health Syst Pharm</i> 2006;63(21): 2116-22. (YES)</p>	<p>Purpose: Outcomes of pharmacist-managed diabetes care in a community health center were studied. Methods: Eligible patients over age 18 years with diagnosis of type 2 diabetes mellitus, randomly assigned by the clinical pharmacist and nurse to intervention (n = 76) or control group (n = 73). Patients in the intervention group were enrolled in a pharmacist-managed diabetes care program. Patients in the control group received the standard diabetes care. The primary endpoint was reduction in HbA1c; secondary outcome measures included weight loss, an improved body mass index, decreased blood pressure, and an improved lipid panel. Quality-of-life measures (health level, satisfaction, impact, worry about disease, and worry about social and vocational issues) were also assessed.</p>	<p>Results: Mean HbA1c levels fell significantly from baseline to nine months in both groups. A difference of 1.0 was reported between the groups' HbA1c levels. Satisfaction level improved from 63.7 to 77.4 in the intervention group, which was significant when compared with the control group, whose satisfaction score improved from 57.0 to 63.4 (p &lt; 0.05). Conclusion: Patients with type 2 diabetes mellitus who received pharmacist-managed diabetes care demonstrated improved HbA1c, systolic blood pressure, and low-density-lipoprotein cholesterol levels and quality-of-life measures and met treatment goals more often than patients receiving standard care.</p>
<p>Sookaneknun P, Richards RM, et al. Pharmacist involvement in primary care improves hypertensive patient clinical outcomes. <i>Ann Pharmacother</i> 2004;38(12):2023-8. (YES)</p>	<p>Objective: To evaluate the effect of pharmacist involvement in treatment with hypertensive patients in primary care settings. Methods: The treatment objective was to stabilize the blood pressure (BP) of hypertensive patients in accordance with the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure guidelines. Patients were randomly assigned to a pharmacist-involved group (treatment) or a group with no pharmacist involvement (control). Pre- and post-test BPs, tablet counts, lifestyle modifications, and pharmacists' recommendations were recorded. The 6-month study was carried out in Mahasarakham University pharmacy and two primary care units. Patients were monitored monthly by reviewing their medications and supported by providing pharmaceutical care and counseling.</p>	<p>Results: From a total of 235 patients, the treatment group (n = 118) had a significant reduction in both systolic (S) and diastolic (D) BP compared with the 117 patients of the control group. The 158 patients (76 treatment, 82 control) with BPs &gt; or = 140/90 mmHg at the beginning of the study showed significant BP reductions. The proportion of 158 patients whose BP became stabilized was higher in the treatment group. The treatment group showed significantly better adherence and exercise control at the end of the study. Physicians accepted 42.72% of medication modifications and 5.34% of the suggestions for additional investigations. Conclusion: Hypertensive patients who received pharmacist input achieved a significantly greater benefit in BP reduction, BP control, and improvement in adherence rate and lifestyle modification.</p>

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<p>Weinberger M, Murray MD, et al. Effectiveness of pharmacist care for patients with reactive airways disease: a randomized controlled trial. <i>JAMA</i> 2002;288(13):1594-602. (YES)</p>	<p>Design: Randomized controlled trial at 36 community drugstores in Indianapolis, Indiana, including 898 participants with asthma or active chronic obstructive pulmonary disease (COPD) over 12 months. Interventions: The pharmaceutical care program provided pharmacists with recent patient-specific clinical data (peak expiratory flow rates [PEFRs], emergency department [ED] visits, hospitalizations, and medication compliance), training, customized patient educational materials, and resources to facilitate program implementation. The PEFR monitoring control group received a peak flow meter, instructions about its use, and monthly calls to elicit PEFRs. However, PEFR data were not provided to the pharmacist. Patients in the usual care group received neither peak flow meters nor instructions in their use; during monthly telephone interviews, PEFR rates were not elicited. Outcome measures: Peak expiratory flow rates, breathing-related ED or hospital visits, health-related quality of life (HRQOL), medication compliance, and patient satisfaction.</p>	<p>Results: At 12 months, patients receiving pharmaceutical care had significantly higher peak flow rates than the usual care group but not higher than PEFR monitoring controls. No significant between-group differences in medication compliance or HRQOL. Asthma patients receiving pharmaceutical care had significantly more breathing-related ED or hospital visits than the usual care group. Patients receiving pharmaceutical care were more satisfied with their pharmacist than the usual care group and the PEFR monitoring group, and were more satisfied with their health care than the usual care group at six months only. Despite ample opportunities to implement the program, pharmacists accessed patient-specific data only about half of the time and documented actions about half of the time that records were accessed. Conclusion: This pharmaceutical care program increased patients' PEFRs compared with usual care but provided little benefit compared with peak flow monitoring alone. Pharmaceutical care increased patient satisfaction but also increased the amount of breathing-related medical care sought.</p>
<p>Yamada C, Johnson JA, et al. Long-term impact of a community pharmacist intervention on cholesterol levels in patients at high risk for cardiovascular events: extended follow-up of the second study of cardiovascular risk intervention by pharmacists (SCRIP-plus).</p>	<p>Objective: Determine the effect of a community pharmacist intervention in patients at high risk for coronary heart disease on LDL levels one year after completion of the Second Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP-plus). Methods: Patients who completed the original study were invited to make a single return visit to their community pharmacy so the pharmacist could measure their fasting LDL level using a point-of-care device. The primary outcome was change in LDL level from the 6-month (final) visit to the extended follow-up evaluation.</p>	<p>Results: Data were collected for 162 patients. The mean +/- SD LDL level at completion of the original study was 107.9 +/- 33.6 mg/dl. Sixty-one (38%) patients were at the target LDL level (&lt; 96.7 mg/dl). Conclusion: The LDL reduction was maintained one year after completion of the extended follow-up. Since most patients were still not at the target LDL level, this finding suggests that continuing intervention is necessary to help patients reach this target.</p>

