Report to the
New York State Legislature

The Impact of Pharmacist-Physician Collaboration on Medication-related Outcomes

Results of the New York State
Collaborative Drug Therapy Management
Pilot Project
As Required by Chapter 21 of the Laws of 2011

May 6, 2014

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EXECUTIVE SUMMARY

Following several years of consideration, the New York State legislature passed S2985/A4579. On May 17, 2011 Governor Andrew Cuomo signed these provisions into law as Chapter 21 of the laws of 2011. The act amended article 137 of the education law to permit certain pharmacists that practice in New York State's teaching hospitals to engage in collaborative drug therapy management (CDTM). The new law defined the parameters of practice in which pharmacists and physicians can voluntarily choose to collaborate, in order to attain more effective therapeutic outcomes. Under the terms of the law, CDTM is defined as "the performance of services by a pharmacist relating to the review, evaluation and management of drug therapy to a patient, who is being treated by a physician for a specific disease or disease state, in accordance with a written agreement or protocol with a voluntarily participating physician and in accordance with the policies, procedures, and protocols of the facility."

The act also requires the Education Department, in consultation with the Department of Health, to prepare a report to the legislature on the implementation of CDTM in New York State. The report shall review the "extent to which CDTM was implemented in New York State and shall examine whether and the extent to which CDTM contributed to the improvement of quality of care for patients, reduced the risk of medication error, reduced unnecessary health care expenditures and was otherwise in the public interest. The report may make recommendations regarding the extension, alteration and/or expansion of these provisions and make any other recommendations related to the implementation of CDTM pursuant to this act." The report that follows fulfills this requirement.

At the time of implementation of the act there were 93 teaching hospitals in New York State. Eleven of these sites chose to participate in CDTM demonstration projects, managing a total of 10 different disease states. However, a number of hospitals declined to formally participate in data-gathering for a variety of reasons, among them being a concern for implementation of provisions that, even if successful, would "sunset" in 2014.

Some other institutions chose to engage in CDTM practices without engaging in formal data collection. Fortunately a number of large, tertiary-care facilities determined to participate and their results are included in this report. In particular, this report documents improved medication compliance, reduced admissions/re-admissions to hospitals, improved quality of life, significant acceptance by physicians and projects significant cost savings. This report quantifies the results of institutions that incorporated CDTM practices in the area of anticoagulation therapy, and treatment of diabetes, heart failure, Human Immunodeficiency Virus (HIV), oncology and pulmonary diseases, each of which is summarized below.

ANTICOAGULATION

Warfarin, or Coumadin®, is the most commonly prescribed oral anticoagulant (blood thinner). Although highly effective for the treatment and prevention of dangerous blood clots, the drug's inherent complexities and potential for life threatening bleeding demand management by knowledgeable and skilled clinicians to maximize effectiveness and safety. This is the basis for the American College of Chest Physicians recommendation to utilize specialized anticoagulation clinics, which are often managed by pharmacists, to improve the quality and safety of anticoagulation care. For the CDTM demonstration project anticoagulation clinics were instituted at four sites throughout the state. A total of 841 patients were managed by pharmacists under collaborative protocols.

Control of anticoagulation, by a test called the international normalized ratio (INR) is necessary to achieve optimal therapeutic outcomes. The best measure of this control is described by the Percent (%) INR Time-in-Range (TTR). Numerous studies have shown that increases in TTR as little as 5% significantly impacts anticoagulation-related hospitalizations, emergency department visits and mortality. The results of this pilot project, which are consistent with previously published literature, demonstrate pharmacist anticoagulation management achieves higher TTR values (71.4 – 84.6%) than expected with usual care (51 – 76%). These differences translate into reductions in adverse events and mortality as well as health care expenditures. Based on the current disease burden of atrial fibrillation (a common reason for anticoagulation) in NYS, it is estimated that increased access to pharmacist-managed anticoagulation could potentially translate into prevention of 9,000 deaths, 15,000 adverse events and a $214 million savings annually.

DIABETES

In 2011, the Centers for Disease Control and Prevention estimated that 25.8 million people in the US (or 8.3% of the population) are affected by diabetes. The percent affected in NYS is even greater, estimated to be 10.4%. Accordingly, the NYS Department of Health has set improved diabetes management and increased access to high-quality chronic disease preventive care and management as part of the 2013 – 2017 prevention agenda**.** Despite the importance of attaining treatment goals, many adult diabetics do not receive guideline-recommended therapy. Comprehensive diabetes management programs created to address this problem have demonstrated improvement in clinical and economic outcomes. Many of these programs have included pharmacist-collaborators.

Four hospital-based ambulatory care clinics implemented CDTM programs for the care of diabetic patients. A total of 300 patients were managed, with data reported on 195. The primary objective of the CDTM programs was to reduce Hemoglobin A1C , a blood test used to determine the effectiveness of diabetes treatment. Decreasing HbA1C to within the established therapeutic targets (< 8%) has been shown to reduce complications as well as overall cost of care. The NYS Prevention Agenda goal for increasing the percentage of patients achieving this target is 7% - 10% over five years. The patients managed by the collaborating pharmacist showed an increase in the percentage achieving the therapeutic target by 22% to 39% over a period of four to 12 months. This far exceeds the NYS prevention agenda goal in a fraction of the time. In addition to improved clinical outcomes, the superior results demonstrated by the pharmacist's management would be anticipated to provide economic benefits. Projected estimates of cost savings for the 195 patients receiving care under the CDTM initiatives is $147,000 - $537,000 annually. Extrapolating this success to the 10.4% of NYS adults with diabetes could result in an annual savings of as much as $1.5 to $5.3 billion.

HEART FAILURE

Heart failure is a major cardiovascular syndrome that affects over five million people in the United States. It is a significant cause of hospitalization and subsequent readmissions, costing New Yorkers over two billion dollars annually. Suboptimal medication utilization, which includes inappropriate medication regimens and poor medication adherence, is a major driver of disease progression and often leads to acute decompensation and hospitalization. Given the fact that medication plays such an important role in the management of heart disease and that up to 50% of patients are non-adherent to therapy, the inclusion of interventions to improve adherence such as by pharmacist collaborations in CDTM will aid in therapy optimization.

Collaborative Drug Therapy Management Programs in heart failure were conducted at two sites. In addition to providing patient focused counseling on medication adherence, the pharmacists optimized therapeutic outcomes by adjusting medication regimens and monitoring physical signs and symptoms as well as ordering and monitoring laboratory results.

Both CDTM heart failure pilot programs demonstrated a substantial reduction in readmission rates at 30 days (9% and 0, respectively), especially when compared to the government-reported nationwide readmission rate of 24%. This represents a decrease in re-hospitalizations of at least 62%. Additionally, readmission rates at 90 days were substantially lower, ranging from 6– 15%.Utilizing cost data provided by the AHRQ Health care utilization project and NYS DOH the expected economic impact for the patients managed by the demonstration project would be $319,000. Extrapolating this to NYS expenditures would give a potential reduction of $600,000,000 annually.

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

The Department of Health and Human Services (DHHS) guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents recommend the use of a multidisciplinary team approach to improve patient adherence to antiretroviral therapy, including a pharmacist. As part of the HIV multidisciplinary team, pharmacists can provide not only strategies for medication adherence, but can also provide therapeutic care plans for chronic disease state management.

The pilot CDTM program in HIV demonstrates that pharmacists play a significant role in the development of appropriate medication regimens and in improving the understanding of and adherence to medications for both HIV as well as concomitant disease states. Patient perceptions indicate that they believe the pharmacist plays a significant role in their care and improves their understanding of medications and the need for adherence to their drug regimens.

ONCOLOGY

Integrated clinical pharmacists in the hematology/oncology setting initiate and manage supportive therapies, provide therapeutic drug monitoring, manage drug interactions, and facilitate access to high cost chemotherapy medications. Through the implementation of CDTM programs, clinical pharmacists at two pilot sites were able to serve as an extension of the physician's care and utilize their specialized drug therapy expertise to provide supportive care for cancer patients undergoing intense chemotherapy treatments. Chemotherapy complications such as cancer pain, nausea and vomiting, constipation, and diarrhea were successfully managed by a clinical pharmacist.

Both oncology based CDTM programs demonstrated benefits to patients and physicians. Interventions initiated by the pharmacist resulted in optimization of efficacy and safety measures which will likely translate into improved patient outcomes. Satisfaction was high for both physicians and patients, with all physicians surveyed strongly agreeing that such programs should be continued.

ASTHMA

Half of the New Yorkers with asthma have disease that is not well controlled, and half of those patients do not use their mediations appropriately. The results of the CDTM program demonstrate that medication utilization and adherence are more than twice what would have been expected, and that improvements in asthma medication regimens were appropriately identified and addressed by the pharmacist. Although the data collected in this pilot project did not include information about hospitalizations, published historical data indicate that through improved adherence to asthma medication regimens, pharmacist-managed asthma programs have shown a reduction in the number of hospital and emergency department visits by 30 to 75%. Extrapolating this data to approximate the economic impact of pharmacist-managed asthma in NYS reveals an annual potential savings of $150 – 400 million dollars.

PATIENT AND PRACTITIONER SATISFACTION

Patient and provider satisfaction were previously stated for both HIV and Oncology patients. In addition to the disease-specific survey data, patient satisfaction surveys were conducted at five of the CDTM sites. A total of 131 surveys were received. All respondents described a positive professional relationship with their pharmacist with 82% indicating the relationship was excellent. When asked if working with their pharmacist improved their understanding of their disease and medication regimen, 99% of the patients responded in the positive. Ninety-eight percent of the patients surveyed felt that the time spent with the pharmacist was adequate to discuss their medication related concerns. The majority (95%) of patients rated the quality of care received by their pharmacist as excellent. Finally, 96% of patients felt their care improved as a result of having a pharmacist on their health care team. Several patients chose to provide additional comments, and are included in the report.

REPORT CONCLUSION

The CDTM demonstration projects undertaken pursuant to Chapter 21 of the Laws of 2011 suggested positive clinical, therapeutic and fiscal advantages of team-based delivery of care, with CDTM as a key facet. Satisfaction surveys demonstrated that CDTM in these settings was supported not only by pharmacists, but physicians and patients as well. These findings are consistent with a 2011 Report to the United States Surgeon General, prepared by the Office of the Chief Pharmacist entitled “Improving Patient and Health System Outcomes through Advanced Pharmacy Practice”.

INTRODUCTION

Collaborative Drug Therapy Management (CDTM) Legislation in NYS

Bills introduced in New York State during five legislative sessions over ten years resulted in an act to amend the education law in relation to authorizing pharmacists to perform collaborative drug therapy management with physicians in certain settings. The resulting legislation (A04579, Canestrari/S02985, LaValle) authorizing certain pharmacists to engage in Collaborative Drug Therapy Management (CDTM) within New York State teaching hospitals and affiliated clinics was signed into law by Governor Andrew Cuomo on May 17th as Chapter 21 of the Laws of 2011.

A "teaching hospital" was defined as any hospital licensed pursuant to Article 28 of the Public Health Law that is eligible to receive direct or indirect graduate medical education payments. The definition includes diagnostic centers, treatment centers and hospital-based outpatient departments, although residential health care facilities and nursing homes were specifically excluded.

Pharmacists engaging in CDTM activities utilized written agreements or protocols with participating physicians to manage drug regimens of patients being treated by those physicians for a specific disease or disease state. Managing drug regimens could include adjusting the drug, drug strength, frequency of administration, and/or route of administration. Pharmacists may also order and evaluate clinical laboratory tests related to drug therapy management for the specific disease or disease state being treated.

The current law designates CDTM as a Demonstration Project and requires the submission of this report in May 2014 documenting the impact of CDTM on patient care prior to the law's sunset in September of 2014.

Overview of the Scientific Evidence Supporting CDTM

While medication therapy has always been one of the foundations of health care delivery, the Accountable Care Act and its focus on appropriate management of chronic diseases has made medication therapy more important than ever. The ability to appropriately manage increasingly complex drug therapies is essential to the outcome of patients as well as to the efficiency and economic performance of our health care system. The goal of Collaborative Drug Therapy Management (CDTM) is to maximize the expertise of pharmacists in the area of medication management to achieve optimal patient care outcomes associated with appropriate medication use.

First implemented in the Federal Indian Health Service in 1960, the concept of CDTM has expanded over the last 50 years to be recognized as the standard of practice in 46 states and the Veterans Administration System. The timeline and extent of CDTM implementation throughout the US is outlined in figures 1 and 2.

The specific scope of pharmacy practice varies among the states, but pharmacists consistently apply their specific knowledge as medication experts to complement the roles of other collaborating professionals. In essence, they act as physician enhancers, not as physician substitutes or extenders. Demand for this type of CDTM services continues to grow and is in fact advocated for by nationally recognized health care leaders such as Terry McInnis, MD, MPH, co-lead for the Medication Management Taskforce for the Patient-centered primary care collaborative (PCPCC), who has called pharmacists "the most transformative force in improving health for patients and reducing costs".

Figure 1. Timeline of National Adoption of CDTM Regulations

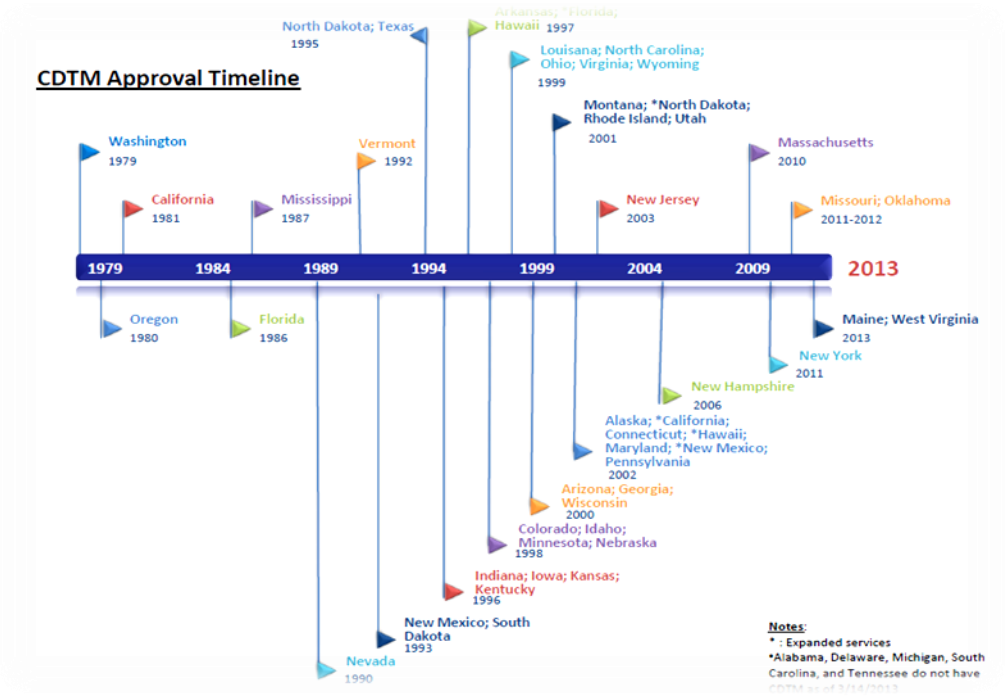
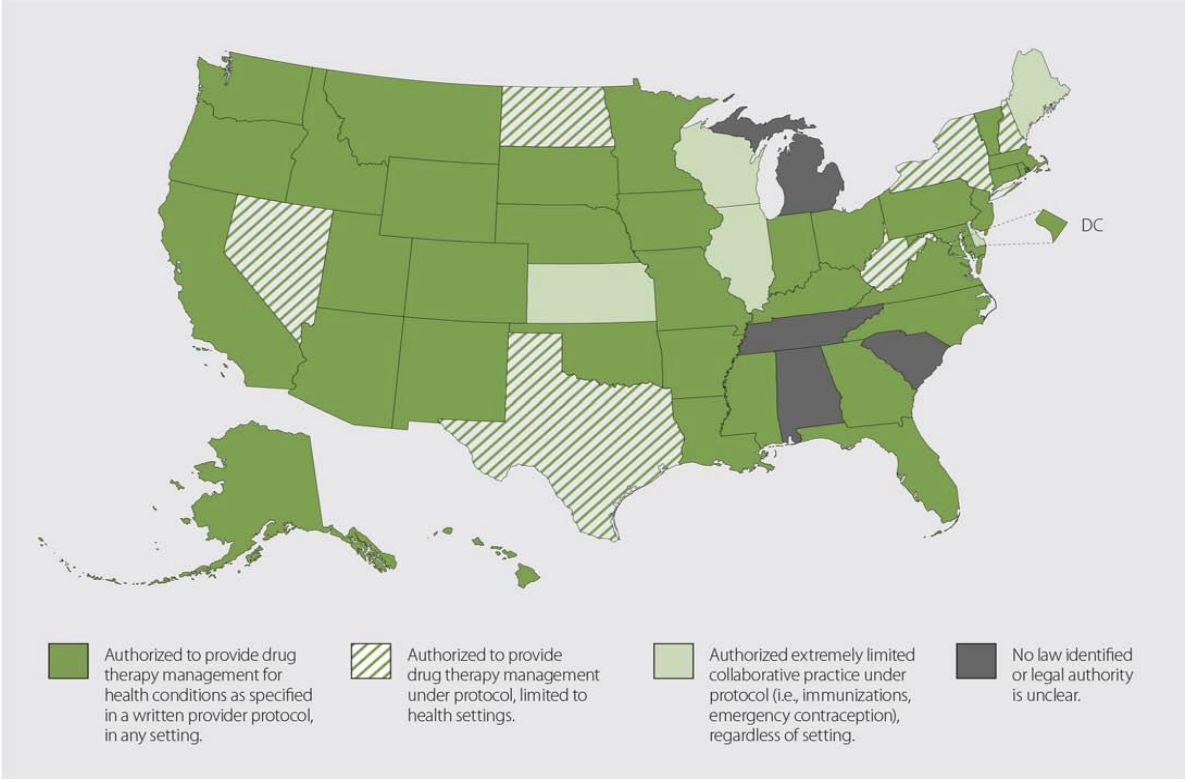


Figure 2. Map of States with Laws Authorizing Pharmacist Collaborative Practice Agreements, 2012 (Centers for Disease Control and Prevention)



The current pharmacy curricula is a complex mix of pharmaceutical sciences, health sciences, epidemiology, pathophysiology, therapeutics, physical assessment and other related coursework leading to a Doctor of Pharmacy (PharmD) degree. In addition to didactic learning, the Accreditation Council for Pharmacy Education, (ACPE) which accredits all 131 colleges of Pharmacy in the United States requires that PharmD candidates spend one third of their professional studies on clinical rotations in all facets of the health care delivery system. According to the American Society of Health System Pharmacists, nationally, nearly half of graduating pharmacists pursue post-graduate residency training and this number is expected to increase. In addition, clinically trained pharmacists frequently pursue rigorous board certifications in specialties such as pharmacotherapy, ambulatory care, diabetes management and several more. As such, today's pharmacist is regarded as a medication expert and well-prepared to collaborate with prescribers to optimize therapeutic outcomes.

The numbers and areas of specialty of CDTM practices vary throughout the country, and the body of evidence that supports the role of pharmacists providing clinical services with associated economic, clinical and humanistic outcomes continues to expand. Scientific studies supporting collaborative programs in the provision of health care are published with increasing frequency, however the most comprehensive and influential document that discusses the outcomes associated with CDTM is the 2011 report to the U.S. Surgeon General from the Office of the Chief Pharmacist (Appendix A).

The report*, Improving Patient and Health System Outcomes through Advanced Pharmacy Practice: A Report to the Surgeon General*, definitively states that pharmacists are effective and integral to health care as primary care providers as proven by many published evidence-based studies. It strongly supports the advanced patient-care roles of pharmacists and makes the case for payment for the services they provide. The report also states that pharmacists can be more effectively utilized in the 21st century to expand access to care as required under health care reform. It cited 55 outcomes-based clinical studies (including meta-analysis of many more studies) showing that pharmacists are effective health care providers and contributed to positive outcomes in both ambulatory and hospital-based clinics. Regardless of the setting or the disease state, the addition of clinical pharmacist services in the care of patients resulted in improved care with no evidence of harm.

The Surgeon General recognized and endorsed the report findings and recommended that leadership explore ways to optimize the pharmacist's role in the health care system through collaborative practice models, as essential members of the healthcare team, and as additional providers of primary care.

Participating Institutions

Pursuant to Chapter 21 of 2011, collaborative practice demonstration projects were instituted at 11 sites across New York from Buffalo to New York City. A total of 10 different disease states were managed at these sites. Data was collected and submitted in accordance with pre-specified endpoints relevant to the disease state managed. In certain circumstances, as outlined in the report, additional information was provided beyond what was originally requested. In addition, limited resources and late implementation prevented collection and submission of data for all programs.

Institution / Location	Program	Data Submitted	Number of Patients
Anthony Jordan Health Center Rochester	Diabetes	Yes	60
Bassett Healthcare Network Cooperstown	Anticoagulation	Yes	503
Bronx-Lebanon Hospital Center Bronx	Heart Failure	Yes	19
Brooklyn Hospital Brooklyn	Anticoagulation	Yes	174
	Antimicrobial Stewardship	No	
	Asthma	Yes	25
	Diabetes	Yes	35
	Heart Failure	No	
	HIV	Yes	864 visits
	Smoking Cessation	No	
Kingsbrook Jewish Medical Center Brooklyn	Anticoagulation	Yes	43
	Cardiovascular Risk Reduction	No	
	Pharmacotherapy	No	
	Smoking Cessation	No	
Memorial Sloan Kettering Cancer Center New York	Oncology	Yes	2306*
Montefiore Medical Center Bronx	Heart Failure	Yes	59
Rochester General Hospital Rochester	Diabetes	Yes	24
Roswell Park Cancer Institute Buffalo	Oncology	Yes	12
United Health Services Binghamton	Anticoagulation	Yes	121
Upstate Medical Center Syracuse	Anticoagulation	No	
	Diabetes	Yes	76

*Indicates number of interventions

RESULTS

Anticoagulation

As part of the CDTM Demonstration project, a total of 841 patients received anticoagulation management by pharmacists at the following institutions: Bassett Healthcare Network (503), Brooklyn Hospital (174), Kingsbrook Jewish Hospital (43) and United Health Services of Binghamton (121). The methods for benchmarking and study parameters are outlined below. These results demonstrate potentially significant reductions in morbidity and mortality as well as significant reductions in health care expenditures if extended to other sites across the State.

Background

Under the New York State Collaborative Drug Therapy Management Provision, pharmacists across the State have been caring for patients and practicing in Anticoagulation Management Clinics. Anticoagulation (blood thinning) therapy is prescribed for a number of health conditions, including:

- Deep Vein Thrombosis (DVT) – blood clots in the leg(s)
- Pulmonary Embolism (PE) – blood clots in the lung(s)
- Prevention of Stroke due to irregular heartbeats (known as Atrial Fibrillation or A. Fib) or artificial (mechanical or replacement tissue) heart valves.
- Prevention of Mural Thrombi (blood clots in the heart that lead to PE or Stroke) which can develop after heart attacks or in patients with Congestive Heart Failure (CHF).

Warfarin, also known by the brand name Coumadin®, is the most commonly prescribed oral anticoagulant. It is a very effective medication when managed properly, but has the potential for patients to develop devastating bleeding or clotting consequences if not managed by qualified clinicians. Likewise, each patient, due to biological differences, requires individualized dosing of the medication, regular monitoring to assess and manage for drug-drug and drug-dietary interactions, making drug therapy management more complex.

Pharmacists, as experts in drug-drug interactions, drug-dietary interactions and complex medication dosing, are uniquely qualified to manage this high-risk medication. As such, the American College of Chest Physicians recommend the use of specialized anticoagulation clinics to improve the quality and safety of anticoagulation care as part of their National Guidelines.[1]

Pharmacists engaged in CDTM practices in anticoagulation, have a common mission and scope to:

- Provide safe and effective management of anticoagulation therapy for outpatients.
- Increase Patient Safety by preventing serious complications, maximizing therapeutic outcomes and reducing healthcare costs associated with such adverse events.
- Provide comprehensive and ongoing education to patients, families and healthcare providers.
  - This measure is consistent with Hospital Regulatory (i.e. The Joint Commission) and Centers for Medicare and Medicaid Services (CMS) charges.
- Increase access to patient care for high-risk patients prone to devastating complications.
- Increase the availability of providers to care for patients.
  - Literature reveals that for each patient managed by an anticoagulation management services (AMS), 13 minutes of eligible patient-care time for staff members, and four minutes of physician provider time is added back to the providers' day.[2]
- Provide a mechanism to improve patient access to high quality care in a cost-effective manner.
- Provide continuity of care in the medical home model as patients transition from the inpatient to outpatient setting.
- Assist in approved research and quality-improvement programs related to anticoagulation, as reported in national literature.