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<i>Pharmacotherapy</i> 2005;25(1):110-5. (YES)		
<b>Improved Clinical Outcomes AND Cost Reduction</b>		
Bond CA, Monson R. Sustained improvement in drug documentation, compliance, and disease control. A four-year analysis of an ambulatory care model. <i>Arch Intern Med</i> 1984 Jun;144(6):1159-62.	The effectiveness of an intervention program involving a clinical pharmacist and nurse clinician in improving drug documentation in medical records, patient compliance, and disease control was analyzed. Medical records and prescription files were reviewed for patients in a rheumatology and renal clinic. Compliance was estimated by examining prescription refill patterns. Reviews were performed before intervention (control group), nine months after intervention (study group 1), and four years and nine months after the intervention program began (study group 2).	A six-month retrospective analysis at each review point demonstrated a significant improvement in drug documentation, compliance, and disease control (BP) for both study groups. Cost reductions associated with the intervention program suggest that this program is cost-effective.
Bunting BA, Cranor CW. (2006). The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. <i>J Am Pharm Assoc</i> (2003) 2006;46(2):133-47. (YES)	Intervention: regular long-term follow-up of 207 adult patients with asthma by pharmacists (reimbursed for medication therapy management [MTM] by health plans) using scheduled consultations, monitoring and recommendations to physicians. Outcomes included changes in forced expiratory volume in one second (FEV1), asthma severity, symptom frequency, the degree to which asthma affected people's lives, presence of an asthma action plan, asthma-related emergency department/hospital events, and changes in asthma-related costs over time.	All objective and subjective measures of asthma control improved and were sustained for as long as five years. FEV1 and severity classification improved significantly. Spending on asthma medications increased; however, asthma-related medical claims decreased and total asthma related costs were significantly lower than the projections based on the study population's historical trends. Direct costs savings averaged \$725/pt/yr and indirect cost savings were estimated to be \$1230/pt/yr. Indirect costs due to missed/non-productive workdays decreased from 10.8 days/year to 2.6 days/yr. Patients were six times less likely to have an ED/hospitalization event after program interventions. Conclusion: patients with asthma who received education and long-term medication therapy management services achieved and maintained significant improvements, and had significantly decreased overall asthma-related costs despite increased medication costs that resulted from increased

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<p>Bunting BA, Smith BH, et al. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. <i>J Am Pharm Assoc</i> (2003) 2008;48(1):23-31. (YES)</p>	<p>Objective: Assess clinical and economic outcomes of a community-based, long-term medication therapy management (MTM) program for hypertension (HTN)/dyslipidemia over a 6-year period. Interventions: Cardiovascular or cerebrovascular (CV) risk reduction education; regular, long-term follow-up by pharmacists (reimbursed by health plans) using scheduled consultations, monitoring, and recommendations to physicians. Main outcome measures were clinical and economic parameters.</p>	<p>use.</p> <p>Data from 620 patients in the financial cohort and 565 patients in the clinical cohort were analyzed. Several indicators of CV health improved over the study – mean SBP, mean DBP, percentage of patients at BP goal, lowered mean LDL, percentage of pts at LDL cholesterol goal, lowered mean total cholesterol and mean serum triglycerides. The CV event rate declined by almost one-half during the study period. Mean cost per CV event was \$9,931 vs. \$14,343. CV medication use increased three-fold, but CV-related medical costs decreased by 46.5%. CV-related medical costs decreased from 30.6% of total health care costs to 19%. A 53% decrease in risk of a CV event and greater than 50% decrease in risk of a CV-related ED/hospital visit were also observed. Conclusions: Patients with HTN and/or dyslipidemia receiving education and long-term MTM services achieved significant clinical improvements that were sustained for as long as six years; a significant increase in the use of CV medications, and a decrease in CV events and related medical costs.</p>
<p>Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and health care costs. <i>Arch Intern Med</i> 1998 Aug 10-24;158(15):1641-7.</p>	<p>The objective was to compare newly anticoagulated patients who were treated with usual medical care (general medicine physicians) with those treated by a clinical pharmacist at an anticoagulation clinic (AC) for patient characteristics, anticoagulation control, bleeding and thromboembolic events, and differences in costs for hospitalizations and emergency department visits.</p>	<p>Results: When compared to usual medical care (UMC), patients treated at the anticoagulation clinic (AC) had fewer international normalized ratios greater than 5.0, spent more time in range, spent less time at an international normalized ratio greater than 5, and had fewer international normalized ratios less than 2.0. The AC group had lower rates of significant bleeding, major to fatal bleeding, and thromboembolic events. The AC group also demonstrated a trend toward a lower mortality rate. Significantly lower annual rates of warfarin-related hospitalizations and emergency department visits reduced annual health care costs by \$13,2086 per 100</p>