Background: Impact of Pharmacist Managed Anticoagulation on Patient Outcomes

A test called the international normalized ratio (INR) is used to determine if anticoagulation with warfarin, the drug of choice for outpatient anticoagulation, is maintained at the appropriate level. The effectiveness of therapy is followed over time by a measure called the Percent (%) INR Time-in-Range (TTR). This measurement is a percentage (reference value 100%) of the anticoagulation treatment period (i.e. number of days) the patient was within their desired therapeutic range. The higher the percentage, the more often the patient is within their desired range, and the safer and more effective therapy becomes.

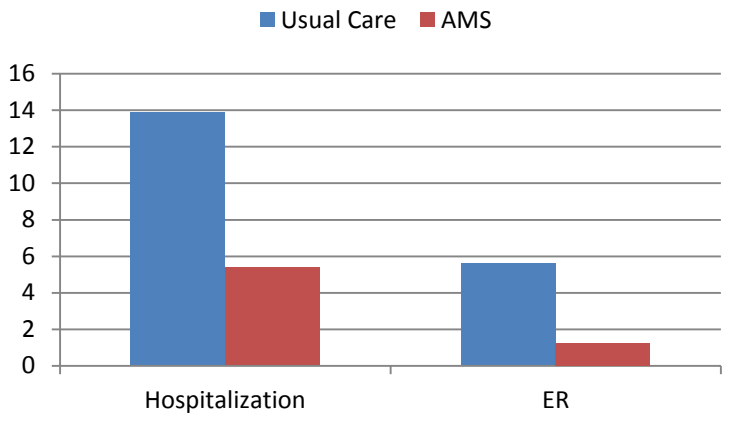
The TTR is a well-documented surrogate outcome for the complications relating to anticoagulation therapy.[3-13] If such therapy is suboptimal, patients may experience a thrombotic (clotting) event. Likewise, if the anticoagulation therapy is excessive, hemorrhagic (bleeding) complications may ensue. Numerous studies have shown that increasing TTR as little as 5%has significant impact on anticoagulation-related hospitalizations, emergency department (ED) visits and mortality.[3,5,7-8,11,13-14] Pharmacist-managed anticoagulation has been consistently shown in studies to achieve higher TTRs in comparison to usual care (standard care).[3,12-23] (Table 1)

Table 1. Time-in-Therapeutic Range with usual vs. pharmacist care

Model of Care	Time in Therapeutic Range[3,12 23]
Pharmacist Collaborative Drug Therapy Management	64-82%
Physician Management (Usual Care)	51-76%

Due to the extensive evidence supporting a pharmacist managed anticoagulation model, Basset Health Care implemented a physician-supervised, pharmacist directed anticoagulation clinic prior to the enactment of CDTM in NYS. Results from this model demonstrated that when compared to usual care (UC) **pharmacist managed anticoagulation (AMS)** improved TTR (57.4% UC vs. 83.6% AMS) and decreased anticoagulation-related adverse events resulting in a substantial ***reduction in hospitalizations*** and ***emergency room visits*** (61% and 67% respectively) [13] (Figure 1). Although able to exceed expectations in terms of patient outcomes, this model is not as efficient as CDTM. Incorporating anticoagulation management into a collaborative practice agreement allows the pharmacist to expedite the care provided and ultimately expand the provision of services to a greater number of patients.

Figure 1. Bassett Health Care study results: Rates of Hospitalizations and Emergency Room (ER) visits with usual vs. Pharmacist care (AMS)



The mean cost per hospitalization was $10,389.03 for an average length of stay of 4.75 days. The mean cost per 1-day ER visit was $1,198.09. Based upon the event rates for hospitalizations and ER visits, had the AMS patients been managed for a one year period under the Usual Care model, 26.9 hospitalizations and 13.9 ER visits would have been incurred. Based on the mean visit costs, the cost-avoidance associated with this change is $278,945.46 in hospitalization and $16,653.45 in ER costs, staggering savings in a patient population of only 500 patients.

This data is consistent with a larger 2011 study of 67,000 pharmacist-managed patients in the Veterans Administration System, **where TTR improvements of 5% and 10% markedly reduced adverse events, as seen below.**[14]

Table 2. Annual Health Outcomes of Pharmacist-CDTM Managed Anticoagulation per 67,000 patients in the Veterans Administration[14]

Measure	Outcome at 5% increase in TTR	Outcome at 10% increase in TTR
Adverse Events Prevented	1114	2087
Number of Deaths Avoided	662	1233
Number of Quality-Adjusted Life Years Gained	863	1606
Healthcare Dollars Saved ***(per 67,000 patients)***	$15.9 million	$29.7 million

Thus, Time in Therapeutic Range (TTR) is an important marker when considering quality of Anticoagulation-Related Care, with numerous direct and indirect impacts on patient care and as well as cost to the healthcare system. (Tables 3 and 4)

Table 3: Benefits of Properly Managed Anticoagulation[24]

Direct Benefits
Reduction in Adverse Events
Decreased use of hospital and medical services
Increased access to medical care
Indirect Benefits
Patient compliance and satisfaction
Increased patient productivity
Improved quality of life

Table 4: Cost Associated with Mismanaged Anticoagulation[24]

	Approximate Cost Estimates PER EVENT	
	Bleeding Events	**Thromboembolic (Clotting) Events**
Resolution	$4,000	$6,000
Death	$8,000	$12,000
Long-Term Morbidity	$14-24,000	$21-26,000

Results

CDTM Anticoagulation management programs were instituted at five sites, with four submitting data as summarized below, with a comparison to usual care values reported in the literature (Table 5). The anticoagulation management of the 841 patients included in the evaluation demonstrated TTRs (71.2 – 84.6%) previously associated with optimal patient outcomes.[12–23] These results would be expected to prevent adverse effects, reduce mortality and decrease expenditures. (Table 6)

Table 5. Summary on 2012 Calendar Year CDTM Demonstration Programs

	Bassett Healthcare	Brooklyn Hospital	Kingsbrook Jewish	United Health	Usual Care
Number of Patients Served	503	174	43	121	
Age Range (years)	25-97	23-91	22-88	35-88	
Number of Medicaid Patients	6	16	NR	25	
Number of Medicare Patients	393	60	19	95	
Number of ADEs *(per 100 patients)*	4.97	3.45	2.32	0.82	19.5
TTR	**84.6%**	**75.1%**	**71.2%**	**Unable to report**	**57.4%**

ADE = Adverse Drug Event (bleeding/clotting secondary to anticoagulation.)
TTR = Time in Therapeutic Range. Per the literature standard, data is reported as +/- 0.2.

Table 6. Aggregate Data for Pilot Project Compared to Usual Care, Annual Outcomes[13-14]

Parameter	Result
Mean TTR	**77%**
Adverse Events Prevented	**52**
Number of Deaths *Avoided*	**31**
Number of Quality-Adjusted Life Years *Gained*	**40**
Healthcare Dollars *Saved*	**$746,000**
Total Number of ADEs *per 100 patients*	**3.9**
Reduction **versus Non Collaborative–Practice Management**	**80%**

ADE = Adverse Drug Event (bleeding/clotting secondary to anticoagulation.) TTR = Time in Therapeutic Range
Estimates are based on usual care values listed in Table 5

The above data confirm that Anticoagulation Management, via Pharmacist-Physician Collaborative Drug Therapy Management in New York State is a successful quality and safety program for patients (Table 6). Direct benefits to the healthcare system are also demonstrated via the ***reduction of adverse events*** as compared to physician management (usual care) Practice Management with Pharmacists, which ***avoid a significant number of hospitalizations, emergency department visits and deaths.*** This not only improves the quality of care of New Yorkers, but also significantly **REDUCES** healthcare costs. Additionally, the above institutions have found implementation of the CDTM programs to be financially sustainable.

Currently, such safety initiatives via CDTM are only available at Article 28 Facilities, which serve only a portion of anticoagulated patients in New York State. The demonstration project shows dramatic safety benefits, noting that the impact is based on a very limited number of patients. The quality improvement organization IPRO, which contracts with the Centers for Medicare and Medicaid Services to provide safety programs to members of New York, notes that there are approximately 242,000 patients 65 and older in New York State on warfarin for Atrial Fibrillation. Although this represents only a portion of the patients on anticoagulation in New York, if the CDTM legislation is expanded beyond Article 28 institutions, the potential safety impact could be quite significant, including:

- More than 15,000 adverse events could be prevented annually
- Greater than 9,000 deaths could be avoided annually
- Approximately11,600 quality-adjusted life years gained
- Cost-savings of $214 million ANNUALLY in New York State

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Diabetes

As part of the CDTM demonstration project a total of 195 patients with diabetes were followed at four institutions: Anthony Jordan Health Center in Rochester (60), the Brooklyn Hospital (35), Rochester General Hospital (24) and Upstate Medical Center in Syracuse (76). This group was especially ethnically diverse. The results demonstrated exceptional, accelerated improvements over a four month – 1 year period of comparison, and achieved measurable improvements far in excess of the desired NYS Prevention Agenda Goal by 2017.

Background

An estimated one out of every 12 adult New Yorkers has diabetes and at the current trajectory, these numbers are expected to rise.[1] In an attempt to address this issue, New York State Department of Health (NYS DOH), through the NYS Prevention Agenda for 2013-2017, has included diabetes management as part of the focus on chronic disease prevention and management. Goals of this initiative are to reduce the prevalence of diabetes from the current staggering 10.4% down to 5.7%, and to increase the percentage of adult diabetics who have "good diabetes control" by 7% -10%.

Despite broad-based agreement on how to manage diabetes, a significant portion of adult patients with diabetes do not achieve guideline-recommended levels of glucose control or receive comprehensive medical care. Comprehensive medical care includes the following:

- Eye exams
- Foot exams
- Vaccinations
- Smoking cessation counseling
- Hypertensive management and/or kidney protection utilizing therapeutic medication classes such as angiotensin enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) to achieve a targeted blood pressure
- Cholesterol management with a statin medication to achieve a targeted cholesterol level or at minimum a 30%-40% reduction in targeted cholesterol values

Reasons behind the inability to achieve standards of care and goals of therapy are complex and not fully understood. However it is appreciated that part of the challenge is the inability to implement all the elements of a comprehensive disease management program including policy development, staffing, outcomes analysis and database management. A publication by Beaulieu et al highlights the challenging economic model behind implementing quality diabetes disease state management programs.[2]Nevertheless numerous publications indicate that comprehensive diabetes management programs improve clinical and economic outcomes, with many of these publications supporting the benefit of pharmacists as collaborators.[3-10] Consider the following:

- The Asheville Diabetes project, including its Community Pharmacy Diabetes initiative, assessed long term clinical and economic outcomes of a Diabetes Care Program and found that total mean direct medical costs decreased by $1,200 to $1,872 per patient per year.[4]
- De Lissovoy et al, through a computer simulated modeling program, showed that a reduction in diabetes-related complications can substantially reduce direct medical costs when Hemoglobin A1C (HbA1c) is maintained at a level of< 8% ("good diabetes control") compared with 10%.[5]

- For patients with diabetes as the primary or secondary diagnosis at admission managed by a clinical pharmacist, the post-intervention costs ($636 ± $1,438 [median = $0]), for inpatient hospitalization and ED admissions were significantly lower than pre-intervention costs ($2,434 ± $4,612 [median]), p=0.015.[15]
- A recent study demonstrated that, after a period as short as 12 weeks, improved glycemic control can achieve a measurable decrease in healthcare utilization, a reduction in days of restricted activity, and improved quality of life.[6]

Pharmacists, as experts in pharmacology and medication therapy are effective collaborators with physicians and other health care providers to optimize medication management and outcomes. Diabetes is a complex disease that not only requires management of high blood sugars with high risk medications (i.e., insulin and drugs that lower blood sugar) but also requires the appropriate selection and monitoring of medications that target the high cardiovascular risk associated with diabetes. The importance of avoiding adverse drug effects (especially low blood glucose) is not only important in regards to patient safety, but data from recently published clinical trials suggest that low blood glucose may be associated with the neutral or even adverse cardiovascular outcomes seen in diabetic patients in spite of improved glucose control and cardiovascular parameters.[7-9]The delicate balance of risk-benefit ratios in managing the complex disease adds to the challenge of achieving desired targets in diabetic patients and adds to the support that pharmacists skilled in the management of pharmacotherapy can collaborate with the doctors and patients to minimize risk and optimize care.

Demographic Data

After inception of CDTM legislation in 2011, four hospital-based ambulatory care clinics implemented CDTM programs for the care of diabetic patients. Sites include:

- Site 1 - Anthony L. Jordan Health Center (AJHC), Rochester, NY
- Site 2 - Upstate Medical University Internal Medicine Clinic (Upstate), Syracuse, NY
- Site 3 - Rochester General Health System Outpatient Clinic (RGH), Rochester, NY
- Site 4 - Brooklyn Hospital Center(Brooklyn), Brooklyn, NY

The programs have grown to provide direct-patient care services to well over 300 patients collectively. However, a systematic data collection process was not consistent across the health-systems thereby adding challenges to collecting data in a uniform fashion. Therefore, data collection for this analysis was done manually by collaborating pharmacists at each site. Due to resource limitations a representative sample of the population from each site was collected totaling 195 patients in this summary.

Demographic data from three sites are highlighted in Table 1. The average age of patients was 57 years with a range of 29 to 86 years. Available insurance data illustrates that 54% of patients were insured by the New York State Medicaid program, 32% were Medicare recipients with very few insured through commercial payers (10%). Encountered patients at Sites 1 and 2 were ethnically diverse with 40% categorized as African American, 20% Hispanic, 21% Caucasian and the remaining 20% of variable ethnic origin (Figure 1). In addition, 39% of patients did not report English as their primary language (Figure 2).

Table 1: Number and Age of Sample Population

Site	Number of Patients Enrolled	Average Patient Age +/ SD (range)
AJHC	60	60.4 ± 10.2 (38 – 83)
Upstate	76	54 ± 11 (29-86)
RGH	24	58.9 ± 7.99 (52-70)
Brooklyn	35	NR

Figure 1: Profile of Ethnic Diversity

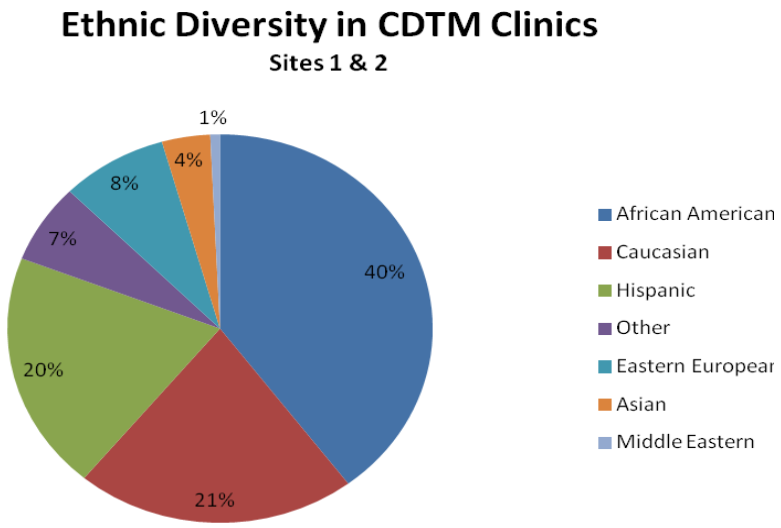
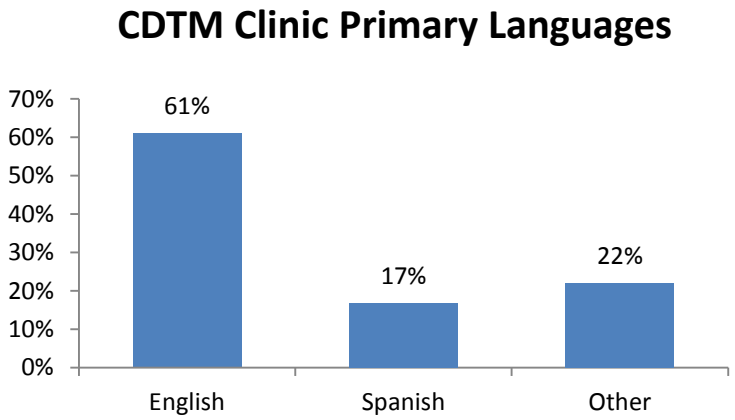


Figure 2: Primary Language sites 1 and 2



The AJHC also collected data on patient disparities with regard to health literacy, barriers to care and medication adherence in 40 patients.(Tables 2 – 4) Health literacy is the ability to obtain, process, and understand basic needed information to make appropriate health decisions. Low health literacy is associated with lack of compliance with medical instruction and prescribed treatment, and decreased health outcomes.[9] At AJHC, over 84% of patients had limited health literacy, defined as a score < 4 using the Newest Vital Sign Assessment tool[10](Table 2).

Table 2: Patient health literacy : Baseline and after 12 months of CDTM using Newest Vital Sign Assessment Tool
Note: The term baseline implies the beginning of the CDTM interventions

Newest Vital Sign Assessment Tool		
Proficiency	**Baseline (n=38/40)**	**12Months (n=34/40)**
<4 (limited literacy)	84% (32)	82% (28)
≥4	16% (6)	18% (6)

Consistent with this observation was the high percentage (79%) of patients who would be classified as having a low to moderate adherence to medications as scored using the Morisky Medication Adherence Scale[11](Table 3).

Table 3: Patient adherence using Morisky Medication Adherence Scale at baseline and after 12 months of CDTM

Morisky Medication Adherence		
Morisky Scale	**Baseline (n=38/40)**	**12 Months (n=35/40)**
High Adherence	21% (8)	37% (13)
Moderate Adherence	53% (20)	60% (21)
Low Adherence	26% (10)	3% (1)

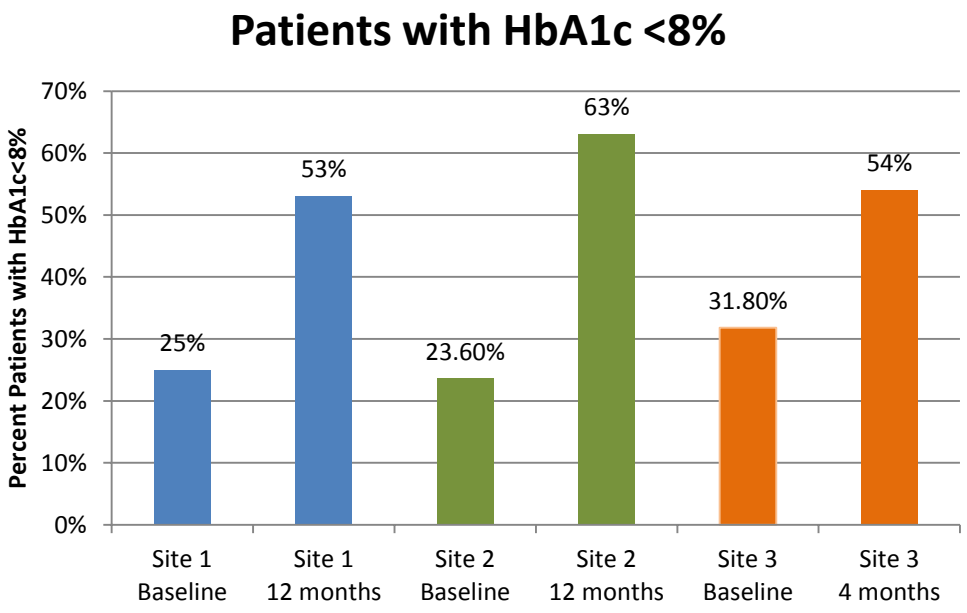
Summary of Outcomes Data Results

Impact on Glucose Control (Hemoglobin A1C)

As a result of the CDTM diabetes demonstration project, collaborating pharmacists involved in the management of diabetic patients were able to increase the percentage of patients achieving good diabetes control, defined by the NYS Prevention Agenda as an HbA1C of < 8% by a range of 22%-39% (Graph 1).[13] The improvement demonstrated far exceeds the NYS Prevention Agenda goal for 2013-2017, which set an increase of 7%-10% over five years.[14]

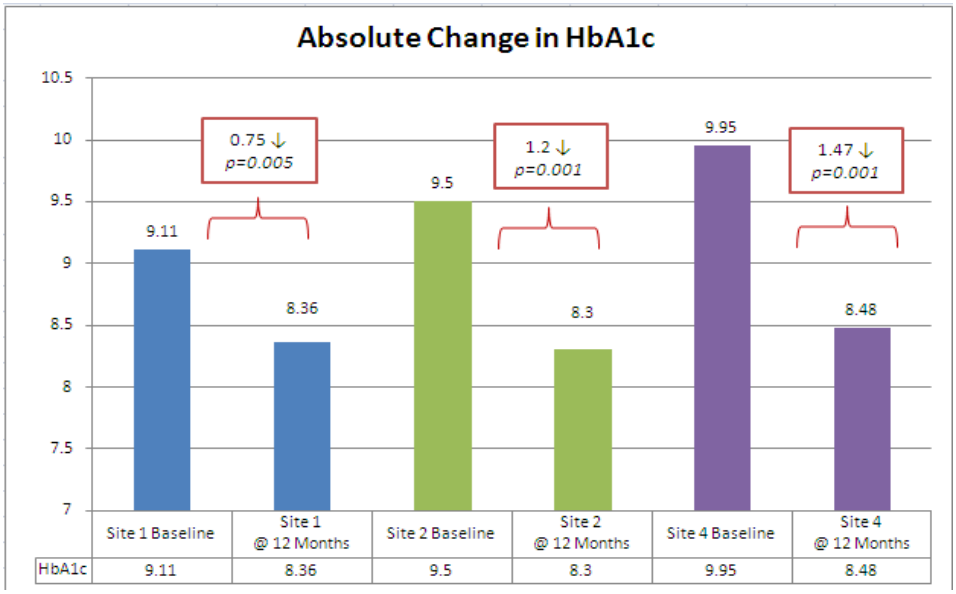
Desired NYS Prevention Agenda Goal by 2017: Increase HbA1C goal attainment by 7-10%
Actual Diabetes CDTM Project Results:
Increased HbA1C goal attainment by 22-39% in 4-12 months

Graph 1: Percentage of patients with an HbA1C < 8% pre- and post-CDTM intervention



The absolute reduction in HbA1C for patients enrolled in CDTM from baseline to 1-year is noted in Graph 2. Reductions in HbA1C ranged from 0.75% to 1.47% which is consistent with published literature.[14,15] Additionally, published diabetes data suggests that with every 1% decrease in HbA1C there is an associated 35% decrease in complications.[16] The opposite holds true as well that with every 1% increase in HbA1C above 5%, there is an associated 28% increase in mortality.[17]

Graph 2: Absolute change in HbA1C from pre-CDTM values compared to post-CDTM values.



Although the NYS Prevention Agenda states objectives over a period of five years, this CDTM Demonstration Project demonstrated exceptional, accelerated results over a four month – 1 year period of comparison.

Impact on Cardiovascular Risks: Hypertension, cholesterol, aspirin and smoking counseling and cessation

Diabetes is a complex medical disease that results in high cardiovascular risk and increased overall mortality. In addition to glucose management, multiple medications are needed to treat high blood pressure, hyperlipidemia and to protect against vascular complications to prevent kidney damage.

Upstate Medical Center, in Syracuse NY (site 2), captured data on the percent of patients achieving evidence based recommendations on managing cholesterol with statin medication, managing either hypertension or kidney disease with Angiotensin-converting enzyme inhibitor (ACEI) or Angiotensin receptor blocker (ARB) medications and appropriate aspirin use.

CDTM site results include:

- 87% of patients were prescribed statin therapy, as per American Diabetes Association (ADA) standard of care, compared to 45% at baseline
- 97% of patients were prescribed ACEI/ARB therapy, as per ADA standard of care, compared to 80% at baseline
- 34% of patients had antiplatelet therapy (i.e. aspirin) appropriately added to medication therapy regimens
- Smoking cessation counseling (standard of care at Upstate's CDTM Diabetes Management Program protocol) achieved a quit rate of 13% at one year

Discussion

The current CDTM initiative focusing on diabetes management has been very successful in achieving and even exceeding the NYSDOH target of improving HbA1C. Additionally, the comprehensive evidence based medicine CDTM initiatives have shown benefits beyond HbA1C reductions with improvements in cholesterol management, antiplatelet use, appropriate use of therapies such as ACEI/ARBS, and smoking quit rates.

Comparison of this smoking cessation quit rate to national statistics is challenging due to variability in definitions, however the NYS initiative goal is to decrease prevalence of smoking by 18%.[13] The demonstrated 13% quit rate achieved with CDTM is consistent with NYS quit goals.

Comprehensive diabetes care, such as the NYS Diabetes CDTM initiative, has been shown to result in decreased cardiovascular events and mortality, and is considered a required component to successful disease state management.[20] Evidence-based literature[4,5,15] also support that improvement in comprehensive diabetes parameters can result in economic benefit, with an average net savings of $918 to $3,356 per person per year.

The NYS DOH reports that the average yearly cost of care for a person without diabetes is $2,560; however the yearly cost for a person with diabetes is $11,744.[19] The expected economic benefit of comprehensive diabetes management is an overall cost reduction of 10%-30%. Applying this estimate to the 160 patients receiving care under CDTM initiatives would be expected to produce an annual savings of $147,000-$537,000. If these reduction estimates were extrapolated to the 10.4% of NYS adults with diabetes, savings of $1.5 to $5.3 billion annually could potentially be achieved.

Estimated cost savings for those patients managed under the CDTM demonstration project is estimated to be $147,000 - $536,960 annually.

Conclusions

The above data confirm that diabetes management under pharmacist-physician CDTM protocols in New York State is a successful initiative to improve the treatment and achieve standards of diabetes care for patients. The ability to achieve therapeutic targets exceeded expectations in a relatively small number of patients. Expansion of CDTM to allow all qualified pharmacists to provide comprehensive diabetes care would reasonably be expected to significantly improve overall disease management, reduce the occurrence of diabetes-related complications and substantially decrease the cost of care.

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Heart Failure

During the CDTM demonstration project 78 patients were treated at 2 institutions: Montefiore Medical Center (59; March 2013-June 2013)and Bronx Lebanon Hospital (19; May-June 2013). Pharmacists were involved with a variety of interventions with this population. Results from this study showed that direct pharmacist care can have a positive impact on heart failure patient outcomes such as 30-day readmission rate and patients' health status, as well as substantially reduce costs.

Background

Heart failure is a major cardiovascular syndrome that affects approximately 5.7 million people in the United States.[1] Although the survival rate after heart failure diagnosis has improved over time, the death rate from this disease remains high. It is estimated that 50% of people diagnosed with heart failure will die within five years.[1] The cost of heart failure is also staggering with total estimated expenditure exceeding $39 billion in the United States in 2010.[2] These costs are mostly due to exacerbations of the disease that require expensive emergency room visits and hospitalizations.[3] Studies have shown that cardiovascular medications reduce morbidity, mortality and hospitalizations in patients with heart failure.[4-7] Unfortunately, about 50% of patients with chronic diseases do not take their medications as directed and non-adherence to medications can lead to cardiac decompensation and subsequent hospitalization for these patients.[8,9] Therefore, issues leading to medication non-adherence, such as lack of patient knowledge and lack of follow-up appointments must be addressed in order to improve medication adherence and subsequent clinical outcomes. Due to their expertise in drug therapy, pharmacists are particularly well-suited to provide the necessary medication education to patients to improve medication adherence.[10]

A 2008 meta-analysis of 12 randomized controlled trials involving 2060 subjects was conducted to clarify the impact of pharmacist care in heart failure patients.[11] Overall results showed that pharmacist care was associated with significant reductions in the rate of all-cause hospitalizations (OR, 0.71; 95% CI, 0.54 to 0.94) and heart failure hospitalizations (OR, 0.69; 95% CI, 0.51 to 0.94) compared with no pharmacist care. In another randomized controlled trial, a significant improvement in medication adherence was observed with pharmacist intervention: 78.8% and 67.9% in the pharmacist intervention and usual care groups, respectively.[3] In addition, emergency department visits and hospital admissions were 19.4% less and annual direct health care costs were lower (-$2960 per patient [CI, -$7603 to $1338]) in the pharmacist intervention group.[3] These, and multiple additional studies, resulted in the publication of a consensus statement from the Heart Failure Society of America, which advocates for drug evaluation by a clinical pharmacist as a necessary component to achieving optimal prescribing and dosing of proven medical therapies in heart failure patients.[12] Additional roles identified for pharmacists within a heart failure team include: providing patients with education regarding their medicines (written information given when appropriate), resolving medication-related problems (such as drug-drug or drug disease interactions; adverse effects; adherence issues; use of unnecessary, inappropriate or duplicate medicines, inappropriate doses; and use of out of date medicines) and assessing the need for resources to aid with patient adherence.[12, 15 - 16]

Montefiore Medical Center

Interventions

At the initial clinic visit each patient in the CDTM demonstration project received a one hour consultation in accordance with the American Heart Association recommendations,[13] which aims to educate patients on their disease states, provide rationale for their medical therapy, establish a medication history and discuss the importance of dietary and medication adherence. Patients were also instructed on how to utilize a management plan for worsening signs/symptoms to prevent decompensations/hospitalization. At subsequent clinic visits, the pharmacist adjusted doses of heart failure medications as dictated by the patient's clinical status and ensured patient follow-up with a cardiologist. They also performed Patient Healthcare Questionare-9 (PHQ-9) depression screening, provided education on anticoagulants, smoking cessation and any other education/counseling required for individual patients.

Assessment of Collaborative Clinic Impact

The Kansas City Cardiomyopathy Questionnaire (KCCQ)[14] was administered to patients at the initial consultation and again at six months. The KCCQ is a 23-item questionnaire that measures impact of disease on functional status and quality of life and has been validated in the heart failure population. Patients were asked to complete the KCCQ at the beginning of the initial one-hour clinic consultation and again at six months after the clinic visit.

Outcome Measures

The primary outcome measure was the 30-day readmission rate compared to the national reported average values. Secondary outcomes included 90-day readmission rate compared to baseline, change in the KCCQ scores from baseline to six months, the proportion of patients who received optimization of their heart failure therapy regimen at the clinic visit.

Results

From March 2012 to June 2013, 62 patients were seen by pharmacists at the clinic. Of these patients, three had no clinical evidence of heart failure in the medical record and were therefore excluded from the analysis. Demographics and baseline characteristics of the remaining 59 patients are described in Table 1. Of the 59 patients, six patients had heart failure with preserved ejection fraction (EF ≥55%) and 53 patients had heart failure with ejection fractions that were below normal (EF <55%). Baseline N-terminal pro-BNP, a marker of cardiac dysfunction that correlates with severity of left ventricular hypertrophy and heart failure, was available in 48 (81%) patients.

Table 1. Demographics and baseline characteristics of heart failure patients

	Number (%) of patients	Mean	SD
Age	59 (100%)	64.2 years	12.8
Gender: Male	32 (54%)	n/a	n/a
Ejection fraction (EF)	57 (97%)	34.1%	11.6
N-terminal Pro-BNP	48 (81%)	7165.5 pg/mL	11128.0
Serum creatinine	52 (88%)	1.7 mg/dL	1.4

Of the 59 patients, two patients (3.4%) were readmitted to the hospital within 30 days after their previous hospital discharge dates, one of which was heart failure related. Among 22 patients who were seen at the clinic within two weeks after discharge, the 30-day readmission rate was 9% (2 /22). Of 42 patients who had at least one hospitalization in the three months prior to their clinic visits:

- 28 patients (67%) were not hospitalized in the three months after their clinic visits
- Three patients (7%) had one less hospitalization in the three months after their clinic visits compared to the three months prior to their clinic visits
- Four patients (9.5%) had one hospitalization in the three months prior to and one hospitalization after their clinic visits
- Two patients (4.5%) had one more hospitalization in the three months after their clinic visits compared to the three months prior to their clinic visits
- Five patients (12%) have not yet reached the three months post clinic visit time point

Ten out of 22 eligible patients were successfully contacted for a six-month follow-up KCCQ evaluation. The average KCCQ score for ten patients improved from 64 to 81, representing a significant improvement in the patient's subjective health self-assessment.

Categories of medications that should be prescribed in heart failure patients to optimize outcomes include either an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB), a beta-blocker, aldosterone antagonist (AA), diuretic and the combination of Isosorbide dinitrate (ISDN)/hydralazine. Of the 59 heart failure patients seen at the clinic, 42 patients (71%) were already receiving (ACEIs) or (ARBs) prior to their clinic visits. ACEIs or ARBs were initiated in ten patients bringing total percentage of patients on either agent to 88% (52/59 patients). Up-titration toward recommended doses occurred in seven of 59 patients (12%). Prior to their clinic visit 55/59 (95%) of patients were receiving a BB and up-titration of beta blockers toward optimal doses was made in 21 of these patients (36%). No initiation of beta-blocker therapy occurred in the remaining four patients.

The interventions made by pharmacists at the clinic are displayed in Figures 1 and 2. Of note, nearly 50% of patients were counseled for non-adherence to medications and more than one-third required an increase in their beta-blockers regimen. In addition, blood work was obtained in nine patients (15%) to ensure safety of medication regimens.

Figure 1. Types of general interventions made by pharmacists

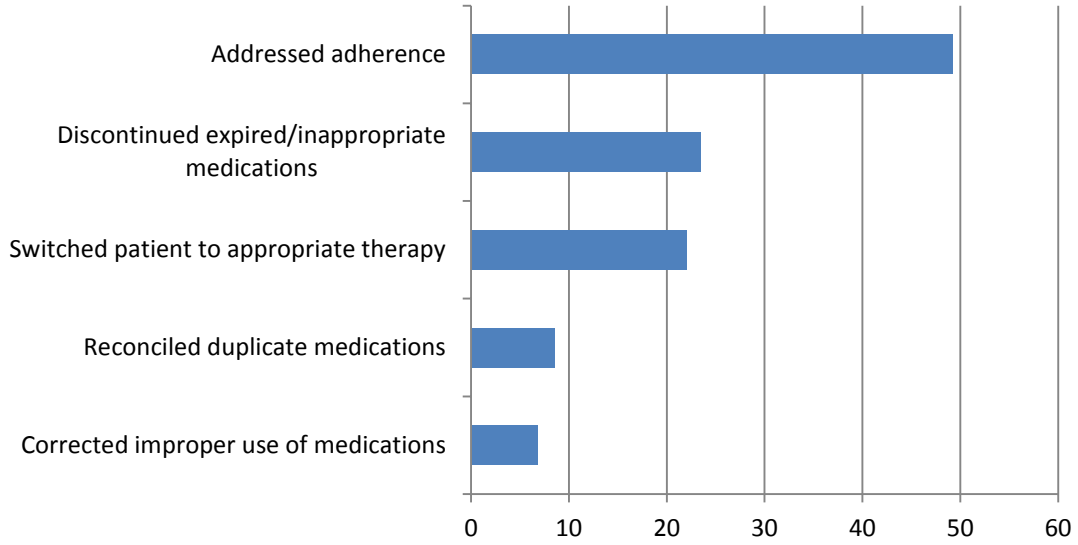
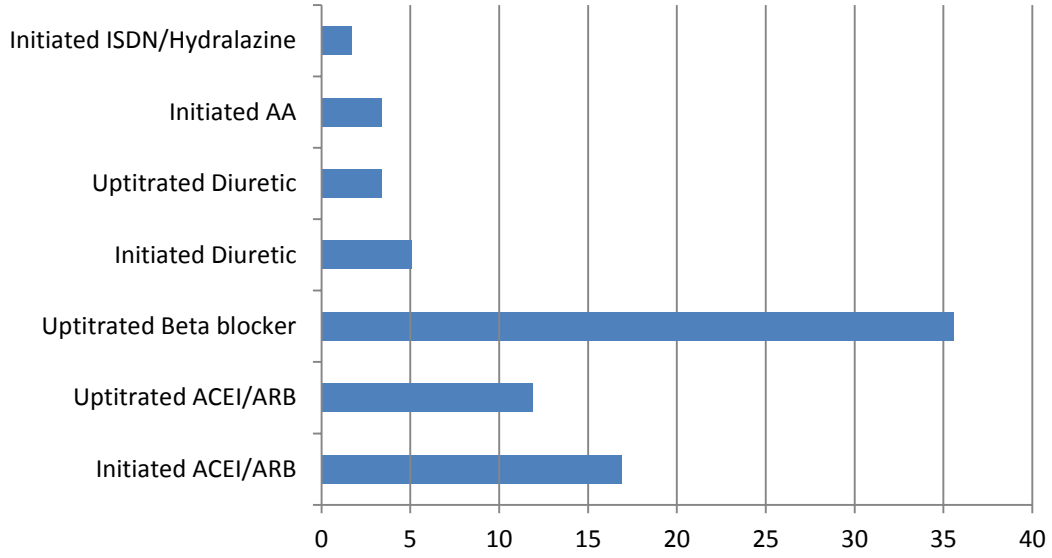


Figure 2. Specific interventions on heart failure medications



ACEI = Angiotensin converting enzyme inhibitor; ARB = Angiotensin receptor blocker; BB = Beta blocker; ISDN = Isosorbide dinitrate; AA = aldosterone antagonist

Bronx-Lebanon Hospital

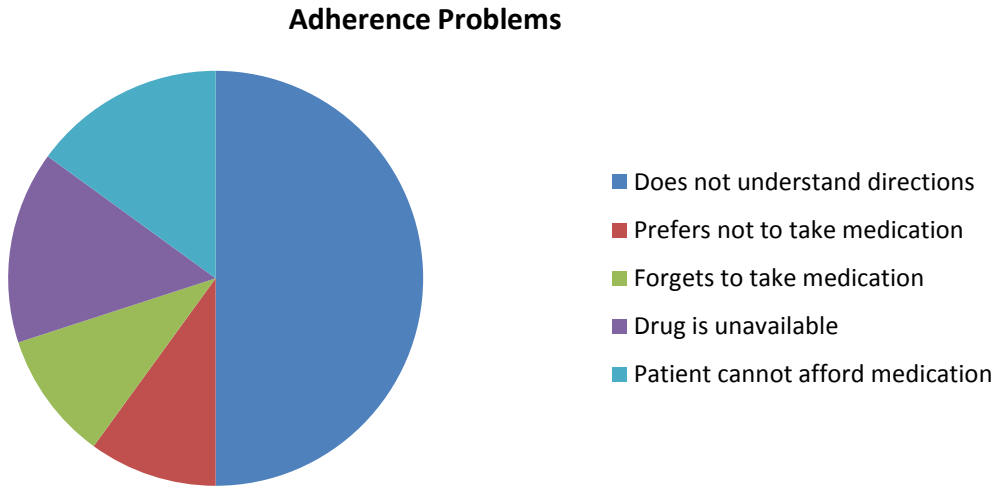
The Bronx-Lebanon Hospital reported outcomes for patients managed in physician-pharmacist collaboration for a four month period beginning in May 2013. During this time a total of 19 patients were seen and evaluated by a pharmacist for the presence of drug-related problems related to efficacy, safety and adherence of their heart failure medication therapy. Results of medication management endpoints are listed in table 2. Adherence to medication therapy was identified as a problem in 17 of 19 patients (89.5%). Each of the adherence problems identified was resolved by the pharmacist. Details of the adherence problems are described in figure 3.

Table 2: Medication Management Endpoints

Intervention Category	N 16 (% of total)
Optimization of therapy by indication	7 (43.7)
Discontinue Unnecessary Drug Treatment	4 (25)
Initiate Therapy for Untreated Indication	2 (12.5)
Optimization of effectiveness	2 (12.5)
Inadequate Dose	1 (6.25)
Increased Monitoring Needed	1 (6.25)
Optimization of Safety	2 (12.5)
Excessive Dose	1 (6.25)
Unsafe drug for patient	1 (6.25)

Analogous to the results demonstrated by the Montefiore Medical Center, a high percentage of patients were receiving therapy proven to improve outcomes in patients with heart failure, ACEI/ARBs (94.7%) and beta-blockers (100%). Similarly, hospital readmission rates were significantly lower than expected: 30 day (0), 60 day (5.2%) and 90 day (5.2%).

Figure 3: Pharmacist-identified Adherence Problems Resolved



Discussion

The readmission rates observed in this series of patients (0 - 9%) are substantially lower than the average 30-day readmission rate of 24% reported as the national benchmark by the Agency for Healthcare Research and Quality[17] In terms of 90-day readmission rate, the majority of patients had fewer admissions to the hospital in the 3 months after pharmacist consultation compared to the three months before pharmacist consultation. This decrease in readmission rate may be due to better medication management and adherence after the patients' clinic visits. Furthermore, patients were taught to weigh themselves and report any sudden increase in weight (often an indication of fluid retention and heart failure exacerbation) to their cardiologists or pharmacists to help avoid unnecessary emergency room visits and hospital admissions. A blood test associated with reduced heart function, N-terminal pro-BNP, was significantly elevated in 81% of patients at baseline (>500 pg/mL). This suggests that many of the patients had worsened heart failure at their initial visit in the clinic.

It is well established that ACE inhibitors reduce morbidity and mortality in patients with heart failure. These agents are given the highest recommendation (level 1) by treatment guidelines[17] for all patients with heart failure symptoms and a reduced ability of the heart to pump effectively (reduced left ventricular ejection fraction). When a patient is unable to tolerate ACEIs, ARBs are recommended. After pharmacist consultations the proportion of patients who received an ACEI/ARB increased from 71% to 88%, resulting in greater compliance with this highly effective therapy. Beta blockers have also demonstrated beneficial effects in patients with heart failure. For these CDTM managed patients, 95 – 100 % were given beta blockers consistent with the heart failure treatment guidelines.[17] Taken together, the two most important classes of drugs in the treatment of heart failure were utilized in more than 90% of patients when a pharmacist participated in patient management.

Through increased education, improvement in self-management and optimization of medication regimens hospital admissions were reduced by more than 60%. Utilizing cost data provided by the AHRQ Health care utilization project[18] and NYS DOH[19] the expected economic impact for the patients managed by the demonstration project would be $319,000. Extrapolating this to NYS expenditures would give a potential reduction of $600,000,000 annually.

Conclusion

Pharmacists are an essential part of a multidisciplinary team caring for patients with heart failure. With the support of a collaborative care environment, pharmacists can make positive impacts on patient care by providing medication education and counseling, as well as assisting in medication therapy management. Results from this study showed that direct pharmacist care can have a positive impact on heart failure patient outcomes such as 30-day readmission rate and patients' health status as well as substantially reduce costs.

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Human Immunodeficiency Virus (HIV)

As part of the demonstration project eight hundred and seventy-four clinic visits managed under CDTM were documented at the Brooklyn Hospital between May 2011 and December 2012. Over the two years reviewed, 1408 pharmacist-led CDTM interventions were documented (692 interventions in 2011 and 716 interventions in 2012) with a mean of 1.6 interventions made per visit. The most commonly made intervention types were in the CDTM categories of "need for additional treatment" and "non-adherence." These factors, as well as others noted in the material below, have significant impact on therapeutic outcomes.

Introduction

More than 1.1 million people in the United States are living with human immunodeficiency virus (HIV) infection while nearly one in five of those people (18.1%) are unaware of their infection.[1] Although the annual number of new HIV infections has remained relatively stable, new infections continue to rise with approximately 50,000 Americans becoming infected each year.

Since the first reported cases of HIV in the early 1980s and the limited choices of antiretroviral therapy (ART), the understanding of this disease and tailoring of treatment has grown exponentially. With over two dozen antiretroviral agents approved by the Food and Drug Administration (FDA), individualized regimens with more tolerable side effects and decreased pill burden are preferred. Patients who demonstrate nearly perfect adherence to their ART will stop the virus from growing (suppression of viral replication) and have normalization of their immune system. As a result, HIV-positive patients are living longer with an increased number of chronic diseases.[2]

Pharmacist's Role

The Department of Health and Human Services (DHHS) guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents recommend the use of a multidisciplinary team approach to improve patient adherence to ART, including a pharmacist.[3] Pharmacists as part of the HIV multidisciplinary team can provide not only strategies for medication adherence, but can also provide therapeutic care plans for chronic disease state management.

The medical literature demonstrates that pharmacists improve outcomes of HIV infected patients.[4 - 11] A 2012 systematic review of thirty two publications assessed the impact of pharmacists on HIV clinical outcomes.[4] The pharmacist's role included patient education and adherence counseling, ART regimen selection and management as well as monitoring for adverse effects and drug interactions. In the majority of studies, the involvement of an HIV pharmacist in patient care was associated with significant improvements in ART adherence and greater suppression of viral loads. One particular trial, a four-year study conducted at a Veterans Affairs infectious diseases clinic demonstrated that medication counseling, recommendation of monitoring parameters, and prescription processing improved adherence and enhanced treatment efficacy. Additional studies have demonstrated reductions in hospitalizations, physician office visits, number of hospital days, visits to the emergency department and pill burden.

Methods

The CDTM pilot program was conducted at the Brooklyn Hospital Center's Program for AIDS Treatment and Health (PATH) Center. Patients are initially evaluated by a team consisting of an internal medicine resident, a pharmacy resident and any medical or pharmacy students rotating through the clinical site. Together, these professionals formulate a preliminary care plan and present to an Infectious Diseases (ID) medical attending and a HIV-specialized ambulatory care clinical pharmacist. Pharmacist-led CDTM interventions are recommended either during the patient's initial assessment with the medical resident or during the case discussion with the ID physician. A member of the pharmacy team may utilize time after the clinic visit for medication adherence counseling and patient education. For patients who require additional time with a pharmacist, a separate appointment is made for a one-on-one counseling session to ensure understanding of both disease state and medications. Interventions made by the pharmacist were documented and collected retrospectively for the demonstration project.

Results

Eight hundred and seventy-four clinic visits managed under CDTM were documented between May 2011 and December 2012. The mean age of patients was 50 years with the majority being male in gender (56%). Over the two years reviewed, 1408 pharmacist-led CDTM interventions were documented (692 interventions in 2011 and 716 interventions in 2012) with a mean of 1.6 interventions made per visit.

CDTM intervention results are presented in Table 1. The most commonly made intervention types were in the CDTM categories of "need for additional treatment" and "nonadherence." Of the 466 interventions included under "need for additional treatment," 399 interventions were made by initiating treatment for an untreated indication, most commonly made in the categories of smoking cessation (29%), hyperlipidemia (10%) and pain management (9%). Seventy-six interventions were made by adding a drug for synergy, mainly in the disease states of hypertension (30%), diabetes (20%) and hyperlipidemia (13%). The addition of low-dose aspirin therapy (75%) for primary or secondary prevention was the most common intervention in the sub-category of preventative treatment.

Of the 444 interventions made in the adherence category, the majority of interventions were completed when clarifying medication administration directions when patients did not understand (45%) and performing adherence counseling when patients did not prefer to take medications (32%). There were no therapeutic interventions in the categories of "potential medication errors" as pharmacists intervened during patient visits to prevent them. Interventions were also categorized by disease state. The three most common intervention categories were additional laboratory tests recommended for monitoring (27%), ART management and adherence counseling (17%) and smoking cessation (11%).