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		<p>patients. Additionally, a lower rate of warfarin-unrelated emergency department visits produced an additional annual savings in health care costs of \$2,972 per 100 patients. Conclusion: A clinical pharmacist-run AC improved anticoagulation control, reduced bleeding and thromboembolic event rates, and saved \$162,058 per 100 patients annually in reduced hospitalizations and emergency department visits.</p>
<p>Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. <i>J Am Pharm Assoc</i> 2003;43(2):173-84. (YES)</p>	<p>Changes in glycosylated hemoglobin (A1c) and serum lipid concentrations, changes in diabetes-related and total medical use, costs over time.</p>	<p>Mean A1c decreased at all follow-ups, more than 50% of patients demonstrated improvements at each follow-up, number of patients with optimal A1c increased at each follow-up, and &gt;50% improved in lipid levels. Costs shifted from inpatient and outpatient services from physicians to prescriptions, mean direct medical costs decreased by \$1,200 to \$1,872 per patient per year, and sick days decreased for one employer group, with increases in productivity estimated at \$18,000 annually.</p>
<p>Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. <i>J Am Pharm Assoc</i> 2003;43(2):149-59. (YES)</p>	<p>Assessment of short-term clinical, economic, and humanistic outcomes of pharmaceutical care services (PCS) for 85 patients with diabetes in community pharmacies. Pharmacists provided education, self-monitored blood glucose (SMBG) meter training, clinical assessment, patient monitoring, follow-up, and referral over seven to nine months. Outcomes: Change from baseline in the two employer groups in glycosylated hemoglobin (A1c) values, serum lipid concentrations, health-related quality of life (HRQOL), satisfaction with pharmacy services, and health care utilization and costs.</p>	<p>Results: A1c concentrations were significantly reduced. Significant dollars 52 per patient per month increase in diabetes costs, with PCS fees and diabetes prescriptions accounting for most of the increase. Patients experienced a non-significant but economically important 29% decrease in non-diabetes costs and a 16% decrease in all-diagnosis costs. Conclusion: A clear temporal relationship was found between PCS and improved A1c, improved patient satisfaction with pharmacy services, and decreased all-diagnosis costs. Findings from this study demonstrate pharmacists provided effective cognitive services and refute the idea that pharmacists must be certified diabetes educators to help patients with diabetes improve clinical outcomes.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Dole EJ, Murawski MM, et al. Provision of pain management by a pharmacist with prescribing authority. <i>Am J Health Syst Pharm</i> 2007;64(1):85-9. (YES)</p>	<p>Purpose: The clinical and financial outcomes of a pain clinic managed by a pharmacist with prescribing authority are described. Summary: Pharmacist clinicians in a for-profit, integrated health system recently received permission to bill for their services in certain ambulatory clinics. A pharmacist clinician, who had an individual DEA number and whose services are billable under New Mexico law, was chosen to assume the medication management responsibilities in a clinic where 90% of the patient population is treated for chronic non-cancer-related pain. No additional personnel were needed, and no additional space was required, eliminating overhead for the space and utilities needed for operating a clinic. The revenue generated was tracked by a medical billing system, and clinical outcomes were tracked using the clinic's database for patients' individual visual analogue scale (VAS) pain scores.</p>	<p>With the ability to bill for the pharmacist clinician's services, a new model for justification of clinical pharmacy services was developed for the ambulatory care clinics. Between June 2004 and June 2005, an average of 18 patients was seen by the pharmacist clinician each day. The clinic generated \$107,550 of actual revenue and saved the health plan over \$450,000. There was a consistent decrease in mean VAS pain scores with continued visits. Conclusion: Patients with chronic non-cancer-related pain were managed effectively by a pharmacist with prescribing authority and refill authorization in a pain management clinic. The favorable clinical outcomes, revenue generated, and cost savings achieved justified the pharmacist clinician's services in this health system.</p>
<p>Farris KB, Kumbera P, et al. Outcomes-based pharmacist reimbursement: reimbursing pharmacists for cognitive services part 1. <i>J Manag Care Pharm</i> 2002;8(5):383-93. (YES)</p>	<p>Methods: A cross-sectional descriptive study was completed using the claims submitted by pharmacists to summarize findings from the first year of operations of this outcomes-based pharmacist reimbursement program (OBPR). The program involved collaboration between pharmacy benefit managers (PBMs) and community pharmacists to improve medication use. Pharmacists were reimbursed for (1) converting therapeutic regimens to generic drugs or preferred formulary medications when a prescriber contact is required; (2) conducting patient education and follow-up after initiation of new medications, changes in drug therapy, or following an over-the-counter (OTC) consultation; and (3) resolving drug-therapy problems. An efficient, no-cost</p>	<p>Results: Data analysis for the first year of operation, July 1, 2000, through June 30, 2001, showed 11,326 enrollees obtained 124,768 prescriptions. The majority of individuals (n = 8335, 74%) received some intervention service. The majority (90%) of intervention services were patient education and follow-up on new prescriptions or changes in prescriptions. More than 200 individuals had drug-related problems. Conclusion: This unique system of outcomes-based pharmacist reimbursement permits community pharmacists to document and bill for cognitive services. It has demonstrated that PBMs and community pharmacists can work together to improve drug therapy, and it may reduce health care costs.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
	<p>billing system was created. The main outcome measures were descriptive statistics of prescriptions, intervention claims, and pharmacist participation in the program. Frequency distributions and descriptive statistics were used to summarize the first year of claims.</p>	
<p>Garrett DG, Bluml BM. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. <i>J Am Pharm Assoc</i> (2003) 2005;45(2):130-7. (YES)</p>	<p>Objective: Assess the outcomes for the first year following the initiation of a multisite community pharmacy care services (PCS) program for 256 patients with diabetes. Interventions: Community pharmacist patient care services using scheduled consultations, clinical goal setting, monitoring, and collaborative drug therapy management with physicians and referrals to diabetes educators. Outcomes: Changes in HbA1c; LDL; BP; flu vaccinations; foot screens; eye exams; patient goals for nutrition, exercise, and weight; patient satisfaction; and changes in medical and medication utilization and costs.</p>	<p>Results: Over the initial year of the program, participants' mean A1C decreased from 7.9% at initial visit to 7.1%, mean LDL-C decreased from 113.4 mg/dL to 104.5 mg/dL, and mean systolic blood pressured decreased from 136.2 mmHg to 131.4 mmHg. During this time, influenza vaccination rate increased from 52% to 77%, the eye examination rate increased from 46% to 82%, and the foot examination rate increased from 38% to 80%. Patient satisfaction with overall diabetes care improved from 57% of responses in the highest range at baseline to 87% at this level after 6 months, and 95.7% of patients reported being very satisfied or satisfied with the diabetes care provided by their pharmacists. Total mean health care costs per patient were \$918 lower than projections for the initial year of enrollment. Conclusion: Patients who participated in the program had significant improvement in clinical indicators of diabetes management, higher rates of self-management goal setting and achievement, and increased satisfaction with diabetes care, and employers experienced a decline in mean projected total direct medical costs.</p>



CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Jameson J, VanNoord G, et al. The impact of a pharmacotherapy consultation on the cost and outcome of medical therapy. <i>J Fam Pract</i> 1995;41(5):469-72. (YES)</p>	<p>This prospective, randomized trial investigated whether a single consultation by a clinical pharmacist with high-risk patients and their primary physicians would result in improved prescribing outcomes. Patients at risk for medication-related problems were identified and randomized to receive a pharmacotherapy consultation (consult group) or usual medical care (control group). Outcomes, including the number of drugs, number of doses per day, cost of medications, and patient reports of adverse effects, were recorded at baseline and at six months following the intervention.</p>	<p>Results: Fifty-six subjects were evaluable: 29 in the control group, and 27 in the consult group. Six months after the consultation, the number of drugs, the number of doses, and the 6-month drug costs all decreased in the consult group and increased in the control group; the net difference was 1.1 drugs (P = 0.004), 2.15 doses per day (P = 0.007), \$586 per year (P = 0.008). The side effects score improved by 1.8 points more in the consult group compared with the control group (P = not significant). Similarly, the prescribing convenience score in the consult group improved by 1.4 points more than that of the control group (P = not significant). Conclusions: This study demonstrated several important benefits of integration of a clinical pharmacist into a primary care setting, including improvement in cost and simplification of the medication regimen with no reduction in quality of care.</p>
<p>Johnston AM, Doane K, Phipps K, Bell A. Outcomes of pharmacists' cognitive services in the long-term care setting. <i>Cons Pharm</i> 1996;11(1):41-50. (YES)</p>	<p>Outcome measures: Number and type of interventions, change in drug therapy, change in medication cost, change in patient health.</p>	<p>Pharmacists made 3,464 interventions. Response rate for interventions requesting a response was 85.7%, with a 68% acceptance rate. Accepted recommendations resulted in a total cost savings of \$15,111.38 for the 1-month period. Accepted recommendations resulted in favorable health outcomes 99.5% of the time.</p>
<p>McLean W, Gillis J, et al. The BC Community Pharmacy Asthma Study: A study of clinical, economic and holistic outcomes influenced by an asthma care protocol provided by specially trained community pharmacists in British</p>	<p>Objectives: The study incorporated a care protocol with asthma education on medications, triggers, self-monitoring and an asthma plan, with pharmacists taking responsibility for outcomes, assessment of a patient's readiness to change and tailoring education to that readiness, compliance monitoring and physician consultation to achieve asthma prescribing guidelines. Methods: Thirty-three pharmacists in British Columbia, specially</p>	<p>Results: Compared with patients in the UC group, the results of those in the EC group were as follows: symptom scores decreased by 50%; peak flow readings increased by 11%; days off work or school were reduced by approximately 0.6 days/month; use of inhaled beta-agonists was reduced by 50%; overall quality of life improved by 19%, and the specific domains of activity limitations, symptoms and emotional function also improved; initial knowledge scores doubled;</p>



CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Columbia. <i>Can Respir J</i> 2003;10(4):195-202. (YES)	trained and certified in asthma care, agreed to participate in a study in which experienced pharmacists would have asthma patients allocated to enhanced (pharmaceutical) care (EC) or usual care (UC). Pharmacists less experienced were clustered by geography and had their pharmacies randomized to two levels of care; each pharmacy then had patients randomized to EC versus control, UC versus control or EC versus UC depending on their pharmacy randomization. 631 patients provided consent, of which 225 in EC or UC were analyzed for all outcomes. Patients were followed for one year.	emergency room visits decreased by 75%; and medical visits decreased by 75%. A patient satisfaction survey revealed the population was extremely pleased with their pharmacy services. Cost analysis reinforces the EC model, which is more cost-effective than UC in terms of most direct and indirect costs in asthma patients. Conclusion: Specially trained community pharmacists in Canada, using a pharmaceutical care-based protocol, can produce impressive improvements in clinical, economic and humanistic outcome measures in asthma patients. The health care system needs to produce incentives for such care.
Simpson SH, Johnson JA, Tsuyuki RT. Economic impact of community pharmacist intervention in cholesterol risk management: an evaluation of the study of cardiovascular risk intervention by pharmacists. <i>Pharmacoth</i> 2001 May;21(5):627-35.	The Study of Cardiovascular Risk Intervention by Pharmacists, a randomized, controlled trial in over 50 community pharmacies in Alberta and Saskatchewan, Canada, demonstrated a pharmacist intervention program improved cholesterol risk management in patients at high risk for cardiovascular disease. In a sub study, costs and consequences were analyzed to describe the economic impact of the program. Two perspectives were taken: a government-funded health care system and a pharmacy manager. Costs were reported in 1999 Canadian dollars.	Incremental costs to a government payer and community pharmacy manager were \$6.40/patient and \$21.76/patient, respectively, during the 4-month follow-up period. The community pharmacy manager had an initial investment of \$683.50. The change in Framingham risk function for the intervention group from baseline also was reported. The 10-year risk of cardiovascular disease decreased from 17.3% to 16.4% (p < 0.0001) during the four months. The intervention program in this study led to a significant reduction in cardiovascular risk in the intervention group during the 4-month follow-up period. The incremental cost to provide the program appeared minimal from both government and pharmacy manager perspectives. It is hoped that these results could support negotiations for reimbursement of clinical pharmacy services with payers.
Sturgess, IK, McElnay JC, et al. Community pharmacy based provision of pharmaceutical care to older patients. <i>Pharm</i>	Methods: A randomized, controlled, longitudinal, clinical trial with repeated measures was performed over an 18-month period, involving community pharmacies (five interventions and five controls) in Northern Ireland. Elderly,	Results: A significantly higher proportion of intervention patients were compliant at the end of the 18-month study and experienced fewer problems with medication compared to control patients (P < 0.05). There was little impact on quality of life and health care