Table 1: Medication Interventions by Category

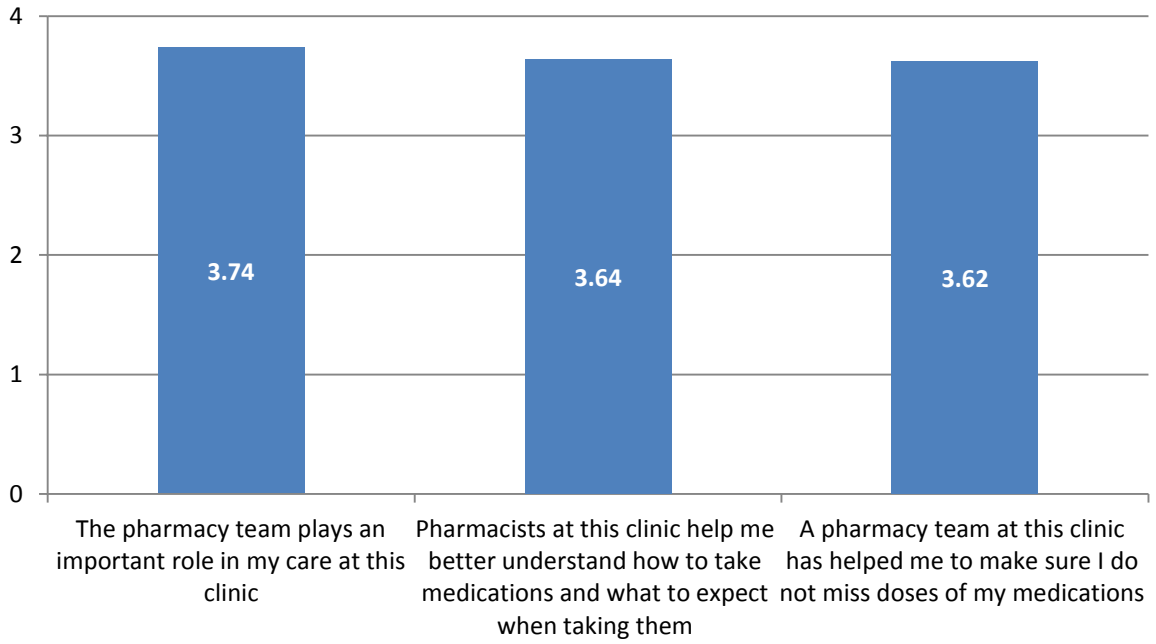
Intervention Category	N = 1408 (% of total)
Optimization of therapy by indication	532 (37.8)
Unnecessary Drug Treatment	66 (4.6)
No valid medication indication	50 (3.5)
Duplicate therapy	14 (1)
Medication being used to treat an avoidable ADR	2 (< 1)
Need for Additional Treatment	466 (33)
Drug added for synergy	76 (5.4)
Untreated indication	339 (24)
Preventative treatment	51 (3.6)
Optimization of effectiveness	146 (10.4)
Inadequate Dose	146(10.4)
Dose too low	133 (9.6)
Need additional monitoring	7 (<1)
Dose interval not frequent enough	1 (<1)
Incorrect administration	3 (<1)
Optimization of Safety	165 (11.7)
Adverse Reaction (prevented/identified)	112 (8)
Unsafe drug for patient	82 (5.8)
Dangerous Drug Interactions	29 (2)
Incorrect administration (dangerous)	1 (<1)
Excessive Dose	53 (3.8)
Dose too high	45 (3.2)
Needs additional monitoring	2 (<1)
Frequency inappropriate	2 (<1)
Duration too long	4 (<1)
Adherence	444 (31.5)
Did not understand directions	201 (45)
Did not prefer to take medication	144 (33)
Forgets to take medication	68 (4.8)
Cannot swallow / administer	2 (<1)
Cannot afford medication	7 (< 1)
Drug is not available	2 (<1)

Patient Perceptions

The clinic conducted a study to assess overall patient satisfaction with care delivered by an interdisciplinary HIV clinic and also identify patients' perceived value of the clinic's interdisciplinary services. Patients were eligible for inclusion if they were at least 18 years and regularly seen by the interdisciplinary team. First-time visitors to the clinic were excluded.

A questionnaire comprised of 24 questions was distributed to eligible patients while they waited for their appointment with the interdisciplinary care team. A total of 104 surveys were returned.
The survey was based on an instrument previously demonstrated to assess satisfaction of care in HIV-positive patients.[13, 14] Ten new and original items intended to measure quality of care for the clinic's individual interdisciplinary components and the overall perception of interdisciplinary HIV care were also included. These ten new items asked whether patients agreed that pharmacists, nurses and social workers, respectively, played an important role in their care at the clinic. Only results pertinent to pharmacist will be presented here. Results of the survey indicated that patients felt strongly that the pharmacist played an important role in their care and helped them improve understanding of and adherence to their medications. (Figure 1)

Figure 1: Interdisciplinary Care Relating to Pharmacist Care



1 = Strongly disagree 2 = Somewhat disagree 3 = Somewhat agree 4 = Strongly agree

Conclusion

This CDTM demonstration project, consistent with the DHHS recommendation, illustrates that pharmacists are an effective part of the interdisciplinary healthcare team during HIV patient visits. Pharmacists can ensure medication information is transferred accurately and completely through direct communication and feedback with patients. CDTM agreements allow the pharmacist to effectively and efficiently manage HIV-positive patients' ART and treatment of other chronic disease states simultaneously in an outpatient clinic setting. Pharmacists impact medication therapy management the most by providing comprehensive medication reconciliation and recommending treatment initiation in order to optimize patient safety and treatment plans. They also impact patient non-adherence. With effective interviewing, pharmacists can identify reasons for non-adherence and modify treatment regimens where necessary to get patients to consistently take their medications. Patient perceptions indicate they value pharmacist's role in helping them improve the medication understanding and adherence.

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Oncology

As part of the CDTM demonstration project, pharmacists collaborated on the treatment of 2,318 patients at Memorial Sloan-Kettering Hospital (2306; November 2012-December 2013) and Roswell Park Memorial Hospital (12; December 2012-March 2013). Of the interventions at Memorial Sloan-Kettering, 94% were made on inpatients and 6% were made on outpatients. While proving the value of pharmacists in collaboration in a number of areas, it is compelling to note that 100% of the physicians surveyed felt that CDTM services improve quality of care and 100% want the practice continued.

Background

The diverse challenges to providing high quality health care are well represented in the treatment of patients with cancer. In the recently published *State of Cancer Report, 2014* by the American Society of Clinical Oncology[1], three critical areas were identified:

- Increased demand for cancer prevention, screening, and treatment due to the aging population and improved survival of cancer patients
- Shortage of physicians specialized in the treatment of cancer
- Rising costs of new cancer therapies.

In response to the oncologist workforce shortage, many cancer centers across the country have increased the use of clinical pharmacists, advance practice nurses and other allied health professionals who are able to attenuate the health care workload through the use of collaborative practice agreements (CPAs).[2 – 6]

Integrated clinical pharmacists are an established necessity in the hematology/oncology setting. Clinical pharmacists provide therapeutic drug monitoring, manage drug interactions, and facilitate access to high cost chemotherapy medications.[7 – 10] With a CPA, clinical pharmacists are able to serve as an extension of the physician's care and utilize their specialized drug therapy expertise to provide supportive care for cancer patients undergoing intense chemotherapy treatments. Chemotherapy complications such as cancer pain, nausea and vomiting, constipation, and diarrhea can be successfully managed by an integrated clinical pharmacist.

Results

Memorial Sloan Kettering Cancer Center

The Memorial Sloan Kettering Cancer Center (MSKCC) implemented CDTM services in the following areas:

Bone Marrow Transplant
Leukemia
Lymphoma
Neuro-Oncology
Infectious Diseases
Geriatrics
Pain and Palliative Care

Between November 2012 and December 2013 pharmacist interventions previously demonstrated to optimize efficacy and improve safety [11] were collected. Utilizing CDTM protocols, a total of 2392 interventions were made for the services previously identified. Of these 94% were made on inpatients and 6% were made on outpatients. Interventions by category and their frequencies are listed in Table 1:

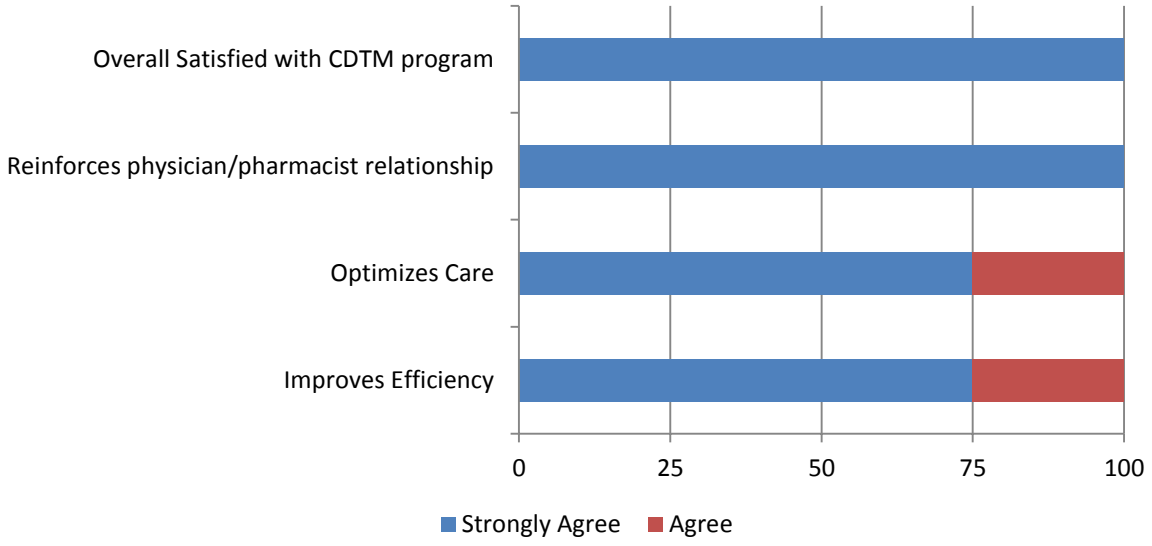
Table 1: MSKCC Pharmacist Interventions by Category

Intervention Category	N 2392 (% of total)
Optimization of therapy by indication	1235 (51.6)
Discontinue Unnecessary Drug Treatment	482 (20.1)
Discontinue Duplicative Therapy	37 (1.5)
Initiate Therapy for Untreated Indication	716 (29.9)
Optimization of effectiveness	694 (16.5)
Incorrect Dose	627 (26.2)
Inappropriate route	67 (2.8)
Optimization of Safety	363 (15.1)
Excessive Dose	119 (5)
Dangerous Drug Interactions	244 (10.2)

All interventions initiated by the pharmacist are considered significant in terms of improving therapeutic outcomes for patients, as more than one half (56%) involved either adding a new medication or adjusting a medication dose and in nearly 25% of cases therapy was removed because it was either duplicative or unnecessary. With regard to safety, almost one in five interventions (15%) were necessary to prevent a potential medication-related adverse reaction through either reducing the dose or eliminating a potentially dangerous drug interaction.

Satisfaction with pharmacist CDTM services was evaluated by conducting a survey of the four collaborating physicians (Figure 1). All physicians either strongly agreed or agreed that pharmacists improved efficiency and optimized care of their patients. When queried about their overall satisfaction with the program they all responded with "strongly agree".

Figure 1: MSKCC Physician Surveys (%)



Roswell Park Cancer Institute

Roswell Park Cancer Institute (RPCI) developed a CDTM program that incorporated a pharmacist into a Gynecology clinic to manage symptoms associated with treatment of those types of cancers. Primarily three symptoms were managed by the pharmacists: chemotherapy induced nausea and vomiting (CINV), chemotherapy induced peripheral neuropathy (CIPN), and vasomotor symptoms. As illustrated in Table 2, patients were seen in regularly scheduled follow-up visits for symptom management and monitoring. Symptom scores were collected at each visit with the CDTM pharmacist and documented in a consult note in the electronic medical record. Validated assessment tools, the McCorkle Symptom Distress Scale[12] and the Patient Neurotoxicity Questionnaire,[13] were utilized to document response. In addition to the patient reported efficacy evaluation, anonymous surveys were sent to the gynecologic oncologists and CDTM patients to determine their perceptions and satisfaction with the program. Data was collected over a four month pilot period, after the CDTM program was initiated in December 2012.

Table 2: RPCI CDTM Follow Up Schedule

Symptom	Follow Up 1*	Follow Up 2	Follow Up 3	Follow Up 4
CIPN	1 week	2 4 weeks	3 8 weeks	8 16 weeks
CINV	24 hours	72 hours	7 days	14 days
Vasomotor Symptoms	2 weeks	4 weeks	8 weeks	16 weeks
***Follow up may be scheduled more frequently based on particular agents prescribed and patient response to treatment**				

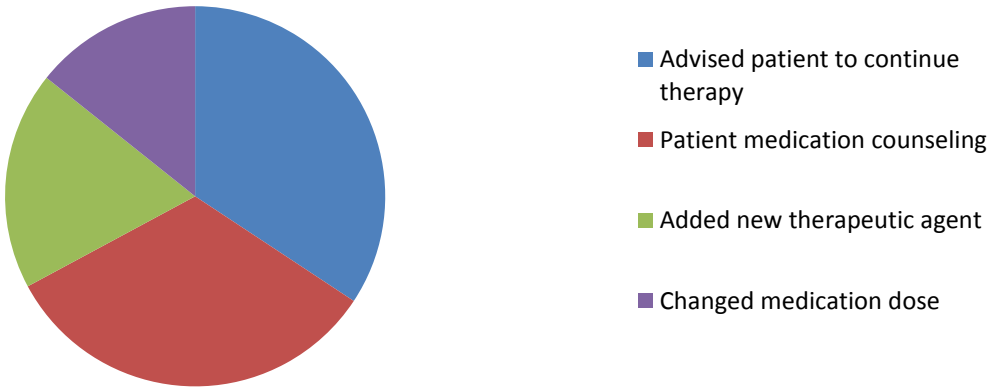
Demographics

The CDTM pilot program took place over four months, from December 10th 2012 to April 20th 2013. A total of twelve patients were enrolled, eight in the CIPN program, two in the CINV program, and one with vasomotor symptoms. All patients were female and the majority of the patients were over the age of 60 years (58%). Sixty-seven percent of patients were of Caucasian race, while others were classified as African American (25%) and Asian (8%). The most common malignancies of patients enrolled in CDTM comprised of ovarian cancer (42%), endometrial cancer (25%), uterine cancer (17%), primary peritoneal cancer (8%), and cervical cancer (8%). Seventy-five percent of patients were currently receiving chemotherapy when they were enrolled in the CDTM program and were in fact symptomatic prior to CDTM initiation.

Outcomes

The pharmacist performed 54 consultations, with 12 being initial visits and 42 follow up visits via phone call or clinic appointments. The CDTM pharmacist also made several interventions during the CDTM pilot program. A total number of 70 interventions were recorded by the CDTM pharmacists for a mean of 5.8 interventions per patient. The most common interventions were advising the patient to continue the current therapeutic regimen, performing medication teaching and counseling, prescribing new medications, and changing the dosing or frequency of medication regimens (Figure 2).

Figure 2: RPCI Pharmacist Interventions



Efficacy Evaluation

Symptom scores were recorded at each visit for the CIPN and the CINV groups. Assessment of vasomotor symptoms in the single patient enrolled are not reported as the program concluded before adequate follow up could be achieved. Comparisons were made from at any time point during CDTM enrollment to the last available symptom score recorded. In the CINV group two of the three patients were asymptomatic at the time of enrollment and remained so throughout the pilot period. The third patient was symptomatic at the time of CINV enrollment and a decrease in the frequency and severity of her CINV was observed at the last follow up appointment. For the eight people enrolled in CIPN group, symptom scores revealed a slight decrease to stabilization. When consideration is given to the fact that many of the medications used to treat neuropathy take several weeks to achieve efficacy and that 67% of patients were actively receiving chemotherapy, stabilization of symptoms may be viewed as a significant accomplishment.

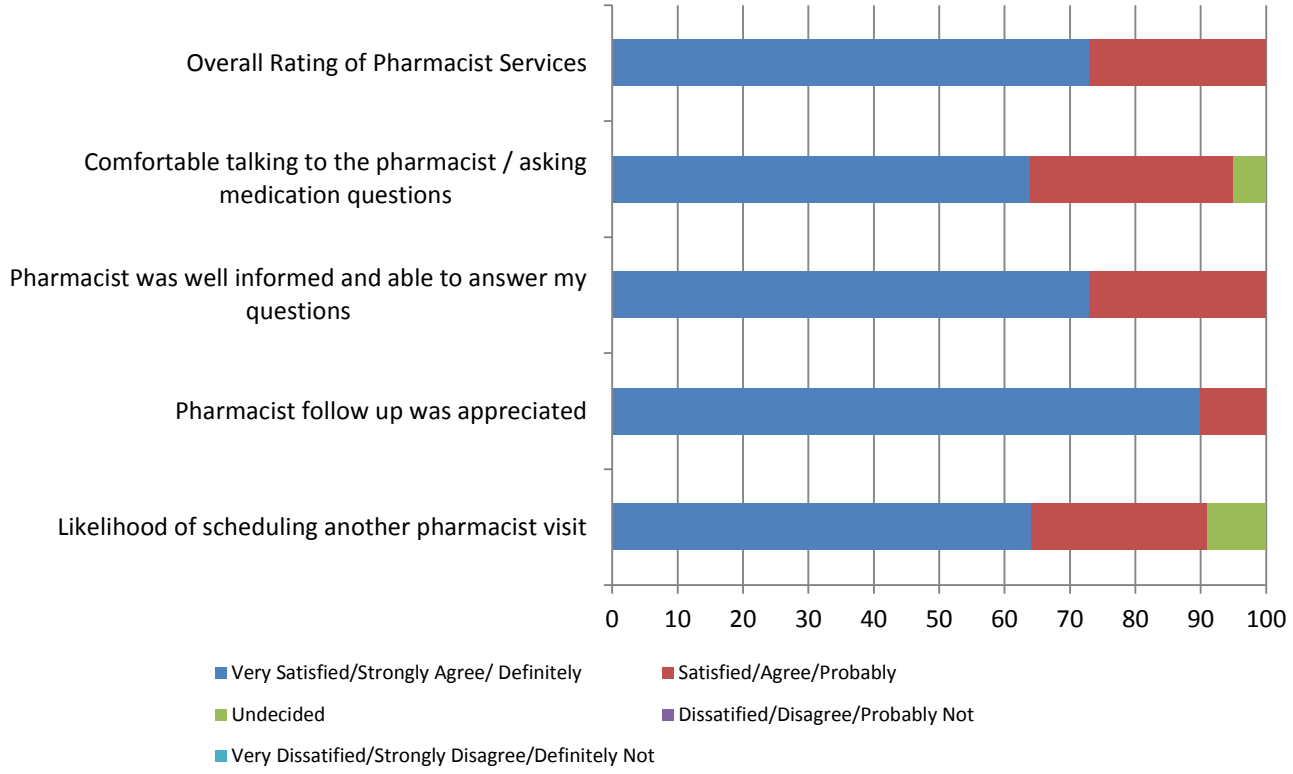
Safety Evaluation

Medication safety was another important endpoint of the pilot program. The CDTM pharmacists were able to identify six medication related adverse events in six individual patients. One event occurred prior to CDTM enrollment and was due to aggressive titration of a sedating medication (gabapentin). This event prompted enrollment into the CDTM program and the medication was successfully restarted at a lower dose with slower titration. Three adverse events occurred as a result of medications prescribed by the CDTM pharmacists. The first was sedation with gabapentin which was addressed by a dose reduction that improved tolerability. The second adverse drug event, confusion and lethargy with duloxetine, was reported after one dose of the medication and resulted in its discontinuation. Finally, a third patient's confusion and lethargy due to dexamethasone was due to the patient taking the medication inappropriately, which was resolved by the CDTM pharmacist after provision of additional counseling. The two other events that occurred were not directly related to CDTM but were reactions secondary to chemotherapy. The CDTM pharmacist also identified six barriers to medication adherence, three of which were successfully resolved.

Patient Satisfaction

There was a high response rate for the patient satisfaction survey of 91.7% (n=11/12) and generally positive results. Favorable responses were considered to be "Very satisfied/Strongly Agree/Definitely," and "Satisfied/Agree/Probably." There were no unfavorable responses received for all endpoints. One patient was undecided about scheduling a return visit and another about comfort with asking questions (Figure 3).

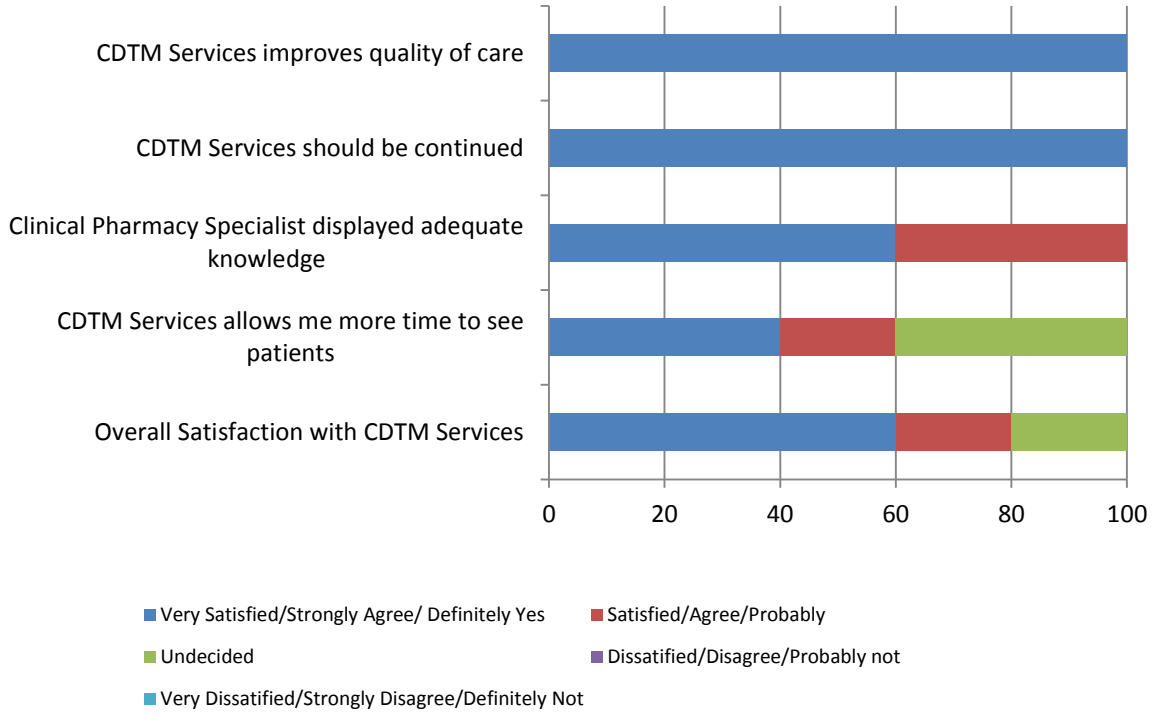
Figure 3: RPCI Patient Surveys



Provider Satisfaction

All the gynecologic oncologists participating in CDTM responded to the physician satisfaction survey (n=5). Favorable responses were considered to be "Very Satisfied/Strongly Agree/Definitely," and "Satisfied/Agree/Probably." No unfavorable responses were received. Undecided responses were directly related to the inability of the pharmacist to write prescriptions for controlled substances. Also of note, all physicians strongly agreed that CDTM increases the quality of care and that the services should be continued (Figure 4).

Figure 4: RPCI Physician Surveys



Conclusions

Both oncology based CDTM programs demonstrated benefits to patients and physicians. Interventions initiated by the pharmacist resulted in optimization of efficacy and safety measures which will likely translate into improved patient outcomes. Satisfaction was high for both physicians and patients, with all physicians strongly agreeing that such programs should be continued. CDTM in the oncology setting provides an important element to the team-based approach to cancer treatment.

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Asthma

During the CDTM demonstration project the Brooklyn Hospital initiated an asthma treatment program. A total of 25 patients were seen and evaluated for asthma management from January – August 2013. Despite the small number of patients included in the asthma management program the results indicate utilization of these important medications is more than twice what would have been expected (100%). Additionally, adherence and self-management were reinforced in all patients as recommended by treatment guidelines. Given the high rates of asthma in New York State, the implications for reduced hospitalizations and health-care expenditures are significant.

Background

Asthma is a major problem in New York State (NYS) with significant public health and financial consequences. In 2008, an estimated 1.3 million adults and 475,000 children had current asthma.[1] Lack of disease understanding and non-adherence to medication contribute to poor outcomes in asthmatics. To improve patient education and management of asthma, The Brooklyn Hospital incorporated collaborative management of the disease into an outpatient clinic in January 2013. This approach to care is consistent with the guidelines published by the National Heart, Lung and Blood Institute, which emphasizes integration of self-management education into all aspects of asthma care.[2] In addition, the benefit of including a pharmacist to provide education, monitoring of therapy and self-management skills and drug therapy management has been well described in the medical literature.[3, 6-8]

Results

The Brooklyn Hospital gathered data on the appropriateness of the drug therapy regimen, patient knowledge of their disease state and adherence to their medication regimens, all endpoints associated with optimal disease management. A total of 25 patients were seen and evaluated for asthma management from January – August 2013. The average age was 48 years (Range 26 – 78) and 80% were female. Outcomes are listed in Table 1.

Table 1: Medication outcomes in asthma patients

Parameter	Frequency
Receiving a controller medication	25 (100%)
Rescue medication prescribed	25 (100%)
Asthma action plan reviewed and educated	25 (100%)
Medication directions reinforced (Patient did not initially demonstrate understanding)	25 (100%)
Optimization of Medication Therapy	
Additional medication needed to optimize therapy	2 (8%)
Unnecessary medication discontinued	1 (4%)
Potentially harmful medication discontinued	1 (4%)

Impact on clinical and economic outcomes

One in every two New Yorkers with asthma have disease that is considered "not well controlled" or "very poorly controlled"[1,5] and less than 50% of these individuals appropriately use medications that are recommended[1] to control symptoms, prevent exacerbations and ultimately avoid emergency department visits and hospitalizations.[1,5] Despite the small number of patients included in the asthma management program the results indicate utilization of these important medications is more than twice what would have been expected (100%). Additionally, adherence and self-management were reinforced in all patients as recommended by treatment guidelines.[2] Finally, optimization of drug therapy by addition or discontinuation of medication was necessary in 16% of patients, indicating relevant opportunities to improve asthma medication regimens were identified and addressed by the pharmacist.

The New York State Department of Health (NYS DOH) Asthma Summary Report[1,5] provides estimates of the economic burden of asthma:

- The 2007 cost of hospitalizations is approximated at $535 million, (average cost per hospitalization of $14,107) representing a 70% increase since 1998.
- For asthmatics enrolled in New York State Medicaid managed care programs, more than $170 million was spent for asthma-related services at an average cost was $1,069 per enrollee.

Although the data collected in this pilot project did not include information about hospitalizations, published information on pharmacist-managed asthma programs have shown a reduction in the number of hospital and emergency department visits.[6-8] These studies demonstrated a reduction in hospital admission between 30 and 75%. Utilizing these results to approximate the economic impact of pharmacist-managed asthma in NYS reveals a potential annual savings of $150 - $400 million.

Conclusions

Asthma is a prevalent disease that is a significant public health and financial problem. Lack of an understanding of the disease process as well as poor adherence to medications is major factors impacting asthma control. Interventions by pharmacists to improve knowledge and adherence can significantly impact disease control and need for hospitalization. Expansion of CDTM has the potential to increase access to appropriate treatment and education, increase the likelihood of positive clinical outcomes and reduce the economic burden of the disease.

Asthma References

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4. NYS Behavioral Risk Factor Surveillance System, Asthma Call-Back Survey data, 2006-2010.

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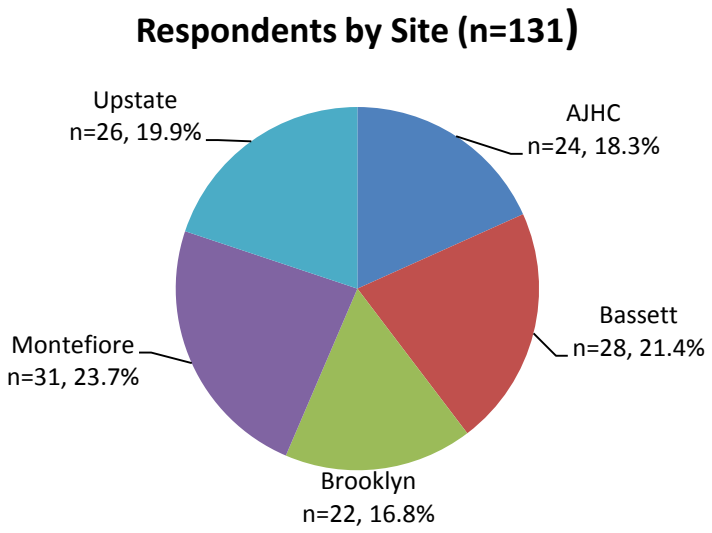
7. Bunting BA, Cranor CW. The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. J Am Pharm Assoc (2003) 2006;46:133-47.

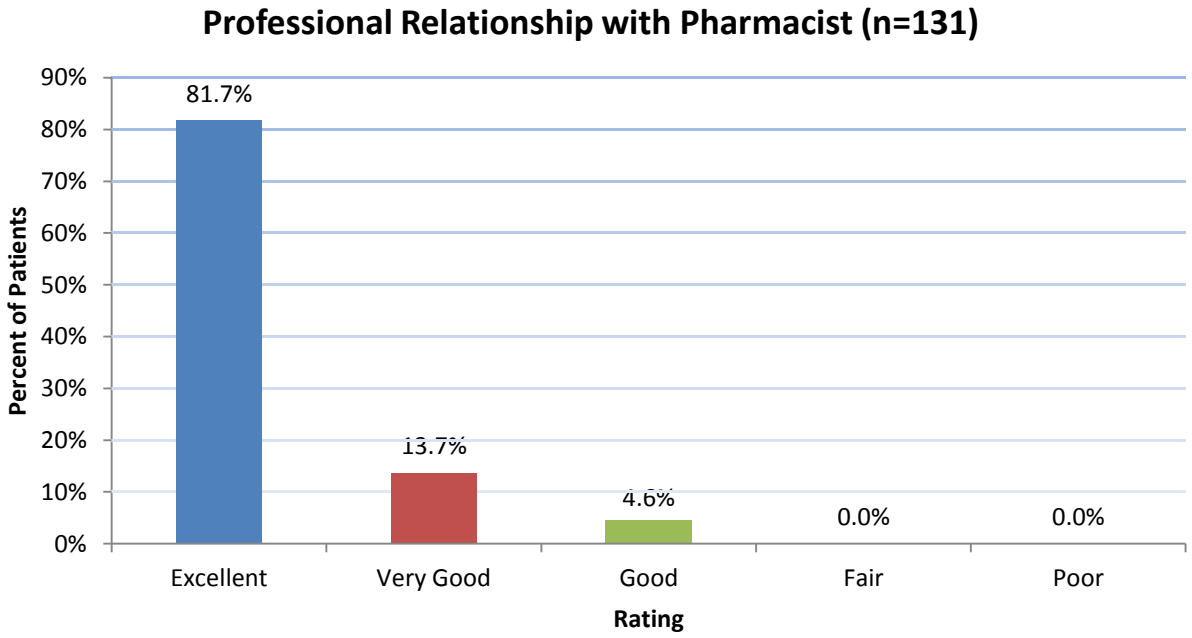
8. McLean W, Gillis J, Waller R. The BC Community Pharmacy Asthma Study: a study of clinical, economic and holistic outcomes influenced by an asthma care protocol provided by specially trained community pharmacists in British Columbia. Can Respir J 2003;10:195-202.

Patient Satisfaction

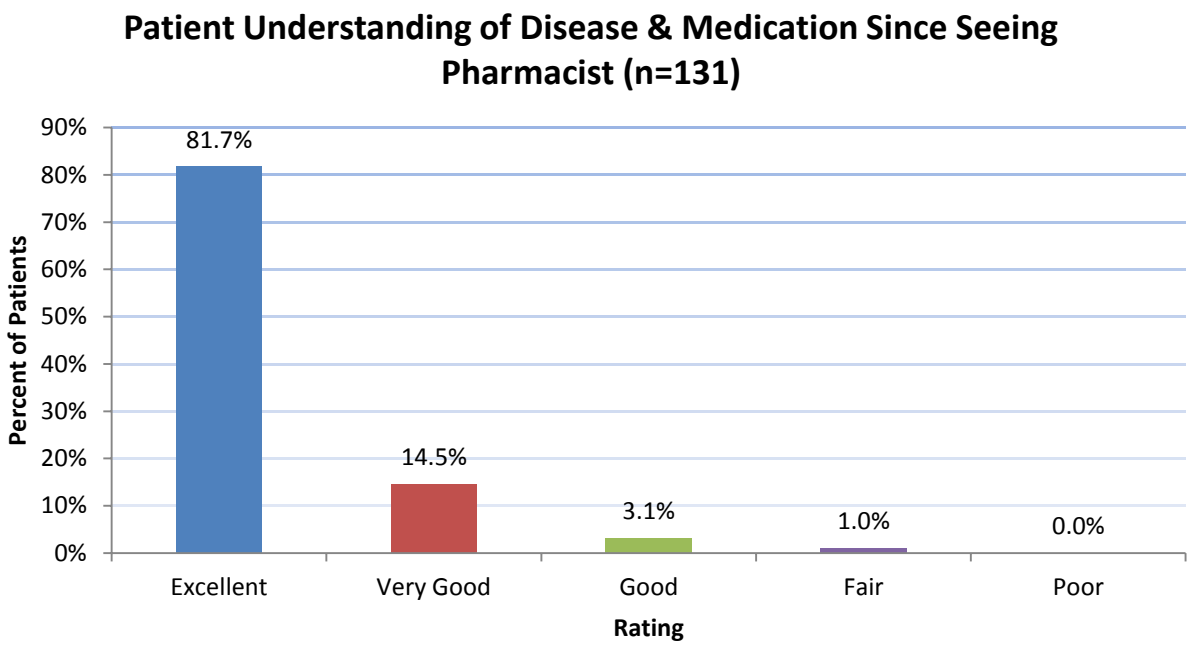
Those CDTM demonstration sites that did not include patient satisfaction in their outcomes were given an option of a global assessment of patient satisfaction using anonymous patient assessment questionnaires. The questionnaires were distributed and conducted from December 2013 to January 2014 and the results computer tabulated and reported. One hundred thirty-one (131) patient satisfaction surveys were received. The surveys were evenly distributed from among five sites:



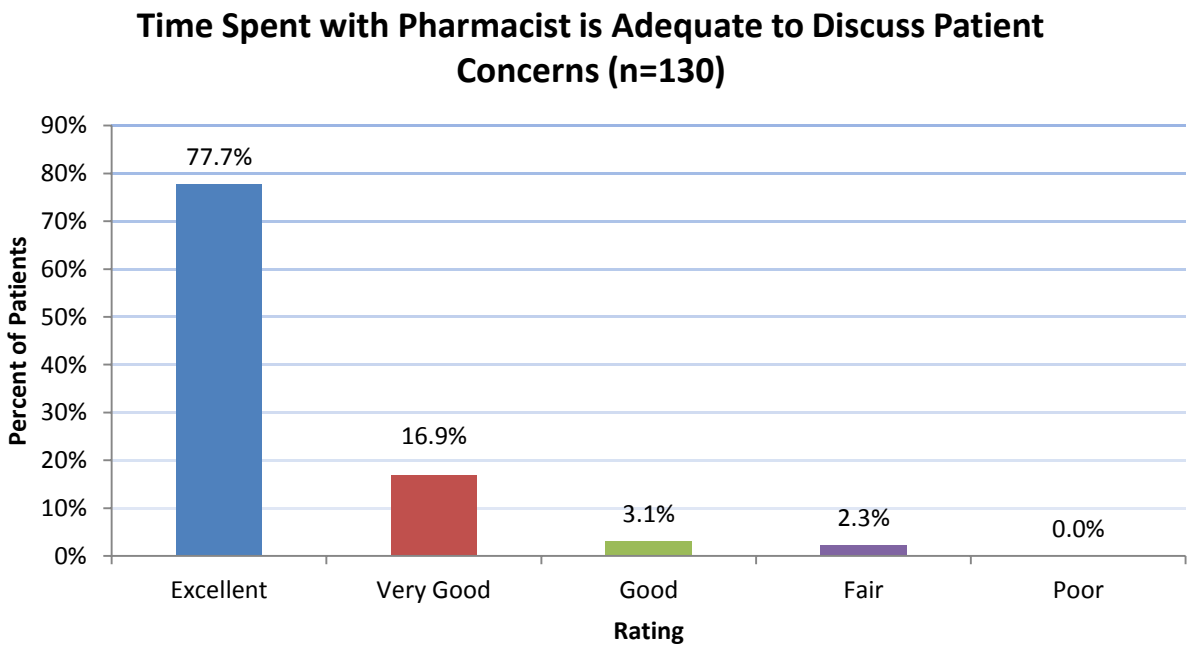
All respondents described a positive professional relationship with their pharmacist with 82% indicating an excellent relationship with their pharmacist.



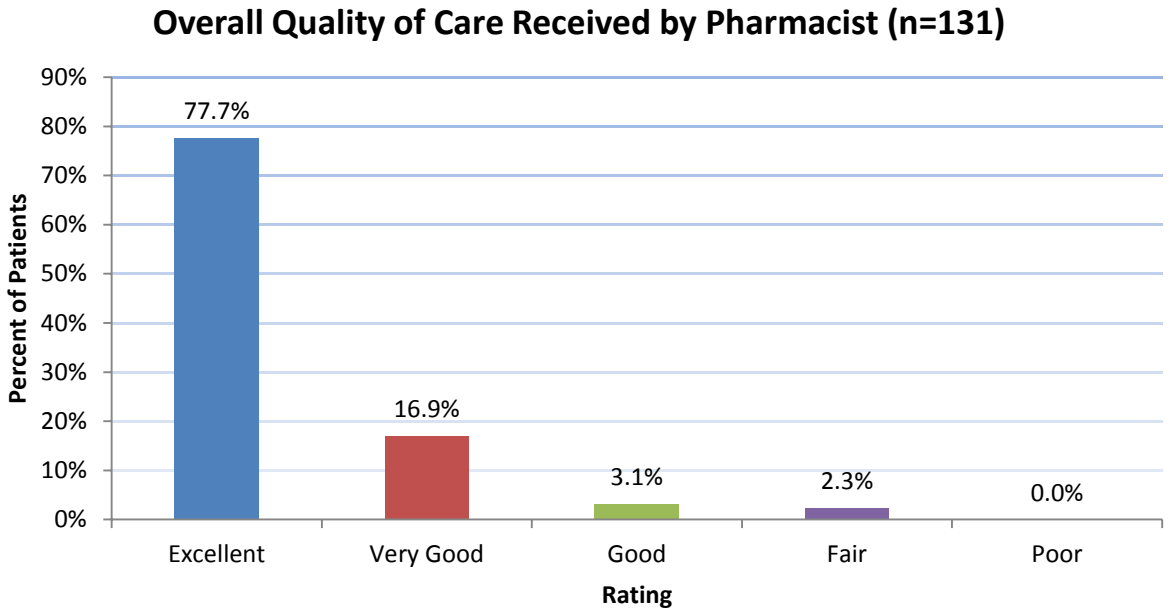
When asked if working with their pharmacist improved their understanding of their disease and medication regimen, 99% of the patients responded in the positive, with 82% stating that they had an excellent understanding of both since working with their pharmacist.



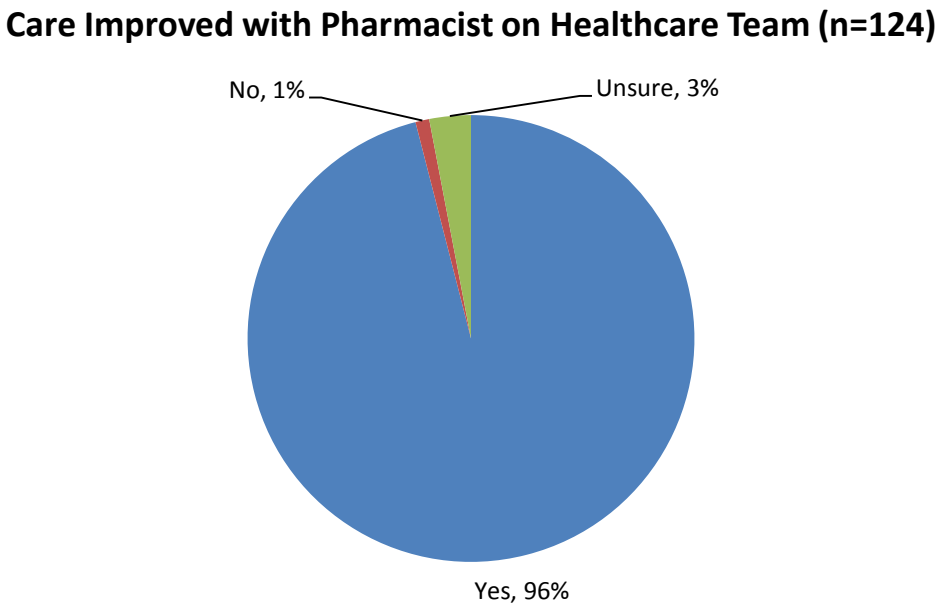
Ninety-eight percent of the patients surveyed felt that the time spent with the pharmacist was adequate to discuss their medication related concerns.



The majority of patients surveyed rated the quality of care received by their pharmacist as excellent.



Most importantly, 96% of patients felt that their care improved as a result of having a pharmacist on their health care team.



Patient Satisfaction Statements

"Always a very professional care and very flexible"
"[My pharmacist] is always helpful, professional and keeps this patient well informed"
"Excellent work"
"Exceptional personnel"
"Feeling better since being here"
"Good job"
"Great effort and care"
"I feel like I'm truly understood at my appts. This has been some of the best care I have ever received"
"I get to know more about my medication and its effectiveness"
"I receive super care from everyone at Upstate"
"I received very good care in every way"
"I wish I had one sooner"
"It was an excellent thing to do because docs are too busy and don't have the time"
"My care is exceptional from my pharmacist"
"My care with my diabetes has improved a lot since I've been seeing my pharmacist"
"My pharmacist always goes above and beyond. I wish she was my primary care provider"
"My pharmacist… is excellent"
"My pharmacists are the best ever."
"Pharmacists give you a better understanding at what your meds is supposed to do"
"Pharmacist is knowledgeable regarding use of warfarin"
"Saved my life. Saved my sister's life. I'm thankful for the patience and taking the time with me"
"She is the best!"
"She is very patient and understanding with me. I enjoy her being the one helping me"
"The care I have received from the CDTM pharmacist has been excellent."
The care I receive ensures that my INR is within limits & there is no interference with any other meds"
"The pharmacist she is great and the team is great"
"The way I see my condition the female CDTM to me is more concerned about my health"
"They are all very considerate and caring with all patients and their families"
"Treatment is professional"
"Willing to answer questions I may have and give me options"

Additional patient perception and satisfaction data supporting the role of the pharmacist in collaborative drug therapy management is included in the HIV and Oncology sections of this report.

Much appreciation is expressed by the report writing committee to Maria Cannito, PharmD, MS for the assistance she provided to compile and analyze the patient satisfaction surveys.

REPORT CONCLUSION

The CDTM demonstration projects undertaken pursuant to Chapter 21 of the Laws of 2011 suggested positive clinical, therapeutic and fiscal advantages of team-based delivery of care, with CDTM as a key facet. Satisfaction surveys demonstrated that CDTM in these settings was supported not only by pharmacists, but physicians and patients as well. These findings are consistent with a 2011 Report to the United States Surgeon General, prepared by the Office of the Chief Pharmacist entitled “Improving Patient and Health System Outcomes through Advanced Pharmacy Practice”.

Appendix A. -Report to the US Surgeon General

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Surgeon General
Rockville, MD 20857
Dec 14, 2011

RADM Scott Giberson, R.Ph, Ph.C, NCPS-PP, M.P.H.
Chief Professional Officer, Pharmacy
U.S. Assistant Surgeon General

Dear RADM Giberson,

I wish to commend you and our Commissioned Corps colleagues, as well as publicly support *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General, 2011.*

The report provides a thorough discussion of the comprehensive patient care services that pharmacists are currently providing through collaborative practice agreements (CPAs) in 43 states and in federal health care settings (e.g. IHS, VA, DOD).

Under CPAs, pharmacists work in collaboration with physicians and primary care clinicians to help patients, particularly those with chronic conditions, manage their medication regimens by:

- Performing patient assessments and developing therapeutic plans;
- Utilizing authorities to initiate, adjust, or discontinue medications;
- Ordering, interpreting and monitoring appropriate laboratory tests;
- Providing care coordination and other healthcare services for wellness and prevention; and
- Developing partnerships with patients for ongoing and follow-up care.

The report demonstrates through evidence-based outcomes, that many expanded pharmacy practice models (implemented in collaboration with physicians or as part of a health team) improve patient and health system outcomes and optimize primary care access and delivery.

Specifically, the report supports the following case:

1. Health leadership and policy makers should further explore ways to optimize the role of pharmacists to deliver a variety of patient-centered care and disease prevention, in collaboration with physicians or as part of the healthcare team. These collaborative pharmacy practice models can be implemented to manage and prevent disease, improve health care delivery and address some of the current demands on the health care system.

2. Utilization of pharmacists as an essential part of the healthcare team to prevent and manage disease in collaboration with other clinicians can improve quality, contain costs, and increase access to care.

3. Recognition of pharmacists as health care providers, clinicians and an essential part of the health care team is appropriate given the level of care they provide in many health care settings.

4. Compensation models, reflective of the range of care provided by pharmacists, are needed to sustain these patient oriented, quality improvement services. This may require further evolution of legislative or policy language and additional payment reform considerations.

This report provides the evidence health leaders and policy makers need to support evidence-based models of cost effective patient care that utilizes the expertise and contributions of our nations' pharmacists as an essential part of the healthcare team.

I look forward to working with you and your team as you implement this report and take its findings to the wider professional pharmacy community.