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p><i>World Sci</i> 2003;25(5):218-26. (YES)</p>	<p>ambulatory patients (&gt; or = 65 years), taking four or more prescribed medications were eligible for participation. Patients attending an intervention pharmacy received education on medical conditions, implementation of compliance strategies, rationalizing of drug regimens and appropriate monitoring; patients attending control sites received normal services. A battery of clinical, humanistic and economic outcomes was assessed.</p>	<p>utilization. Conclusions: Pharmaceutical care provision to community-dwelling patients resulted in an improvement in medication compliance and evidence of cost-savings. Future pharmaceutical care studies may benefit from a more focused selective approach to data collection and outcomes measurement.</p>
<b>Cost Reduction</b>		
<p>Bootman JL, Harrison DL, et al. The health care cost of drug-related morbidity and mortality in nursing facilities. <i>Arch Intern Med</i> 1997;157(18):2089-96. (YES)</p>	<p>Objective: to assess the impact of pharmacist-conducted, federally mandated, monthly, retrospective review of nursing facility residents' drug regimens in reducing the cost of drug-related morbidity and mortality. Methods: Using decision analysis techniques, a probability pathway model was developed to estimate the cost of drug-related problems within nursing facilities. An expert panel consisting of consultant pharmacists and physicians with practice experience in nursing facilities and geriatric care was surveyed to determine conditional probabilities of therapeutic outcomes attributable to drug therapy. Health care utilization and associated costs derived from negative therapeutic outcomes were estimated.</p>	<p>Results: Baseline estimates indicate the cost of drug-related morbidity and mortality with the services of consultant pharmacists was \$4 billion compared with \$7.6 billion without the services of consultant pharmacists. Conclusions With the current federally mandated drug regimen review, it is estimated that consultant pharmacists help to reduce health care resources attributed to drug-related problems in nursing facilities by \$3.6 billion.</p>
<p>Brooks JM, McDonough RP, Doucette W. Pharmacist reimbursement for pharmaceutical care services: Why insurers may flinch. <i>Drug Benefit Trends</i> June 2000;45-62. (YES)</p>	<p>Researchers developed complex economic model to evaluate whether pharmaceutical care is cost-effective.</p>	<p>Researchers concluded that enrolling high-risk patients into pharmaceutical care programs can be of value to insurers if the savings incurred is more than the program expense. Based on the model, authors conclude that reimbursing pharmacists to provide pharmaceutical care is optimal if a relatively inexpensive patient screening method is available that enables insurers to limit visits to those patients who offer cost savings to the insurer.</p>