Yours sincerely,

Regina Benjamin MD

Regina Benjamin, MD, MBA
U.S. Surgeon General
VADM USPHS

Improving Patient and Health System Outcomes through Advanced Pharmacy Practice

A Report to the U.S. Surgeon General 2011

Office of the Chief Pharmacist

Rev: 5/2011, 8/2011, 12/2011

Suggested Citation

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RELEVENT 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.[1] 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[2] 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 dieticians/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.[3] 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.[4] 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.[5] Additionally, of all Medicare spending, 99% goes to beneficiaries with chronic disease.[6]
- **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.[7] 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.[8] 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.[9] 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."[10] 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.[11] 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…"[3]

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[12] 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.[3] 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."[13] 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.[13]

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.[14] More concisely, primary care can be described as consisting of four basic attributes: access, longitudinality, comprehensiveness of care, and care coordination.[15] 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.[15] 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."[16] 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.[1] 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.[17] By 1974, over 90 percent of the IHS sites had one or more pharmacist-run disease management programs in place.[18]

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.[1,19] 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.[20] 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 1970s, 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.[14] Additional examples of clinical pharmacy practice in the VA date back to 1995 and can be discussed in similar contexts.[21] 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."[22]** 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.[22,23] **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.[12]**

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 CDTM 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".[12] While this definition is very close to the pharmacy associations' consensual term "CDTM",[24] 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.[12] 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 pharmacy practice 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.[25] 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.[26] 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,"[11] 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.[11] 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.[27]

From an academic perspective, the American Association of Colleges of Pharmacy (AACP) annually convenes an Argus Commission comprised of the five immediate past AACP 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.[28]

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.[29] 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.**[30] 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.[31] 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.[31]

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.[31] 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 NPCS 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."[32] 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.[33] 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.[33] 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.[34] 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.[34,35] 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.[36] 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.[35]

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.[37] 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.[38] 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.[31] 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).[39]

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.[40] 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.[41] 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.[40,41] 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.[23] 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.[12,42] 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).[43] 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.[23] **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."[44] 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.[45] 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."[46] 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.[46] 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.[47] 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 dieticians 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."[48] 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.[49]

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.[50]

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.[51]

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.[52] 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.[53] It was cleared from the books with the convening of the 111th 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.[54]

- 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.[55]

- 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.[56]

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 (Ph.C).[57] 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.[58] 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.[59] 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.[59] 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 increases to 12%.[60]
- 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.[61] 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.[59]

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." [62]

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.[63] 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.[64]
- 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.[65]
- 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.[66]
- 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.[67,68]
- 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.[69]
- 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.[4]

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.[25,70-104]

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."[105]

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."[106] 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 preventing 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.[107,108] 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.[109] 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.[110]

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.[111] 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.[107,108] 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.[70]

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.[112] 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.[113]

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 regimes. 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.[114]

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.),[115,116] reduced outpatient visits, cost savings to a health care institution or health insurance plan,[93,95,112,116-123] direct cost savings to the patient,[124,125] or less missed/non-productive workdays.[112,115] 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.[126]

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.[127]
- More than $1,600 in direct health care costs per patient at a pharmacist-run anticoagulation clinic, compared with usual medical costs.[93]
- $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.[112]
- $918 per patient in direct health care costs for patients with diabetes enrolled in the Patient Self-Management Program for Diabetes for one year.[113]
- $1,230 per patient in indirect costs for those with asthma and direct cost savings of $725 average per patient.[115]
- $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.[114] (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.[115] Even after paying the pharmacists to provide these services, net costs were lower.[112]

Schumock et al.[123,128] and Perez et al.[129] 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

Benefit to Cost Ratio	**1988-1995**	**1996-2000**	**2001-2005**
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.[130 131]

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.[3] 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.[132-135] 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.[135-137] The "backbone of the American medical system" is threatened by this severe shortage of primary care physicians, which could lead to fragmented health care.[135]

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.[134] It has been said that "having insurance coverage without a source of care is like having currency without a marketplace."[132] 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,[138] and a 38 percent increase in demand for general internists is projected by the year 2020.[136] 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).[133] 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.[139] 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."[140] 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.[133] 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.[141] 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.[142] 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." [143] 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.[93,132,134] 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."[144] 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.[145] **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.[146] 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.[136 147] 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.[148] 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."[149]**

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.[150]

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.[31, 11,48,111,151-153] 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**."[111]

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."[10] 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
Improved Clinical Outcomes		
Barbanel D. Eldridge S, et al. (2003). Can a self-management program delivered by a community pharmacist improve asthma control? A randomized trial. *Thorax* 58(10):851-4. (YES)	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.	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.
Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilization, costs, and patient outcomes. *Cochrane Database Syst Rev* 2000(3):CD000336	Cochrane Review of articles discussing pharmacists with expanded roles	Twenty-five studies included >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.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Bluml BM, McKenney JM, Cziraky MJ. (2000). Pharmaceutical care services and results in project ImPACT: hyperlipidemia. *J Am Pharm Assoc* 40(2):157-65. (YES)	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.	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.
Bogden PE, Koontz LM, et al. The physician and pharmacist team. An effective approach to cholesterol reduction. *J Gen Intern Med* 1997;12(3):158-64.	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.	Results: The rate of success in achieving NCEP goals in the intervention arm was double the rate in the control arm (43% vs 21%, $P < .05$). Total cholesterol levels in the intervention arm declined 44 +/- 47 mg/dL versus 13 +/- 51 mg/dL in the control arm ($p < .01$). 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.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Bozovich M, Rubino CM, Edmunds J. Effect of a Clinical Pharmacist-Managed Lipid Clinic on Achieving National Cholesterol Education Program Low-Density Lipoprotein Goals. *Pharmacotherapy* 2000;20(11):1375-1383. (YES)	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.	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.
Carson, J. J. Pharmacist-coordinated program to improve use of pharmacotherapy for reducing risk of coronary artery disease in low-income adults. *Am J Health Syst Pharm* 1999;56(22):2319-24. (YES)	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.	Results: In secondary-prevention group, mean LDL fell by 26% ($p < 0.0001$), and 24 (73%) of the patients had a reduction in LDL concentration. Mean total cholesterol concentration among secondary-prevention patients decreased by 11% ($p = 0.007$), and the mean HDL concentration increased by 19% ($p < 0.0001$). The percentage of secondary-prevention patients achieving their NCEP LDL goal of <100 mg/dL increased from 6% to 27% ($p < 0.04$). In the primary-prevention group, the mean LDL concentration fell by 27% ($p < 0.0001$), 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% ($p = 0.0002$), and the mean HDL concentration increased by 12% ($p = 0.009$). The percentage of patients achieving their NCEP-recommended LDL goal of <130 mg/dL increased from 20% to 51% ($p = 0.006$). 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.

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Carter BL, Barnette DJ, et al. (1997). Evaluation of hypertensive patients after care provided by community pharmacists in a rural setting. *Pharmacotherapy 1997;*17(6):1274-85. (YES)	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.	Results: Systolic blood pressure was reduced in the study group (151 mmHg baseline, 140 mmHg at 6 mo., $p < 0.001$) 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.
Coast-Senior EA, Kroner BA, Kelley CL, et al. Management of patients with type 2 diabetes by pharmacists in primary care clinics. *Ann Pharmacother* 1998 Jun;32(6):636-41.	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,	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% ($p = 0.00004$), 65 mg/dL ($p < 0.01$), and 82 mg/dL ($p = 0.00001$) 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.

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	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. *Clin Pharmacol Ther* 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. *Pharmacotherapy* 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.

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Erhun WO, Agbani EO, et al. Positive benefits of a pharmacist-managed hypertension clinic in Nigeria. *Public Health* 2005;119(9):792-8. (YES)	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.	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.
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. *Arch Intern Med* 1999;159(16): 1939-45. (YES)	181 patients with heart failure and left ventricular dysfunction (ejection fraction <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.	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 < 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

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		multidisciplinary heart failure team. This observation may be due to higher doses of ACE inhibitors and/or closer follow-up.
Goode JV, Swiger K, et al. Regional osteoporosis screening, referral, and monitoring program in community pharmacies: findings from Project ImPACT: Osteoporosis. *J Am Pharm Assoc* (2003) 2004;44(2):152-60. (YES)	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.	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.
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. *Am J Med* 1996 Apr;100(4):428-37.	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 (> 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	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%; $P < 0.001$). Conclusion: A clinical pharmacist providing pharmaceutical care for

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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. *Ann Pharmacother* 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. *J Intern Med* 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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	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.	
Kaboli PJ, Hoth AB, et al. Clinical pharmacists and inpatient medical care: a systematic review. *Arch Intern Med* 2006;166(9):955-64. (YES)	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.	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.

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Koshman SL, Charrois TL, et al. Pharmacist care of patients with heart failure: a systematic review of randomized trials. *Arch Intern Med* 2008;168(7):687-94. (YES)	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.	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.
Leal S, Herrier RN, Glover JJ, Felix A. Improving quality of care in diabetes through a comprehensive pharmacist-based disease management program. *Diabetes Care* 2004;27(12):2983-84. (YES)	Pharmacist worked under a collaborative practice agreement as the PCP for a diabetic population; collaboration also included HTN and lipid management in 199 patients	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"
Lee J, McPherson ML. Outcomes of recommendations by hospice pharmacists. *Am J Health Syst Pharm* 2006;63(22): 2235-9. (YES)	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	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

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	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.	(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.
Lipton HL, Bero LA, et al. The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing. A randomized controlled trial. *Med Care* 1992;30(7):646-58. (YES)	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.	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.
Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to	Meta-analysis of pharmacist intervention in diabetes management	Diabetes education and medication management were the most frequently utilized interventions. Significant reduction in HbA1c in pharmacist intervention

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pharmacist interventions. Part I: systematic review and meta-analysis in diabetes management. *Ann Pharmacother* 2007;41:1569-82. (YES)		
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. Ann Pharmacother 2007;41:1770-81. (YES)	Meta-analysis of pharmacist intervention in hypertension management	Hypertension education and medication management were the most frequently utilized interventions. Significant reduction in systolic blood pressure (BP) in pharmacist intervention
McKenney JM, Slining JM, Henderson HR, et al. The effect of clinical pharmacy services on patients with essential hypertension. *Circulation* 1973 Nov;48(5):1104-11.	Compared clinical pharmacy services provided to 25 study patients vs. 25 control patients with regard to essential hypertension.	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.
Radley AS, Hall J, et al. Evaluation of anticoagulant control in a pharmacist operated anti-coagulant clinic. *J Clin Pathol* 1995;48(6):545-7. (YES)	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	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.

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Reeder TA, Mutnick A. Pharmacist- versus physician-obtained medication histories. *Am J Health Syst Pharm* 2008;65(9):857-60. (YES)	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.	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 (p < or = 0.001). The pharmacist documented significantly more medication doses and dosage schedules than did physicians (614 versus 446 and 614 versus 404, respectively) (p < or = 0.001 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.
Rosen CE, Copp WM, Holmes S. Effectiveness of a specially trained pharmacist in a rural community mental health center. *Public Health Rep* 1978:93(5);464-7. (YES)	Compared pharmacist-provided care with psychiatrist-provided care to mental health patients in eight clinics over a three year period.	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.

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Rothman R, Malone R, et al. Pharmacist-led, primary care-based disease management improves hemoglobin A1c in high-risk patients with diabetes. *Am J Med Qual* 2003;18(2):51-8. (YES)	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.	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.
Sadik A, Yousif M, et al. Pharmaceutical care of patients with heart failure. *Br J Clin Pharmacol* 2005;60(2):183-93. (YES)	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%).	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.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Scott DM, Boyd ST, et al. Outcomes of pharmacist-managed diabetes care services in a community health center. *Am J Health Syst Pharm* 2006;63(21): 2116-22. (YES)	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.	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 ($p < 0.05$). 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.
Sookaneknun P, Richards RM, et al. Pharmacist involvement in primary care improves hypertensive patient clinical outcomes. *Ann Pharmacother* 2004;38(12):2023-8. (YES)	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.	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 > 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.

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Weinberger M, Murray MD, et al. Effectiveness of pharmacist care for patients with reactive airways disease: a randomized controlled trial. *JAMA* 2002;288(13):1594-602. (YES)	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.	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.
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).	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.	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 (< 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.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Pharmacotherapy 2005;25(1):110-5. (YES)		
Improved Clinical Outcomes AND Cost Reduction		
Bond CA, Monson R. Sustained improvement in drug documentation, compliance, and disease control. A four-year analysis of an ambulatory care model. *Arch Intern Med* 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. *J Am Pharm Assoc* (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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		use.
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. *J Am Pharm Assoc* (2003) 2008;48(1):23-31. (YES)	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.	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.
Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and health care costs. *Arch Intern Med* 1998 Aug 10-24;158(15):1641-7.	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.	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

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		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.
Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc* 2003;43(2):173-84. (YES)	Changes in glycosylated hemoglobin (A1c) and serum lipid concentrations, changes in diabetes-related and total medical use, costs over time.	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 >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.
Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc* 2003;43(2):149-59. (YES)	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.	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.

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Dole EJ, Murawski MM, et al. Provision of pain management by a pharmacist with prescribing authority. *Am J Health Syst Pharm* 2007;64(1):85-9. (YES)	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.	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.
Farris KB, Kumbera P, et al. Outcomes-based pharmacist reimbursement: reimbursing pharmacists for cognitive services part 1. *J Manag Care Pharm* 2002;8(5):383-93. (YES)	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	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.

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	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.	
Garrett DG, Bluml BM. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. *J Am Pharm Assoc* (2003) 2005;45(2):130-7. (YES)	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.	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.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Jameson J, VanNoord G, et al. The impact of a pharmacotherapy consultation on the cost and outcome of medical therapy. *J Fam Pract* 1995;41(5):469-72. (YES)	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.	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.
Johnston AM, Doane K, Phipps K, Bell A. Outcomes of pharmacists' cognitive services in the long-term care setting. *Cons Pharm* 1996;11(1):41-50. (YES)	Outcome measures: Number and type of interventions, change in drug therapy, change in medication cost, change in patient health.	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.
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	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	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;

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Columbia. *Can Respir J* 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. *Pharmacoth* 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$) during the four months. The intervention program in this study led to a significant reduction in cardiovascular risk in the intervention group during the 4-month follow-up period. The incremental cost to provide the program appeared minimal from both government and pharmacy manager perspectives. It is hoped that these results could support negotiations for reimbursement of clinical pharmacy services with payers.
Sturgess, IK, McElnay JC, et al. Community pharmacy based provision of pharmaceutical care to older patients. *Pharm*	Methods: A randomized, controlled, longitudinal, clinical trial with repeated measures was performed over an 18-month period, involving community pharmacies (five interventions and five controls) in Northern Ireland. Elderly,	Results: A significantly higher proportion of intervention patients were compliant at the end of the 18-month study and experienced fewer problems with medication compared to control patients ($P < 0.05$). There was little impact on quality of life and health care

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World Sci 2003;25(5):218-26. (YES)	ambulatory patients (> 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.	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.
Cost Reduction		
Bootman JL, Harrison DL, et al. The health care cost of drug-related morbidity and mortality in nursing facilities. *Arch Intern Med* 1997;157(18):2089-96. (YES)	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.	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.
Brooks JM, McDonough RP, Doucette W. Pharmacist reimbursement for pharmaceutical care services: Why insurers may flinch. *Drug Benefit Trends* June 2000;45-62. (YES)	Researchers developed complex economic model to evaluate whether pharmaceutical care is cost-effective.	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.

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Christensen DB, Neil N, et al. Frequency and characteristics of cognitive services provided in response to a financial incentive. *J Am Pharm Assoc* 2000;40(5):609-17. (YES)	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.	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 ($P < 0.05$) 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 < or = 6 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.

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Christensen D, Trygstad T, et al. A pharmacy management intervention for optimizing drug therapy for nursing home patients. *Am J Geriatr Pharmacother* 2004;2(4):248-56. (YES)	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.	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, > 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.
McMullin, ST, Hennenfent JA, et al. A prospective, randomized trial to assess the cost impact of pharmacist-initiated interventions. *Arch Intern Med* 1999;159(19):2306-9. (YES)	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.	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 < 0.001). Interventions involving anti-infective agents had the greatest cost savings (mean, $104.08 vs. $58.45; P < 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

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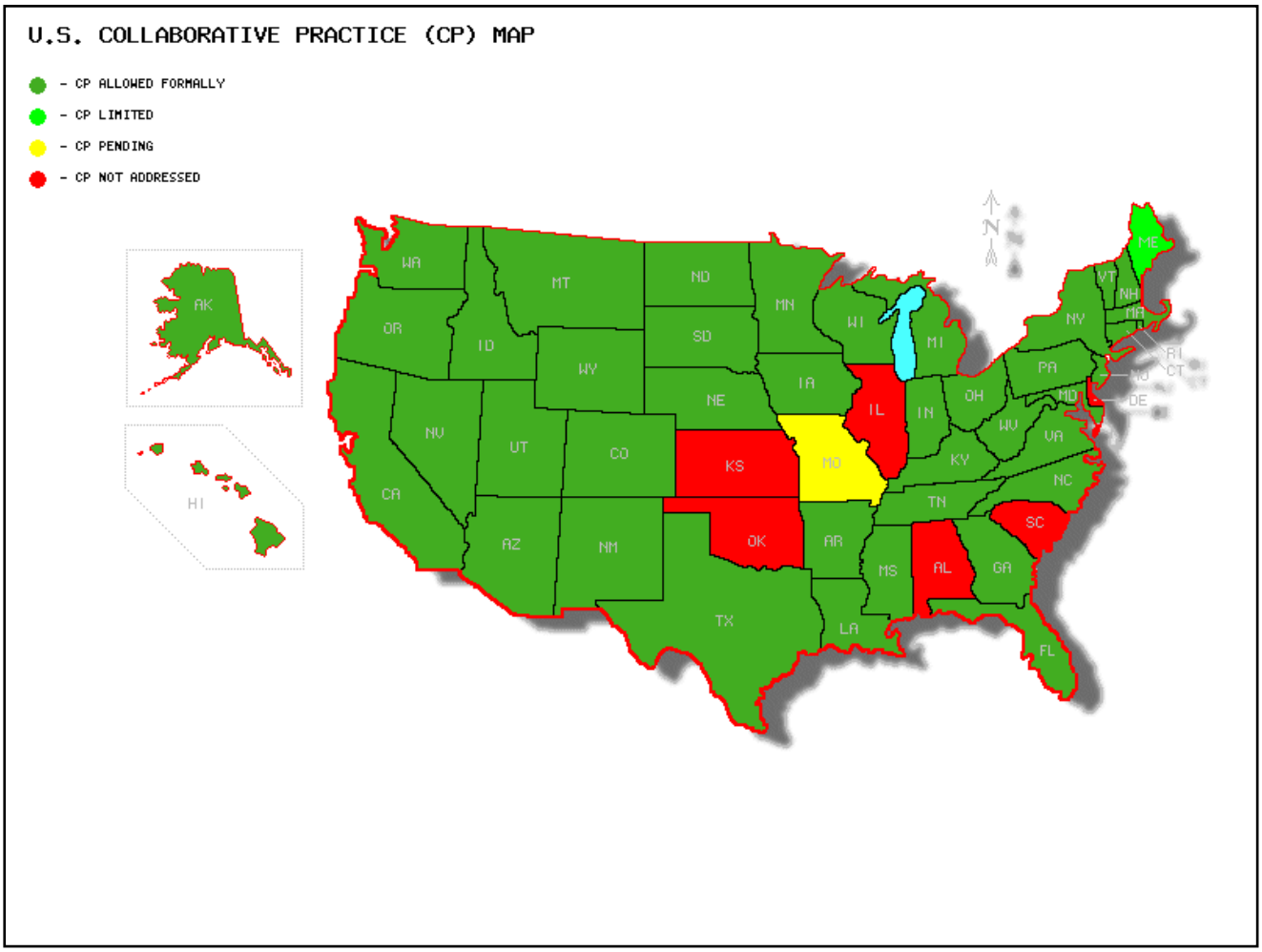
		impact on length of hospital stay, in-hospital mortality, 30-day readmissions, or the need to re-administer the targeted medication or restart IV therapy. Conclusion: While interventions solely aimed at reducing costs represent a small portion of a pharmacist's activities, they can result in significant savings for an institution.
Schumock GT, Meek PD, Ploetz PA. Economic evaluations of clinical pharmacy services – 1988-1995. The Publications Committee of the American College of Clinical Pharmacy. *Pharmacotherapy* 1996 Nov-Dec;16(6):1188-208.	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%).	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.
Walker S, Willey CW. Impact on drug costs and utilization of a clinical pharmacist in a multisite primary care medical group. *J Manag Care Pharm* 2004;10(4):345-54. (YES)	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.	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.

CITATION; (PEER REVIEWED)	OUTCOME VARIABLES	RESULTS/CONCLUSIONS
Carmichael JM, Alvarez A, Chaput R, DiMaggio J, Magallon H, Mambourg S. (2004). Establishment and outcomes of a model primary care pharmacy service system. *Am J Health-Syst Pharm* 2004 Mar 1;61(5):472-82. (YES)	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.	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.

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

- ☐ Anticoagulation
- ☐ Asthma
- ☐ Chronic Kidney Disease
- ☐ Heart Failure
- ☐ Lipid Management
- ☐ Pain Management
- ☐ Tobacco Cessation

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?	◯	◯	◯	◯	◯

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?	◯	◯	◯	◯	◯

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?	◯	◯	◯	◯	◯

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?	◯	◯	◯	◯	◯

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?	◯	◯	◯	◯	◯

. 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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Appendix B.- Practitioner and stakeholder support

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Shelly Abraham, MD	The Brooklyn Hospital Center New York-Presbyterian Healthcare System	13
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David L. Battinelli, MD	Chief Medical Officer Sr. Vice President North Shore- LIJ Health System Dean for Education Betsy Cushing Whitney Professor of Medicine Hofstra-North Shore- LIJ School of Medicine	16
Susan J. Beane, MD	Vice President Medical Director Healthfirst	17
Dr. J. Bella, Director of Cardiology Dr. S.Chilimuri, Chief of Medicine Dr. S. Megalla, Director of CHF	Bronx- Lebanon Hospital Center Health Care System	18-19
Leonard Berkowitz, MD	The Brooklyn Hospital Center New York-Presbyterian Healthcare System	20
Henny H. Billett, MD, MSc	Chief, Division of Hematology Professor, Clinical Medicine and Pathology Montefiore Medical Center Albert Einstein College of Medicine	21-22
Debra Buchan, MD, FACP	Associate Professor Department of Medicine Upstate University Hospital	23
Cynthia Carlyn, MD	Chief Infectious Disease Stratton VA Medical Center	24
Lisa M. DeAngelis, MD	Chair, Department of Neurology Lillian Rojtman Berkman Chair in Honor of Jerome B. Posner Memorial Sloan Kettering Cancer Center	25
John G. Dier, MD, FACP	AMS Medical Director Bassett Medical Center	26
Russell J. DiGate , Ph.D.	Dean St. John's University College of Pharmacy & Health Sciences	27-28
Anthony DiRubbo, MD, FAAP	Clinical Assistant Professor of Medicine Upstate Medical Center Upstate University Hospital	29
Robert Downes, RPH, MPH	Assistant Director NYU Langone Medical Center Pharmacy Department	30
Marie L. Eloi-Stiven, MD	Attending Physician The Brooklyn Hospital Center New York-Presbyterian Healthcare System	31

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Dr. Ghassi	Primary care Albany Stratton VA Medical Center	38
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Sergio Giralt, MD	Chief, Adult Bone Marrow Transplant Service Memorial Sloan Kettering Cancer Center Professor of Medicine Weil Cornell Medical College	40-41
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Michael Krastins, MD	Staff Physician, Primary Care Albany VA Medical Center	49
Vicki LoPachin, MD	Chief Medical Officer Senior Vice President for Excellence in Patient Care The Mount Sinai Hospital	50
John E. Lukaszewicz, MD	Family Medicine Glens Falls Primary Care Practice	51
Sheran Mahatme, DO, MPH	Infectious Diseases Medical Subspecialty Director Assistant Professor of Medicine Stratton VA Medical Center Section of Infectious Diseases	52-53
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Lewis Nelson, MD	New York City Poison Control Cneter Bellevue Hospital Center South Manhattan Healthcare	56-57
James M. O'Donnell, PhD	Dean and Professor University at Buffalo, SUNY School of Pharmacy and Pharmaceutical Sciences	58

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Mark F. Perry, MD	Chief Medical Officer Lifetime Health Medical Group	61
Robert A. Press, MD, PhD	NYU Langone Medical Center Chief Medical Officer	62
Donald Raum, MD	Regional Director Montefiore Medical Group 1 & 3 Montefiore Medical Center Assistant Professor of Medicine Albert Einstein College of Medicine, Yeshiva University	63
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Viswanath Vasudevan, MD	Chair, P &T Committee The Brooklyn Hospital Center New York-Presbyterian Healthcare System	75-76
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Jerel Zoltick, MD, FACC	AMS Medical Director FoxCare Center Cardiology Bassett Healthcare Network Bassett Medical Center	78

AMCP Academy of Managed Care Pharmacy®

Practice Advisory on Collaborative Drug Therapy Management

I. Introduction

Collaborative drug therapy management (CDTM) is a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy.[1] In this role, pharmacists augment the physician, applying their specific drug therapy knowledge, skills and abilities to complement other types of care provided by collaborating professionals.[1] People may refer to CDTM differently and use terms such as collaborative practice agreements or collaborative practice. The CDTM designation is used primarily because it is descriptive of the usual scope of the practice agreement between the physician and the pharmacist, i.e., the management of patient drug therapy regimens.

Because these arrangements typically allow pharmacists to engage in professional activities that fall outside of traditional pharmacy practice laws, authorization in each individual state has been required to establish laws governing how CDTM can be administered in a given state. Authority for collaborative drug therapy management is generally found in the state pharmacy practice act and/or through regulations promulgated by state boards of pharmacy. As of this writing, 46 states have authorized CDTM arrangements between pharmacists and physicians.[1] These regulations establish the criteria for participation and the range of services that the pharmacists may provide when working under such agreements.

Responsibilities placed upon pharmacists working with physicians under CDTM agreements can include:

- Implementing or modifying drug therapy of individual patients or groups of patients (patients with diabetes, asthma, hypertension, etc);
- Ordering and evaluating the results of laboratory tests directly relating to drug therapy;
- Administration of medications, including immunizations.

The following activities (within most pharmacists' usual scope of practice) are also integral to meeting the responsibilities delineated above:

- Collecting and reviewing patient drug histories;
- Obtaining and checking vital signs;
- Performing physical assessment consistent with the disease state and drug therapy;
- Evaluating and rendering advice regarding adjustments in the patient's drug regimen.

II. Collaborative Drug Therapy Management and Managed Care Organizations

Managed care organizations have three primary goals in managing the health of their enrollees: improving the quality of patient outcomes, increasing patient satisfaction and managing costs. CDTM agreements between physicians and pharmacists serving a managed care organization's enrollees can contribute to each of those goals. CDTM agreements take maximum advantage of the physician's training and expertise in disease diagnosis and the pharmacist's training and expertise in drug therapy and disease management.

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This collaboration allows the physician and pharmacist to share the responsibility for patient outcomes.