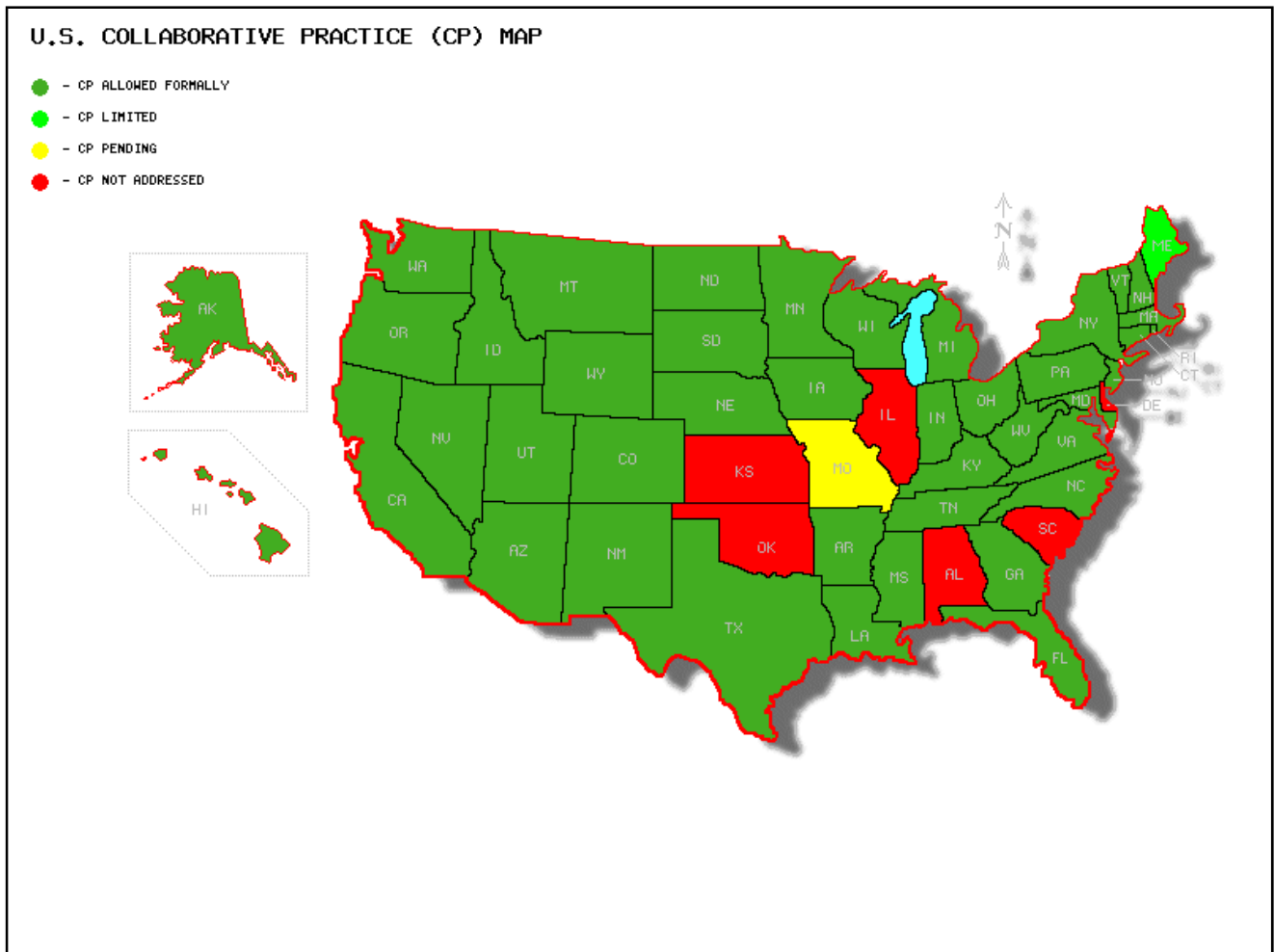
CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Christensen DB, Neil N, et al. Frequency and characteristics of cognitive services provided in response to a financial incentive. <i>J Am Pharm Assoc</i> 2000;40(5):609-17. (YES)</p>	<p>To determine the effects of a financial incentive on the number and types of cognitive services (CS) provided by community pharmacies to Medicaid recipients in the State of Washington. CS were reported using a problem-intervention-result coding system over a 20-month period.</p>	<p>Results: Study pharmacists documented an average of 1.59 CS interventions per 100 prescriptions over a 20-month period, significantly more than controls, who documented an average of 0.67 interventions (<math>P &lt; 0.05</math>) per 100 prescriptions. One-half (48.4%) of all CS were for patient-related problems, 32.6% were for drug-related problems, 17.6% were for prescription-related problems, and 1.4% were for other problems that did not involve drug therapy. A change in drug therapy occurred as a result of 28% of all CS documented in this demonstration. Changes were rarely (2.4%) due to generic or therapeutic substitution and almost always (90%) followed communication with the prescriber. The average self-reported time to perform CS was 7.5 minutes; 75% of interventions were <math>\leq 6</math> minutes. Considerable differences existed between study and control groups in the types of problems identified, intervention activities performed, and results of interventions. Conclusion: A financial incentive was associated with significantly more, and different types of, CS performed by pharmacists.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Christensen D, Trygstad T, et al. A pharmacy management intervention for optimizing drug therapy for nursing home patients. <i>Am J Geriatr Pharmacother</i> 2004;2(4):248-56. (YES)</p>	<p>The goals of this study were to determine: (1) the frequency with which recommendations were made by pharmacists in response to targeted profile alerts aimed at high-risk patients, (2) the frequency and type of drug therapy changes, and (3) the impact on drug-related quality and costs. Objective was to reduce polypharmacy in Medicaid recipients.</p>	<p>Prescription profiles were generated from Medicaid claims data and sent to consultant pharmacists for 9,208 patients in 253 nursing homes. Pharmacists returned 7548 (82%) of all profiles sent to them. After excluding 1,204 patients (13%) who were discharged or deceased, 6,344 patients (69%) remained for analysis. Baseline mean was 9.52 prescriptions per month, with mean drug cost of \$502.96 to North Carolina Medicaid program. Pharmacists offered a mean of 1.58 recommendations to prescribers. After physician consultation, &gt; or = 1 recommendation was implemented for 72% of patients with a change recommendation, 68% of whom experienced a switch to a lower-cost drug. After intervention, mean reduction in drug cost was \$30.33 per patient per month. Cost savings from one month alone covered the compensation paid to pharmacists for consultation efforts. Conclusion: This supplemental program of medication reviews for targeted nursing home patients resulted in a reduction of polypharmacy and was beneficial based solely on drug cost savings.</p>
<p>McMullin, ST, Hennenfent JA, et al. A prospective, randomized trial to assess the cost impact of pharmacist-initiated interventions. <i>Arch Intern Med</i> 1999;159(19):2306-9. (YES)</p>	<p>Objective: To assess the impact of pharmacist-initiated interventions on cost savings. Methods: Six pharmacists at a large university hospital recorded patient-specific recommendations for 30 days. All quality-of-care interventions were completed by the pharmacists, but those strictly aimed at reducing costs were stratified by drug class and randomized to an intervention or control group. Pharmacists contacted physicians with cost-saving recommendations in the intervention group, while control group patients were simply observed. Outcome measure: Drug costs after randomization.</p>	<p>Results: Most (79%) of the 1,226 interventions recorded were aimed at improving quality of care. The remaining 21% provided equivalent quality of care, but at less expense. These cost-saving interventions typically involved streamlining therapy to less expensive agents, discontinuing an unnecessary medication, or modifying the route of administration. The group randomized to receive a pharmacist's intervention had drug costs that were 41% lower than those in the control group (mean, \$73.75 vs. \$43.40; P &lt; 0.001). Interventions involving anti-infective agents had the greatest cost savings (mean, \$104.08 vs. \$58.45; P &lt; 0.001). For the institution, this extrapolates to an annual savings of approximately \$394,000 (95% confidence interval, \$46,000-\$742,000). As expected, these interventions had no</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
		<p>impact on length of hospital stay, in-hospital mortality, 30-day readmissions, or the need to re-administer the targeted medication or restart IV therapy. Conclusion: While interventions solely aimed at reducing costs represent a small portion of a pharmacist's activities, they can result in significant savings for an institution.</p>
<p>Schumock GT, Meek PD, Ploetz PA. Economic evaluations of clinical pharmacy services – 1988-1995. The Publications Committee of the American College of Clinical Pharmacy. <i>Pharmacotherapy</i> 1996 Nov-Dec;16(6):1188-208.</p>	<p>Literature review of 104 articles identified as economic assessments of clinical pharmacy services. The articles fell into four main categories: disease state management (4%), general pharmacotherapeutic monitoring (36%), pharmacokinetic monitoring services (13%), and targeted drug programs (47%).</p>	<p>The majority (89%) of the studies reviewed described positive financial benefits for the variety of clinical pharmacy services evaluated, and studies that were well-conducted were most likely to demonstrate positive results.</p>
<p>Walker S, Willey CW. Impact on drug costs and utilization of a clinical pharmacist in a multisite primary care medical group. <i>J Manag Care Pharm</i> 2004;10(4):345-54. (YES)</p>	<p>Objectives: To measure the cost and utilization outcomes of a pharmacist intervention in a primary care medical group operating under a financial risk contract with a health plan. Methods: A prestudy-poststudy design using national drug utilization for the comparison was employed to assess the impact of physician-prescriber education using information derived from prescriber-specific drug cost and utilization analyses. Drug costs were measured as net medical group costs per enrolled member per year (PMPY), the product of the average cost per prescription, and the number of prescriptions PMPY, over two year period.</p>	<p>Drug costs per patient per year increased 1.7% versus national increase of 31.2%. Prescriptions per patient per year increased 4% versus unchanged national rate. Cost per prescription decreased 2.1% versus national increase of 31.2%. Results due to increase in use of generics. Conclusion: A targeted educational program for physician-prescribers conducted by a clinical pharmacist working for a primary care medical group can reduce the expenditures for outpatient drug therapy by lowering the average cost per pharmacy claim.</p>

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
<p>Carmichael JM, Alvarez A, Chaput R, DiMaggio J, Magallon H, Mambourg S. (2004). Establishment and outcomes of a model primary care pharmacy service system. <i>Am J Health-Syst Pharm</i> 2004 Mar 1;61(5):472-82. (YES)</p>	<p>A primary care pharmacy practice model was established at a government health care facility in March 1996. The original objective was to establish a primary pharmacy practice model that would demonstrate improved patient outcomes and maximize the pharmacist's contributions to drug therapy.</p>	<p>Many outcomes studies have been performed on the pharmacist-initiated and managed clinics, leading to improved patient care and conveying the quality conscious and cost-effective role pharmacists can play as independent practitioners in this environment. A system using pharmacists as independent practitioners to promote primary care has achieved high-quality and cost-effective patient care.</p>

## Appendix C: U.S. Collaborative Practice Map



Appendix C displays a map of the United States. Color-blocked states depict where regulatory authority for pharmacists and physicians to collaborate exist. As of May 2011, 44 states have specific regulatory authority for pharmacist-physician collaboration, six states do not (AL, DE, IL, KS, OK, SC and DC), and one is pending legislation (Missouri). Maine is color-blocked but has limited application, (emergency contraception only).

The authors used the 2011 Survey of Pharmacy Law available from the National Association of Boards of Pharmacy as a source for this map. Under Section 28 - Miscellaneous State Pharmacy Laws, the answer to “May Pharmacists Initiate, Modify, and/or Discontinue Drug Therapy Pursuant to a Collaborative Practice Agreement or Protocol?” was utilized in determining Collaborative Practice status.

## Appendix D: Physician Survey

**Objective:** The Indian Health Service (IHS) National Clinical Pharmacy Specialist (NCPS) Program sought to obtain information from IHS physicians on their attitudes and perceptions 1) toward pharmacists that deliver patient care services, and 2) on the effectiveness of this model of health care delivery (in terms of patient outcome and health care system improvement). The goal of the survey was to collect data regarding physicians' perceptions in terms of effectiveness and impact of health care delivery working with NCPS pharmacists. This is the first physician-only survey completed regarding IHS clinical pharmacy specialists distributed IHS-wide and provides a unique look at physician attitudes within a mature (experienced) collaborative practice setting between physicians and pharmacists.

**Methods:** An internet-based survey tool was developed and distributed by the NCPS Program to sites that have IHS physicians who work with NCPS pharmacists practicing through collaborative practice agreements (CPAs). The survey was distributed to approximately 356 IHS physicians from IHS (n=20) and Tribal (n=13) facilities, spanning 13 states across nine of the 12 IHS geographic Areas. The respondent-driven sampling survey was disseminated by email.

**Results:** A total of 118 (33%) of 356 physicians responded. Physician demographics included diverse practice environments such as referral medical centers, small hospitals and ambulatory health clinics. Physicians reported CPAs were utilized to work with NCPS pharmacists. The majority of disease states managed by pharmacists included anticoagulation, dyslipidemia and tobacco cessation. However, many other conditions such as heart failure, pain management, asthma, chronic kidney disease, diabetes, infectious disease (HIV, tuberculosis, etc.) and alcohol abstinence clinics were also reported. Pharmacist-delivered patient care services included (but were not limited) to prescriptive, laboratory and assessment privileges. Many CPAs also include care coordination, patient follow-up and disease prevention/health promotion services. Overall, respondent physicians reported seeing positive patient and health system outcomes from these patient care services (96%). More specifically, respondents indicated that collaborative practice with pharmacists in their facilities helped them to improve overall primary care (88%). Additionally, they reported reductions in complications of therapy (77%). Respondents reported that pharmacist-based primary care clinics increase patient access to care and improved disease outcomes (75%). A decreased physician workload was noted by physicians (82%), which allowed them to shift the focus of care to more critically-ill patients. Physicians agreed that these pharmacists have adequate knowledge and training to provide clinical services to patients (85%) and that these services are necessary to optimize patient care (72%). Respondents felt that the scope of diseases managed by NCPS pharmacists was adequate (80%), while some even reported the scope was too narrow (11%).