CDTM:

- Makes drug therapy changes easier, more efficient and convenient for the patient, pharmacist and physician
- Expands the ability of health care professionals to provide optimal care for their patients;
- Provides a means for physicians to satisfy the unmet needs or unsolved problems of their patients;
- Reinforces relationships between pharmacists and physicians;
- Extends access to health education, health screening and other services to underserved populations in minority communities, in poorer areas, in urban centers, in rural areas and in institutions where physician access is limited.

As such, the return on investment calculated by the managed care organization is expected to be positive and may allow for the organization to take a proactive role in proposing new CDTM arrangements between willing physicians and pharmacists to be used within a managed care organization.

A large array of CDTM arrangements exists within health plans, including:

- Emergency contraception
- Asthma therapy management
- Immunization administration
- Hypertension therapy management
- Dyslipidemia therapy management
- Warfarin/anticoagulant therapy management
- Diabetic therapy management
- Depression therapy management
- Smoking cessation therapy
- Flu/antiviral therapy

These programs have been shown to be successful in managing therapy in a wide variety of medical conditions. CDTM programs improve the quality of medication therapy, and improve the satisfaction of the patient, physician and pharmacist.[1,2,3,4] In addition to pharmacy organizations, CDTM programs have been recognized by the American College of Physicians, the American Society of Internal Medicine and the Infectious Diseases Society of America.[5] Each organization has issued statements in support of the value of CDTM programs.

What are the benefits to patients?

- Increased access to health care
- Enhanced patient care through optimized drug therapy management
- Decreased drug-related problems (adverse drug reactions, drug interactions, poor compliance, etc.) through the use of scientifically designed drug therapy protocols and management
- Reduced costs through optimal use of medications and minimization of drug related problems
- Pharmacist identification of underlying conditions that require the care of a physician.

What are the benefits to physicians?

- Reduced visits for chronic disease patients, freeing more time for physician patient interaction and for management of complex case
- Delegation of medication management to the drug therapy specialist, the pharmacist, who has unique skills and knowledge that can be used to support the physician's therapy strategies
- Referral of patients by pharmacists to physicians
- Enhanced ability to achieve pay-for-performance goals

What are the benefits to pharmacists?

- Allows pharmacists to move from a product-oriented service to a patient-focused practice using their unique knowledge to improve clinical outcomes
- Allows pharmacists to demonstrate their value as an integral part of the health care team

What are the benefits to health plans/managed care organizations?

- Utilizing the pharmacotherapy skills of the pharmacist to decrease chronic disease physician visits for medication therapy related issues
- Enhanced drug therapy outcomes through optimization of drug therapy regimens
- Improved patient satisfaction
- Reduced costs of care
- More targeted physician referrals

What is the potential liability to a pharmacy?

CDTM arrangements include an added potential of practice liability to the pharmacist caring for patients under a CDTM agreement. Health care professionals have a duty to provide patient care in a manner consistent with applicable laws, medical evidence and standard of care. If practitioners, within the scope of a CDTM setting, are found to be negligent, pharmacists and physicians are placed at risk of legal repercussions consistent with any harm done to a patient. Since each CDTM agreement is unique, and each state allowing CDTM does so under its own laws, it is not possible to identify specific risk issues in the context of this document.

III. Differences between Medication Therapy Management and CDTM

In discussions involving CDTM, a common question that arises is the distinction between CDTM and medication therapy management (MTM). Medication therapy management is a distinct service or group of services that optimize therapeutic drug outcomes for individual patients. MTM services are independent of, but can occur in conjunction with the provision of a medication.

As many of the services provided under MTM are consistent with CDTM activities, the terms CDTM and MTM have at times been used interchangeably. However, the two programs should not be thought of as one in the same, as several important distinctions exist.

In contrast to CDTM, MTM services do not require the development of formal practice agreements between individual pharmacists and physicians or groups of pharmacists and physicians, and MTM services may be provided by other ancillary health care personnel. In addition, individual state pharmacy

practice laws do not establish the scope of MTM services that may be offered unlike CDTM requirement. It is assumed that pharmacists practicing under MTM agreements will abide by existing state pharmacy practice laws.

The distinction between CDTM and MTM programs is important given that formalized agreements between physicians and pharmacists are not required for MTM and the scope of services provided under CDTM is typically broader than those for MTM.

IV. Considerations for Successful CDTM Programs

CDTM agreements are formalized, written documents outlining the scope of services to be provided by each party. Sections of a CDTM agreement typically include:

- Overview of program
- The purpose of the agreement
- Criteria for patient inclusion
- Responsibilities of the involved professionals
- Monitoring and treatment guidelines
- Detailed instructions as to how to operate the CDTM agreement, including referral back to physician
- Training requirements
- Quality improvement process

Effective CDTM agreements require the presence of the following key elements:

1. An environment whereby one or more pharmacist(s) and one or more physician(s) have professional relationships sufficient to allow pharmacists under a written and signed agreement to perform certain patient care functions under certain specified conditions;
2. Access to patients and pertinent information from their medical records;
3. Access to pertinent patient laboratory tests and results;
4. The knowledge, skills and ability to perform authorized functions;
5. Documentation and communication of pertinent information for the patient's medical record;
6. Accountability for the quality measures;
7. The ability to be reimbursed for drug therapy management activities;
8. Commitment of the time and resources necessary to achieve stated goals and objectives.

Within health care systems, such as health maintenance organizations, the relationships between pharmacists and physicians, developed through the normal course of patient care activities, may be strong enough to allow quick transitions to formal CDTM agreements. Outside of such organizations, in a community setting, pharmacists wishing to develop CDTM arrangements with local physicians must first develop credibility and rapport through a communication plan. The plan should include basic information about the range of services offered, the benefit to the physician and patient, and a means to identify areas how the program could benefit a physician's practice.

In addition to a successful physician communication strategy, patient communication must also be put in place. In many instances, patients will be unfamiliar with the role of the pharmacist outside the traditional

drug dispensing function. Education about how a CDTM program will benefit the patient through improved compliance, decreased medication costs and improved outcomes should be undertaken. Patients should understand that drug therapy management services administered under a CDTM agreement require compensation and patient-specific information.

Compensation

Compensation may depend on the type of managed care organization model. In a group model managed care environment, CDTM pharmacists can work as do other nonphysician health care providers with advanced training, as part of a patient care team. In a fee-for-service environment, pharmacists have three options: they can work as part of a physicians' group practice and file for payment under the physician's provider number; they may be recognized as a provider and bill a managed care organization directly; or patients can pay cash for their services. Pharmacists are not currently recognized as a provider under Medicare and, therefore, cannot bill Medicare directly for services under the Part B benefit. In the first scenario, a pharmacist would file a "level 2" visit claim for a typical anticoagulation visit, and the reimbursement would return to the practice for which the pharmacist works. Pharmacists who are not directly employed by the medical group or work in an individual practice setting in ambulatory settings (e.g., community pharmacy) may establish provider status with payors and bill directly under the medical reimbursement system. [6] Additionally, pharmacists sometimes electronically bill for CDTM services as a component of a patients drug benefit using a pharmacy claims system.

While physician office billing functions are well supported, pharmacist billing functions for non-distributive services are typically not well defined, nor are they well supported by care systems. As such, the three billing scenarios described above may all be necessary when providing services to a range of patients enrolled in different medical and pharmacy benefit plans, as determined by the benefit plan design.

As of May 23, 2007 all claims for CDTM activities must be submitted under a provider's National Provider Identification (NPI) code number. NPI status may be granted to both individuals and organizations. Therefore, individual pharmacists and the pharmacy practice site may each have unique identifier status. Health plans may have a limited network of pharmacists that provide CDTM activities and may require an NPI number for reimbursement.

Operation of a successful CDTM program must include adequate resource allocation to provide patient care activities, administrative functions and marketing/communication activities. In addition, there should be a means of calculating the return on investment gained through decreased use of other health care resources such as physician office visits, emergency room visits, hospitalizations and medications.

V. Examples of CDTM Use in Managed Care Settings

CDTM arrangements appear very differently across various managed care settings. Two examples can be demonstrated in programs involving patients of Blue Cross Blue Shield of Minnesota and Scott & White Health Plan.

In 1999, Fairview Health Services of Minneapolis-St. Paul established a CDTM program in six primary care clinics called the Collaborative Practice of Pharmaceutical Care. Through 2004 the Fairview CDTM practice has led to improvements in patients' goals of therapy achieved and identification and resolution of

more than 12,000 drug therapy problems in 4000 patients receiving CDTM services.[7] Through a collaborative practice agreement signed by the medical director of Fairview Clinics and individual "certified pharmaceutical care practitioners," these specially trained pharmacists were authorized to provide pharmaceutical care services to patients in Fairview Clinics and Pharmacies. These "pharmaceutical care services" were defined as "a practice in which a practitioner takes responsibility for all of a patient's drug-related needs and is held accountable for this commitment."[8] Blue Cross Blue Shield of Minnesota and Prime Therapeutics have worked with the University of Minnesota and Fairview Health Services to design a study to measure the outcomes of the program. Results from this study are pending.

Scott & White Health Plan implemented a CDTM program for members meeting certain criteria. This program initially focused on diabetes and heart failure (CHF), and now includes asthma. In this program, Scott & White Health Plan members meet with a pharmacist monthly and are then eligible for copayment waivers of medications and supplies for the identified disease state. The care is provided in Scott & White retail pharmacies, and the pharmacists are working under a collaborative practice agreement with the Scott & White physicians. The pharmacies are billing for pharmacist services.[9] A study was conducted to evaluate the impact of the pharmacist-run medication management program on medication adherence and to measure the effect of the medication management program on medical utilization costs and glycemic control. In a preliminary analysis of results patients in the intervention group demonstrated an improvement in medication adherence and a trend of greater decline in hemoglobin A1c compared to controls after 12 months of enrollment in the medication management program.[10,11]

In a 2011 update, Scott & White indicated that the program was still operational for diabetes for the fourth year, and for asthmatic patients and patients with refractory hypertension. A clinical and economic evaluation was completed for the diabetes group with the intervention group showing a 58 percent greater sustained reduction in hemoglobin A1c (HgA1c) over a two year period compared to matched controls. The health economic outcomes associated with the diabetic program showed a significant reduction in inpatient medical costs in the intervention group while the medication costs and the outpatient costs were greater in the intervention group. The average reduction in total medical costs during the second year of management in the intervention group vs the control group reflected a reduction of $1,800 per enrolled diabetic per year over their matched controls. For the 400 patients currently enrolled in the program that reflects an annual savings of $720,000 per year for the intervention group. Savings are inclusive of all costs associated with administering the program, including copay waivers and visit charges for the monthly pharmacist visit.[12]

VI. Conclusion

CDTM agreements in which pharmacists use their therapy expertise to provide drug therapy management services under formal agreements with physicians have been demonstrated to increase the quality of patient medication therapy while decreasing costs and improving patient, physician and pharmacist satisfaction. These agreements are dependent upon state specific regulations governing the depth and breadth of services provided and are allowable in 46 states as of this writing.

The future of CDTM is dependent upon pharmacist practitioners accepting the challenge of assuming both the risks and benefits of providing patient care activities outside the normal scope of prescription dispensing practice. Yet the challenges are well within the scope of expertise for the pharmacist. As

additional reports show positive outcomes for patients cared for through these arrangements, continued expansion is expected.

---

[1] Finley PR, et al. Impact of a collaborative pharmacy practice model on the treatment of depression in primary care. *Am J Health-Syst Pharm*. 2002; 59:1518-26.

[2] Kiel PJ, McCord, AD. Collaborative practice agreement for diabetes management. *A J Health-Syst Pharm.* 2006; 63:209-210.

[3] Schumock, GT, ,et al. Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996-2000. *Pharmacotherapy* 2003;23(1):113-32.

[4] Thomas J, et al., Survey of pharmacist collaborative drug therapy management in hospitals. *Am J Health-Syst Pharm.* 2006; 63:2489-99.

[5] Hammond R W, et al.

[6] Koch KE, "Trends in Collaborative Drug Therapy Management" *Drug Benefit Trends* 12(1):45-54, 2000.

[7] Isetts B, et al. "Effects of collaborative drug therapy management of patients' perceptions of care and health-related quality of life." *Research in Social and Administrative Pharmacy.* 2(2006) 129 – 142.

[8] Collaborative Practice Agreement for the Provision of Pharmaceutical Care: Agreement Between Fairview Clinics and Fairview Pharmacy Services. Received via e-mail from Brian Isetts, January 8, 2008.

[9] Information received via e-mail from Tricia Tabor, Scott & White Health Plan, January 10, 2008.

[10] Hanson K, et al. "Evaluation of medication adherence and economic outcomes of a member benefit medication management program for high-risk managed care patients with diabetes." Poster presented at the American Society of Health-System Pharmacists Mid-year Clinical Meeting, December 2007.

[11] Klein M, et al. "Evaluation of medication adherence and economic outcomes of a member benefit medication management program for high-risk managed care patients with diabetes." Poster presented at the American Society of Health-System Pharmacists Mid-year Clinical Meeting, December 2007.

[12] Information received via e-mail from Paul Godley, Scott & White Health Plan, December 19, 2011.

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American Society of Consultant Pharmacists, New York Chapter
Policy Statement Regarding CDTM, October 2013

Consultant Pharmacists have expertise in Geriatric Pharmacology. Consultant Pharmacists are mandated by CMS to monitor medication therapy in Nursing Homes in collaboration with the Facility's Resident Management Team. Many Consultant Pharmacists with and without a Doctor of Pharmacy degree have also earned the credential of Certified Geriatric Pharmacist (CGP). Patients in Nursing Homes, other forms of institutionalized care such as Adult Homes and those residing in the community currently receive the expertise of NY ASCP members.

Pharmacists that practice in specialized Long-Term Care Pharmacies have serviced this patient mix for more than forty years. These Pharmacists provide clinical consultation to the Medical and Nursing Staff's serving these patients. Services include developing a Medication Formulary for a Nursing Home and performing Therapeutic Substitution. LTC Pharmacists also perform Therapeutic Monitoring and dosing of medications such as Warfarin and Antibiotics. This practice is easier today because these Pharmacists have access to patient health records and lab data through access to the patient's electronic health record and various portals such as Regional Health Information Exchanges.

New York's law that authorizes physicians and pharmacists to collaborate in managing drug therapy for the citizens of NY can expand this healthcare service for more New Yorkers if its current restrictions are removed.

Under the law, collaborative drug therapy management (CDTM) agreements are limited to

- Teaching hospitals that have a policy authorizing CDTM;
- Physicians and pharmacists employed by or otherwise affiliated with teaching hospitals
- Pharmacists that meet certain experience and education criteria.

While these restrictions may have been suited to a pilot study, they are now out of date, inconsistent with the competencies of licensed pharmacists across all practice settings, and out of step with new health-care delivery models that rely on clinical teams to deliver positive results. New York's overly restrictive practice statute and tentative approach to collaboration between pharmacists and physicians place both professions at a distinct disadvantage when compared to practice opportunities in other states and, in a more global sense, hold the state back from achieving better health care outcomes for its citizens. Well-managed patient-centered medication therapy has great value in health care; both in outcomes achieved and financial. No licensed profession other than Pharmacy can deliver it. State law should be

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changed to allow a primary care practitioner to authorize a Pharmacist to adjust medications in the context of a written collaborative agreement. The limitation on practice setting should be removed. The collaborating primary care practitioner should determine the Pharmacists' credentials beyond licensure; not statute.

The current law was implemented in September 2011. Since then health care delivery and payment incentives have changed dramatically. New emphasis is placed on achieving therapeutic outcomes in an efficient, cost-effective integrated delivery system. Patient-centered medical homes, health homes and accountable care organizations achieve savings by coordinating care, reducing redundancy and achieving measurable clinical results. Not only has the Pharmacist's value been well documented, but it has become clear that Pharmacists are strategically necessary in today's changing health delivery environment. The Pharmacists value is especially needed in rural and medially underserved areas of NY.

The NY Chapter of ASCP recommends replacing present law with a progressive new statute that authorizes voluntary written collaboration between a licensed Pharmacist and a licensed Physician, Nurse Practitioner or other recognized primary care provider that is not tied to an institution or practice setting and does not impose additional education requirements on the collaborating Pharmacist. The Collaborating Parties can best address these issues in the written agreement.

Sincerely,

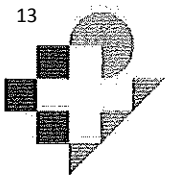
Kelly Flynn

Kelly L. Flynn RPh, CGP

New York Chapter President

Cc: Vince Galletta, Mike Zandri

Co-Directors, Professional and Government Affairs



The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am a Family Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", diabetes, patients who are tobacco-dependent, who have recently been discharged from the hospital and are at high risk for readmission.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Shelly Abraham MD

member
NewYork-Presbyterian
Healthcare System
affiliate: Weill Cornell Medical College

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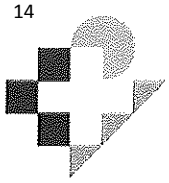

The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am an Internal Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", as well as asthmatics, patients who are tobacco-dependent.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

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Sincerely,

Sawsan Al-Izzi, MD

member
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affiliate: Weill Cornell Medical College

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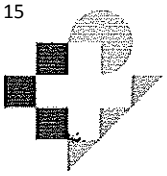

The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am an Infectious Disease physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with HIV disease. However, as this patient population has an increasing life expectancy, our practice incorporates management of other primary care disease states such as diabetes, hepatitis, hyperlipidemia, hypertension, and asthma/COPD for example.

Our patients receive comprehensive quality care from our pharmacists. Our pharmacists spend more time educating our patients on medications than is possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of a clinic visit. Our pharmacists are well versed in antiretrovirals and especially helpful in preventing drug-drug/drug-food interactions. They are knowledgeable and skilled in the selection of medications, as well as dosing modifications for inadequate efficacy or concern for toxicity. Our pharmacists are dedicated to improving the care of our patients and are an asset to the clinic, especially for their counseling and preventing medication errors. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to improved outcomes, fewer adverse events, and better overall care. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Anj Bakshi

ANJALI BAKSHI, MD.

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David L. Battinelli, MD
Chief Medical Officer
Sr. Vice President
North Shore-LIJ Health System

Dean for Education
Betsy Cushing Whitney Professor of Medicine
Hofstra North Shore-LIJ School of Medicine

March 13, 2014

Lawrence Mokhiber
Executive Secretary, NYS Board of Pharmacy
89 Washington Avenue
Albany, NY 12234

Dear Mr. Mokhiber:

I am writing to strongly support the continuation and expansion of the 2011 law that allows pharmacists to enter into Collaborative Drug Therapy Management (CDTM) agreements with physicians (S3292/A6448).

The use of collaborative agreements maximizes the expertise of pharmacists and prescribers to achieve optimal patient care outcomes through appropriate medication use and enhanced patient care services. As we move into this new era of accountable care, medication adherence and appropriate medication use will be key factors in the effective care of our patients with chronic diseases. The medical literature continually demonstrates that CDTM programs improve the quality of medication therapy and leads to enhanced satisfaction for the patients, the providers, and the pharmacists.

The North Shore-LIJ Health System includes 17 hospitals, 3 skilled nursing facilities and nearly 400 physician practice locations throughout New York, including Long Island, Manhattan, Queens and Staten Island. Having pharmacists available to work in collaboration with our providers in all areas will be critical to our success in caring for these patients. With the current shortage of health care practitioners, expanding the role of credentialed pharmacists to work with our providers to prescribe and monitor medication use will significantly improve our ability to provide efficient, safe and effective patient care.

I urge the New York State Legislature to remove the sunset and expand Collaborative Drug Therapy Management so that patients and providers in all areas may benefit from these programs.

Sincerely,

David L. Battinelli, MD

Sr. Vice President & Chief Medical Officer

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Hofstra North Shore-LIJ School of Medicine, 500 Hofstra University, Hempstead, NY 11549-5000 • Tel (516) 463-7198, Fax (516) 463-7543 • david.battinelli@hofstra.edu

healthfirst

March 28, 2014

Lawrence M. Schiller, MS, RPh
Director of Pharmacy
Bronx Lebanon Hospital Center
1650 Grand Concourse
Bronx, NY 10457

Dear Mr. Schiller:

Healthfirst is a not-for-profit managed care plan that is sponsored by 21 major voluntary hospitals and academic centers serving New York City and Long Island. We have approximately 900,000 covered lives - 760,000 Medicaid Managed Care members and 110,000 Medicare Advantage members, half of whom are dual-eligible. Primary care for our members is delivered by a diverse network of large provider groups, medical homes and community health centers; in many of these groups, Healthfirst is the payor for a large number of patients. In turn, Healthfirst aims to meet the needs of our diverse communities through close provider partnerships and strong community involvement.

The current joint effort with Bronx-Lebanon Hospital Center supporting Collaborative Drug Therapy Management (CDTM) is a demonstration of our mission. CDTM enables clinical coordination to help patients stay connected with the healthcare system, become knowledgeable about their medications and disease states, remain productive in the community, and avoid unnecessary hospitalizations.

Pharmacists are known to be among the most accessible health care providers. Promoting a care team level collaboration with Bronx-Lebanon physicians via CDTM can enhance the quality of primary care and potentially reduce unnecessary healthcare expenses among our Healthfirst clients in the South Bronx community. We expect the CDTM pharmacists at Bronx Lebanon to accomplish this by continuing to educate patients on appropriate medication utilization, assisting physicians with monitoring patients' response to medications, and outreaching to primary care physicians as necessary to ensure continuity of care.

Our pharmacy Brown Bag clinic that currently focuses on CHF patients is just a first step for Healthfirst and Bronx Lebanon. The future plan is to expand pharmacy services to asthma/COPD, diabetes, psychiatric conditions, pharmacy based immunizations and more.

Healthfirst fully supports public health initiatives that focus on accountability and quality. CDTM has been a time-tested clinical model that will greatly benefit patients, help exceed quality benchmarks and most importantly serve the health care needs of the Bronx community.

Since CDTM can have such a profound impact on patient care, Healthfirst supports the elimination of the sunset clause in the CDTM New York State law so that it becomes a permanent practice standard as it is in many other states.

Sincerely,

Susan Beane, MD

Susan J. Beane, MD
Vice President, Medical Director

BRONX-LEBANON HOSPITAL CENTER
HEALTH CARE SYSTEM

To whom it may concern:

This letter is in support of Collaborative Drug Therapy Management (CDTM), New York State Education Law 6801-a, at Bronx Lebanon Hospital Center. Many of our patients have already benefited from one-on-one visits with pharmacists in our Brown Bag Clinic. We have referred several heart failure patients to that clinic to receive education about their medications and reinforcement about the importance of adherence, particularly to their heart failure regimen.

A CDTM program that proactively guides our patients by assisting clinicians with managing appropriate medication usage, identifying adverse events and monitoring therapeutic goals will only serve as an asset to our hospital. It will ultimately be an additional way in which we improve quality of care -- by helping to keep our patients stable in the community and ultimately helping to reduce unnecessary hospital admissions.

We are currently in collaboration with the pharmacist(s) who sees our patients in the Brown Bag Clinic. Patients are asked to take all of their medications with them to their visits with the pharmacist, which allows the pharmacist to educate the patient about each specific medication as well as to identify and resolve any medication problems. One patient was found to be on two medications in the same class, for example. The pharmacist contacted the clinician about discontinuing one of the medications and also contacted the patient's pharmacy to ensure that the patient did not receive any future refills of the discontinued medication. Having a CDTM agreement in place that allows the pharmacist to engage in such activity according to an established protocol is a great way to meet both the clinician's and the patients' needs. It allows the pharmacist to make the interventions necessary to ensure the patients' care is optimized without spending additional time trying to get in contact with other care providers. The pharmacist(s) can then continue to alert the clinicians to changes made in a patient's regimen as well as document it in the patient's medical record.

CDTM is a practice model that has over a decade of experience in serving the public health interest. It has demonstrated effectiveness in helping patients manage today's powerful and complex medications that may often require additional monitoring for safety and efficacy. We again reiterate our full support of CDTM at our hospital as a

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AFFILIATED WITH ALBERT EINSTEIN
COLLEGE OF MEDICINE

means to ease the patient load on the clinicians in our heart failure clinic and to ultimately ensure the best care for our patients.

Considering the significant values of Collaborative Drug Therapy Management, we support the elimination of the sunset clause of CDTM in NYS and making CDTM a standard practice as it already is in many other states.