Physicians also agreed or strongly agreed that services provided by pharmacists provide adequate evidence to recognize them as billable non-physician practitioners (76%). Several physicians commented that because of these pharmacist-delivered patient care services, they are able to expand the ability to provide primary care in underserved settings. Other comments included:



- “In the IHS, I depend on pharmacists to aid in providing the best quality of care for my patients.”
- “Pharmacy-based health care providers have been an integral part of the IHS during my tenure with the agency and have almost uniformly improved/elevated health status for Native Americans. These services should be recognized by CMS.”
- “In an extremely underserved setting, our clinical pharmacists provide excellent care to patients who would otherwise receive no care at all or less frequent and therefore lower quality care.”
- “Clinical pharmacists have greatly expanded the ability of our department to provide care in a very underserved setting.”
- “Our department [Family Medicine] feels that we could improve patient care/access/education/compliance by having more pharmacist clinicians in our clinics.”

**Conclusion:** An overwhelming majority of IHS physician respondents, who work with NCPS pharmacists delivering primary care services, believe this collaborative approach improves health outcomes, health care delivery, and access to care. To sustain and scale up these valued services to the patient and health care system, more formal recognition as health care providers and appropriate compensation mechanisms are essential.

[The survey tool is displayed as four pages; original format is electronic. The survey consists of Section 1-Purpose of Survey and NCPS Program Background, Section 2-NCPS Provider Survey (12 questions), Section 3-Demographics, and Section 4-Feedback.]

# 1. NCPS Program Background

This survey seeks the input of IHS, Tribal, and Urban (I/T/U) providers opinion on the clinical and administrative impact of pharmacists working in disease management roles. We will be collecting and analyzing this data to help justify our position and garner support for future (and expanded) compensation mechanisms for pharmacists providing primary care.

## Background:

The Indian Health Service (IHS) established a national certification process for IHS, Tribal, and Urban (I/T/U) and Bureau of Prison (BOP) pharmacists, the National Clinical Pharmacy Specialist (NCPS) Program. The NCPS has a national committee composed of practicing pharmacists and physicians from IHS and BOP. The NCPS program was established in response to meetings with the Center for Medicaid and Medicare Services (CMS, formerly HCFA) to ultimately promote enhanced patient outcomes, increase access to care and improve quality of care through the following:

- Define advanced scopes of practice for I/T/U and BOP pharmacists;
- Establish critical elements for developing collaborative practice agreements (CPA) within a physician-driven privileging system;
- Develop a review process to approve CPAs and clinical pharmacy specialists by a national group of subject matter experts to help ensure uniformity of scope and competence;
- Promote uniform clinical competency among I/T/U and BOP pharmacists;
- Review credentials, protocols, training, education and experience of I/T/U and BOP pharmacists and grant NCPS certification to recognize a pharmacist's local privileges that meet the specified national standards for certification;
- Establish the above elements to help promote universal recognition of NCPS pharmacists as billable providers.

## 2. NCPS Provider Survey

**\* 1. In your facility, do you have pharmacists practicing under collaborative practice agreements/protocols?**

- YES  
 NO

**\* 2. Have you ever (or currently) worked with a pharmacist who was NCPS certified?**

- YES  
 NO

If yes, describe your experience:

**3. If yes, what disease areas? Check all that apply**

- |   |  |
|---|--|
| <input type="checkbox"/> Anticoagulation        | <input type="checkbox"/> Lipid Management  |
| <input type="checkbox"/> Asthma                 | <input type="checkbox"/> Pain Management   |
| <input type="checkbox"/> Chronic Kidney Disease | <input type="checkbox"/> Tobacco Cessation |
| <input type="checkbox"/> Heart Failure          |  |

Other (please specify)

**4. What benefits in the clinical services that pharmacists provide have you seen in your facility? (Check all that apply)**

- Decreased physician workload
- Allows physicians to shift workload to more critical patients
- Increased patient access to care
- Reduction in complications of therapy (e.g. interactions, duplicate drugs, drug allergies, appropriate dosing, hospitalizations)
- Improved disease management outcomes
- Increased return on investment

Other (please specify)

**5. Mark the answer that best agrees with your opinion.**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you feel that NCPS certified pharmacists have adequate knowledge/training to provide clinical services for patients?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**6. Mark the answer that best agrees with your opinion.**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you feel that clinical services, such as disease management, provided by pharmacists are necessary to optimize patient care?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**7. Mark the answer that best agrees with your opinion.**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you feel that the collaborative practice has helped you to improve overall primary patient care?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**8. Mark the answer that best agrees with your opinion.**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Have you seen improvements in medication adherence in patients who are seen by clinical pharmacists?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**9. The NCPS Committee sets specific criteria that applicants and collaborative practice agreements must meet. Do you feel the standards and protocols set by the NCPS program to establish national uniformity for clinical pharmacy are adequate?**

- YES
- NO
- Not familiar with standards

**10. How do you feel about the scope of diseases that are managed by NCPS pharmacists?**

- Adequate
- Too broad
- Too narrow

**11. Mark the answer that best agrees with your opinion.**

**NCPS pharmacists provide a level of primary care which includes some prescriptive authority, laboratory monitoring and physical assessment.**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
From your experience, do you feel these services provide adequate evidence to recognize them as billable non-physician practitioners?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**12. Are there any additional comments?**

**3. Demographics**

**Please let us know where you practice.**

**Company:**

**City/Town:**

**State:**

**4. Feedback**

Thank you for completing this survey and for your support of the NCPS Program.

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