Best regards,

Sherry Megalla 1/29/14

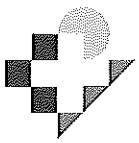
Director of CHF Date
Dr. S. Megalla

1/29/14

Director of Cardiology Date
Dr. J. Bella

1/29/14

Chief of Medicine Date
Dr. S. Chilimuri



The Brooklyn Hospital Center

Keeping Brooklyn healthy.

Leonard Berkowitz, MD
CHIEF, DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF INTERNAL MEDICINE

January 29, 2014

To the Members of the New York State Legislature:

I am extremely pleased to have the opportunity to provide a letter in strong support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am Chief of the Infectious Diseases Division and Medical Director of our comprehensive HIV program at The Brooklyn Hospital Center in Brooklyn, New York. We are a New York State Designated AIDS Center serving over 1200 patients. I currently am privileged to work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with HIV disease, however we also provide management of other primary care disease states such as diabetes, hepatitis B and C, hyperlipidemia, hypertension, and asthma/COPD.

Our patients receive comprehensive quality care from our pharmacists. Our pharmacists spend more time educating our patients on medications than is possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of a clinic visit. Our pharmacists are extraordinarily knowledgeable about the complexities of antiretroviral therapy and especially helpful in preventing drug-drug/drug-food interactions. They are highly skilled in the selection of medications, as well as dosing modifications for inadequate efficacy, changes in renal or hepatic function, or concern for toxicity. Our pharmacists are dedicated to improving the care of our patients and are an asset to the clinic, especially for their counseling and preventing medication errors. They are invaluable in performing medication reconciliation, often calling the patient's pharmacy to obtain the most accurate information possible. Our pharmacists also provide excellent teaching for our medical residents.

I firmly believe that all patients deserve this level of care and should be afforded the option of having a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting in which the patient receives their care. Our patients enjoy having a "personal pharmacist." This enhanced relationship between the physician, pharmacist, and patient has led to improved outcomes, fewer adverse events, and better overall care. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Leonard Berkowitz, M.D.

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Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

Henny H. Billett MD MSc
Chief, Division of Hematology
Professor, Clinical Medicine and Pathology

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Albert Einstein College of Medicine
Ullmann Bldg, Room 921
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Bronx, NY 10461
Henny.Billett@einstein.yu.edu

March 7, 2014

To Whom It May Concern:

I am writing this letter in support of continuation of a bill passed in 2011 as S.3292/A.6448, allowing pharmacists to prescribe and manage medications under a collaborative practice agreement with physicians. I am the Director of the Thrombosis Prevention and Treatment Program (TP^2) at Montefiore Medical Center and I collaborate with Clemencia Solorzano, PharmD in the management of our patients' anticoagulation therapy.

Pharmacist's impact in Thrombosis clinic

As part of the TP^2 at Montefiore, patients are monitored weekly in an Anticoagulation Clinic, run primarily by Nurse Practitioners under my supervision. Since 2006, Dr. Solorzano has been an integral part of the Thrombosis clinic practice. We see on average approximately 60 to 80 patients who come to the Anticoagulation clinic for management if their Coumadin therapy. To date, Dr. Solorzano has independently and effectively managed over 400 patients / year.

There are several benefits we have realized from our collaboration with Dr. Solorzano:

1. **Improvement of quality of care for patients**
    a. The NPs can consult a PharmD when uncertain of drug interactions. Dr. Solorzano has been a good resource for the NPs who deliberately request her advice w/ concomitant medications especially with the addition of herbals and OTC medications.
    b. Medication counseling and eliciting adherence through patient empowerment is a skill that pharmacists have mastered through training and practice. Dr. Solorzano has demonstrated this skill by providing detailed but understandable explanations of how coumadin works, why the INR may fluctuate in response to food and other medications and how the patients themselves can help us to properly manage their therapy.
    c. Patients seek out the advice of the pharmacist when they have to add new medications to their regimen.
    d. In addition to the invaluable pharmacologic knowledge of the PharmD in the Anticoagulation Clinic, the medical decisions made in adjusting patients' INRs under a PharmD are equivalent to that of a Nurse Practitioner. Dr. Solorzano's supervision result in appropriate time within range for a majority of the patients she sees. By having a PharmD in the clinic, we get therefore both medical and pharmacologic expertise.
2. **Reduced the risk of medication error and unnecessary health care expenditures**
    a. PharmDs can identify problems with patient self-medication that impact not only the patient's warfarin therapy but can also affect their medical therapy as well. Dr.

Solorzano will routinely review the medications and then address them with the medical staff.

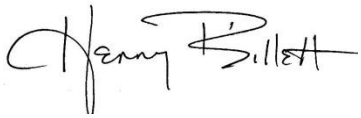
b. Pharmacy training teaches to think “outside the box” when assessing drug efficacy and effectiveness. As an example, Dr. Solorzano has taught us that not only should medications added to a patient’s regimen be reviewed when dealing with significant INR fluctuations, but also to assess the influence of newly discontinued medications.
c. Pharmacists are also trained to think beyond the obvious prescription medication interactions to address patient factors such as smoking and recreational drug use.
d. Key new adverse effects and warning signs when noted or reported by the patient are immediately brought to the attention of an approved health care provider for follow-up.

3. Otherwise in the public interest

a. The best advantage of having a pharmacist in a collaborative practice is the multidisciplinary approach to patient care that allows for problems to be addressed from various health care perspectives. This can only result in the best care of the patient.

I understand that the 2011 Collaborative Drug Therapy Management law is due to expire soon. It should be extended indefinitely. Dr. Solorzano’s contribution to our patients and their care has been invaluable and we need not only to keep Pharmacy in our clinics but to extend their presence.

Sincerely,



University Health Care Center

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UNIVERSITY HOSPITAL

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Dermatology
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Coumadin
Tel 315 464 5240
Fax 315 464 3791

January 21, 2014

Larry Mokhiber MS, RPh
Executive Secretary NYS Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY, 12234-1000

Re: Impact of CDTM Legislation

Dear Mr. Mokhiber:

I serve as an attending internist in a large, inner city primary care clinic in Syracuse, NY. I am writing to share my thoughts about the Collaborative Drug Therapy Management program (CDTM) here at the Adult Internal Medicine Clinic at SUNY Upstate. We have been partnering with our pharmacists in the care of adult ambulatory care patients for the last several years. This collaboration is thanks, in large part, to the approval of the CDTM legislation in 2011.

Our outpatient pharmacy program is substantial. We currently have four pharmacists, one full time PGY2 resident, six rotating PGY1 residents and 12 -20 pharmacy students per year working in our clinic. They run the anticoagulation clinic and a diabetic teaching/management service. They are available to answer general pharmacy questions as well as teach our Medicine residents and staff. In addition to specific disease state management, they offer teaching sessions for our medicine interns on general medication therapy management. They have helped to systematize the prior authorization process in our busy practice as well which is a burden for all clinic settings.

It has been very fulfilling to work collaboratively with our pharmacy team. They have not only improved the care of our patients, but they have also enhanced the quality of life for our medical providers and staff. They have helped to make our clinic a great place to work. Thank you for providing the leadership and vision for the CDTM. I hope that the CDTM legislation will continue in New York State and perhaps expand to other clinical sites so as to benefit patients and the healthcare system as it has done in my medical practice.

Sincerely,

Debra Buchan

Debra Buchan, MD, FACP
Associate Professor
Department of Medicine

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F58058 11/2012

>>> "Carlyn, Cynthia" <Cynthia.Carlyn@va.gov> 01/23/14 16:24 >>>

To Dr. Mokhiber:

Working with a dedicated pharmacy pain specialist in our Infectious Disease Clinic has made an enormous difference in caring for our patients with HIV. These patients are particularly complex and often have multiple comorbidities including current or prior substance abuse, depression, post -traumatic stress disorder, co infection with Hepatitis B and or C, diabetes, hypertension, hyperlipidemia, liver disease, chronic kidney disease, cancer as well as chronic pain syndromes. In this complex patient population on potent antiretroviral combinations, we function as Primary Care Providers as well as HIV specialists. As you can imagine in these patients polypharmacy is common and an understanding of drug interactions and basic pharmacology is incredibly useful. My colleagues (2 other ID physicians) and I do not have the high level expertise in pharmacokinetics and pharmacodynamics to optimize treatment and avoid adverse effects. The majority of these individuals have chronic pain of some form either disease or medication induced pain (older antiretroviral therapy such as AZT, DDI, D4T having caused permanent neuropathy for example). Many have a history of IV drug use complicating their pain management (eg real pain plus possible pain seeking behavior). As you can imagine the average ID/HIV physician does not have extensive knowledge about pain therapeutics.

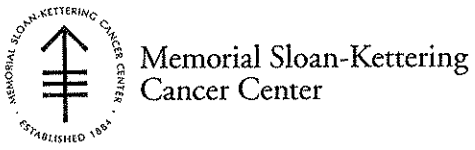
Since July, we have been most fortunate to have Dr. Timothy Atkinson, PharmD, a PGY II pharmacy pain management resident in our HIV clinic. Twice weekly he attends our HIV clinics. During that time we thoroughly discuss each of the patients, including the clinical history, physical exam, psycho social issues and etiology of the patients' pain. Dr. Atkinson provides insight and recommendations to assure effective and safe treatment while avoiding potential drug interactions and offers specialized solutions to individualize the patient's care. This often includes advice about alternative dosage forms, liquid or crushable, as well as adjustments for renal and hepatic dysfunction. His specialized training is particularly useful for patients with a history of substance abuse and legitimate pain. While in our HIV clinic he separately meets with each individual patient both in the clinic to establish a therapeutic plan and with frequent follow up. We now schedule patients for him with the expectation he will review and provide recommendations. The patients love this new service that we have been able to offer.

We have come to HEAVILY rely on Dr. Atkinson's expertise so much so that his presence in our multidisciplinary team is vital and critical.

My goal in writing to you is to strongly endorse and support continuation and expansion of pharmacy services in specialized care settings particularly in pain management.

Sincerely,

Cynthia Carlyn, MD
Chief Infectious Disease
Stratton VA Medical Center
Albany, NY 12208



Lisa M. DeAngelis, MD

Chair, Department of Neurology
Lillian Rojtman Berkman Chair in Honor of Jerome B. Posner

January 31, 2014

Lawrence H. Mokhiber, Executive Secretary
NY State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000

Dear Mr. Mokhiber:

Patients who suffer from brain tumors require significant skill and expertise from a multidisciplinary team to provide the safest and most effective care. These patients not only require carefully designed treatments to manage their disease, but they also need support for numerous complications due to seizures, infections, and adverse side effects from chemotherapy. The increasing availability of chemotherapeutic agents that can be taken orally has also increased the complexity of a patient's already extensive list of medications.

In 2013, the Neuro-Oncology service expanded the diversity of the multidisciplinary team with the integration of Clinical Pharmacy Specialists in both the inpatient and ambulatory areas. The Collaborative Drug Therapy Management (CDTM) program was a major factor in this decision, as it not only incorporated pharmacist expertise in the therapeutic use of medications, but it also allowed them a greater capacity to:

- Improve medication order accuracy and decrease medication errors
- Increase the precision of admission and discharge medication histories
- Modify and monitor treatment-related complications involving anti-seizure medications, pain medications, and anti-nausea medications

The addition of Clinical Pharmacy services and CDTM has improved the care we able to provide to our patients through:

- Increased collaboration between health care professionals
- Increased efficiency in drug therapy modifications
- Optimization of drug therapy management.

I strongly support the Clinical Pharmacy Specialist program recommend continuing the success of CDTM at our institution and across the state of New York.

Sincerely,

Lisa M. DeAngelis

Lisa DeAngelis, MD

1275 York Avenue, Box 52 | New York, NY 10065
Phone: 212-639-7123 | Fax: 212-717-3296
deangell@mskcc.org | www.mskcc.org

January 20, 2014

Lawrence Mokhiber
Executive Secretary, NYS Board of Pharmacy
89 Washington Avenue
Albany, New York 12234

Dear Mr. Mokhiber:

I am writing this letter in support of continuation of a bill passed in 2011 as S.3292/A.6448, allowing pharmacists to prescribe and manage medications under a collaborative practice agreement with physicians. As the Medical Director of the Anticoagulation Management Service at Bassett Medical Center, I have firsthand knowledge of the positive impact pharmacists have in the care of patients.

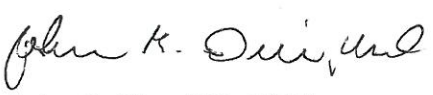
My colleagues and I collaborate with Kelly Rudd, PharmD, BCPS, CACP in the management of our patients' anticoagulation therapy within the Bassett Healthcare Network, which provides care to patients in a 150 mile radius of the central campus. In such a rural setting, providing patients ready access safety-enhancing services akin to those of more metropolitan areas is extremely important, and is at the core of Dr. Rudd's practice.

Since 2005, Dr. Rudd has been an integral part of the care of our patients, managing over 8,000 INR tests annually. Her positive therapeutic outcomes are some of the highest around the country. In our publication, *"Comparison of Two Different Models of Anticoagulation Management Services with Usual Medical Care,"* Dr. Rudd and I were able to document that pharmacists practicing collaboratively were able to reduce hospitalizations for anticoagulation-related adverse events by over 60% and emergency department visits for such events by over 75% compared to care provided outside of the collaborative agreement. (Pharmacotherapy 2010; 30(4): 330-338.)

Patients clearly benefit from improved safety, increased access to healthcare, and my colleagues and I greatly appreciate the ability to consult Dr. Rudd on complex medical cases and drug-drug interactions. Such expertise earned Dr. Rudd recognition from the Federal Health Resources and Services Administration, receiving the "Patient Safety and Clinical Pharmacy Services Collaborative Life-Saving Patient Safety Award" this year. Despite this impressive achievement, Dr. Rudd is quick to point out that this is the role pharmacists in collaborative practice agreements are designed to fill.

I understand that the 2011 Collaborative Drug Therapy Management law is due to expire soon. It should be extended indefinitely. Dr. Rudd's contribution to our patients and their care has been invaluable and we need not only to keep Pharmacists in our clinics but to extend their presence.

Sincerely,



John G. Dier, MD, FACP
AMS Medical Director
Bassett Medical Center

One Atwell Road • Cooperstown, New York 13326
Ph 1-800-BASSETT (227-7388) • **Web** www.bassett.org
Bassett Medical Center is affiliated with Columbia University

ST. JOHN'S UNIVERSITY

8000 Utopia Parkway, Queens, NY 11439

Russell J. DiGate Ph.D.
Dean
College of Pharmacy &
Health Sciences

Tel: 718-990-6411
Fax: 718-990-8070
Email: digater@stjohns.edu
8000 Utopia Parkway
Queens, NY 11439

March 19, 2014

Lawrence H. Mokhiber, R.Ph., MS
Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, New York 12234-1000

Dear Mr. Mokhiber,

St. John's University College of Pharmacy & Health Sciences is thankful for the opportunity to express our support for the expansion of the scope of pharmacy practice in New York State to include Collaborative Drug Therapy Management (CDTM) on a permanent basis in both the community and inpatient practice settings. Such an expansion of the current state Collaborative Care Law is essential for both improving the provision of healthcare within the state as well as the continued ability of accredited schools of pharmacy in the state to provide an appropriate educational experience for our students.

As you are aware, CDTM is a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy. Under such practices, a pharmacist may collaborate with physicians to perform many functions to improve the care of their patients. Such interventions may include implementing or modifying a patient's medication therapy, ordering and evaluating the results of laboratory tests directly related to a patient's drug therapy, and the administration of medications and immunizations. CDTM has proven to be an effective and economically efficient method of improving health outcomes of patients with complicated and chronic disease states including diabetes, depression, asthma, heart failure, HIV-infection, hyperlipidemia, and hypertension, to name a few. In addition, CDTM is supported by numerous medical societies including the American Society of Internal Medicine, the American College of Physicians, and the Infectious Disease Society of America.

CDTM is considered a standard of pharmacy practice in over forty-six states. However, collaborative drug therapy management in New York State is limited by law to pharmacists practicing in academic medical centers. We support expanding this practice to community-based hospitals and smaller acute care facilities to improve patient access to this effective practice model.

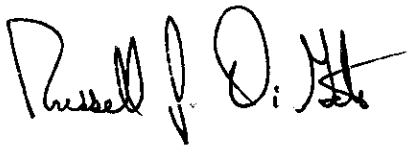
Schools and colleges of pharmacy in New York State are expected to provide quality programs and experiential educational experiences for their students that are consistent with contemporary practice across the country. The latest accreditation standards from the Accreditation Council for Pharmacy

Education (ACPE) requires pharmacy preceptors and students to practice in a collaborative fashion. In addition, the importance of practicing in a collaborative fashion is emphasized as an expected educational outcome in the 2013 report from the Center for the Advancement of Pharmacy Practice (CAPE) of the American Association of Colleges of Pharmacy.

Based upon the documented effectiveness of CDTM in improving the quality of care as well as enhancing patient and provider-satisfaction with the health care system, we strongly support the expansion of the current state Collaborative Drug Therapy Management Law.

Thank you for the opportunity to express my support of this very important practice issue.

Respectfully,



Russell J. DiGate

RECEIVED
MAR 13 2014
STATE BOARD OF PHARMACY

University Health Care Center

UPSTATE
UNIVERSITY HOSPITAL

90 Presidential Plaza
Syracuse, NY 13202

Adult Medicine
Tel 315 464 5240
Fax 315 464 3751

Dermatology
Tel 315 464 3833
Fax 315 464 3791

Coumadin
Tel 315 464 5240
Fax 315 464 3791

February 24, 2014

Larry Mokhiber
Executive Director
NYS Board of Pharmacy

Dear Mr. Mokhiber:

I am writing to you in support of the Collaborative Drug Therapy Management initiative as it has been a valuable asset to the care of our patients here at University Health Care Center Ambulatory Medicine in Syracuse, NY.

Our collaborating pharmacists play a huge role in the daily care of our primary care patients. They run a "Coumadin clinic" which provides ongoing management and monitoring of our patients requiring anticoagulation. The day to day dosing and monitoring of medications is monitored by our pharmacists and decisions regarding stopping and starting anticoagulation are made in conjunction with the physicians.

The most significant change to our practice since the inception of this initiative is the intensive diabetes medication management that our pharmacists provide. Across the board I have seen real improvements in hemoglobin A1C levels as well as patient understanding of diabetic medications and their administration. Our patients who need it are followed more closely than could be done if they were seeing a physician alone. Finally, our physicians (both attending and house staff) have gained significant knowledge from working with our pharmacists. This is not something that I was exposed to in either my training or in private practice.

Finally, our clinic serves a challenging patient population which unfortunately has many barriers to compliance. The services that our pharmacists provide with respect to medication reconciliation and management, patient compliance, and education is invaluable. It is this area that if time and money allowed, could be expanded even further.

I could not be more pleased that we have the ability to collaborate with such an excellent group of pharmacists here at University Health Care Center and I encourage you to convey that message to our legislators in Albany.

Sincerely,

Anthony DiRubbo, MD FAAP
Clinical Assistant Professor of Medicine
Upstate Medical University

750 East Adams Street | Syracuse, NY 13210 | Ph 315 464 4513 | Fax 315 464 5275 | www.upstate.edu | State University of New York

E88038 11/2012

Langone Medical Center

RECEIVED
JAN 30 2014
STATE OF PHARMACY

ROBERT DOWNES

New York State Board of Pharmacy

Lawrence H. Mokhiber
Executive Secretary
89 Washington Ave, 2nd Floor W
Albany, NY, 12234-1000

January, 27, 2014

Dear Mr. Mokhiber:

I am writing you to inform you of a collaboration of the medical and nursing staffs with the NYU Langone Medical Center (NYULMC) Department of Pharmacy. We participated in an initiative to provide vaccination to eligible adults at risk for shingles. The purpose was to reduce morbidity and mortality from Herpes Zoster by vaccinating adults who meet the criteria established by the Center for Disease Control and Preventions Advisory Committee on Immunization Practices and/or Food and Drug Administration.

The Pharmacy Department formulated policies and procedures for the administration of the shingles vaccine (Zostavax) to patients with a prescription from their doctor by nurses in the Pharmacy. The project started in October 2011 with the designation of a zostavax clinic in the NYULMC outpatient pharmacy and education aimed at the NYULMC medical staff and patients.

When the project began, pharmacists would screen patients for contraindications, answer any questions and concerns of the patient and prepare the zostavax vaccine. A registered nurse would administer the vaccine, as New York State law precluded pharmacists from administration. The clinic vaccinated 762 patients in the outpatient pharmacy from October 2011 to Oct 2012. This project promoted collaboration between the health care team with pharmacists working directly with nursing staff and medical staff to maximize patient care. The pharmacy provided monthly reports for review.

In November 2012, after a change in state law, pharmacists took over the role of vaccinators, and since then the pharmacy staff has vaccinated an additional 780 patients at our NYULMC outpatient pharmacy. Physicians are notified the same day by fax when their patients get the zoster vaccine at the pharmacy. We continue to maintain communication regarding progress of the vaccination program.

Sincerely,

Robert Downes RPH, MPH
Assistant Director NYULMC Pharmacy Department

The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 31, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am a Family Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", diabetes, who are tobacco-dependent, or who have recently been discharged from the hospital and are at high risk for readmission.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Marie L. Eloi-Stiven, MD

Marie L. Eloi-Stiven, MD
Attending Physician
The Brooklyn Hospital Center, Family Medicine Department
121 DeKalb Ave| Brooklyn, NY 11201

The Nurse Practitioner Association New York State
12 Corporate Drive, Clifton Park, NY 12065 P 518.348.0719 F 518.348.0720 W www.TheNPA.org

February 13, 2014

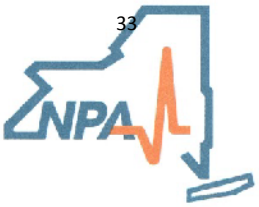
Lawrence H. Mokhiber
Executive Secretary
New York State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, NY 12232-10000

Re: Collaborative Drug Therapy Management

Dear Mr. Mokhiber:

The Nurse Practitioner Association New York State ("NPA") is the only statewide professional association of nurse practitioners ("NPs") in New York, nearly 16,000 of who practice throughout New York State. The NPA and its members are committed to maintaining the highest professional standards for nurse practitioners, and ensuring the greatest quality care for health care consumers. This organization provides continuing education programs, assists in NP training, and advocates with respect to legislative and regulatory issues which affect nurse practitioners and the patients they serve.

Chapter 21 of 2011 permitted pharmacists that practice in teaching hospitals, including diagnostic center, treatment center, and hospital-based outpatient departments, to engage in collaborative management of drug therapy pursuant to voluntary agreements with physicians. The Chapter also required the State Education Department ("SED"), in consultation with the Department of Health ("DOH"), to issue a report on the implementation of collaborative drug therapy management ("CDTM"), and make recommendations regarding extension, alteration and/or expansion of this demonstration program, on or before May of 2014. It is our understanding that SED is now preparing this report. As is described below, the NPA has long believed that the CDTM program could provide patients around the State with improved health care outcomes though better medication therapy. However, we believe that more patients would have the opportunity to benefit from CDTM if SED's report includes a recommendation to include NPs



The Nurse Practitioner Association New York State
12 Corporate Drive, Clifton Park, NY 12065 P 518.348.0719 F 518.348.0720 W www.TheNPA.org

The CDTM statute sought to improve patient care outcomes and reduce medication errors within certain hospital settings, by having pharmacists work directly with the attending physician. Toward this end, it established a greater role for clinical pharmacists. Under this program, pharmacists are generally authorized to manage the drug regimen of patients, evaluate and order clinical laboratory tests, collect and review patient histories, and order or check patient vital signs. Much like the physician contemplated in the existing law, NPs are wholly qualified to participate and collaborate in all of these functions. Nurse practitioners are highly skilled, trained and experienced individuals who exercise independent judgment, and collaborate with multiple specialists and healthcare practitioners every day. NPs are authorized to diagnose illness and physical conditions and perform therapeutic and corrective measures, order tests, prescribe medications, and devices and immunizing agents, without supervision from any other professional.

Moreover, NPs are already working in teaching hospitals and other the healthcare settings where CDTM may be used. Nurse practitioners care for acute care patients in hospitals, direct their care, and prescribe medications and test for these individuals. It is only logical to enable clinical pharmacists to also collaborate with NPs in the delivery of patient care. The success of the CDTM program can be significantly improved by amending the statute to make clear that NPs may partner with these pharmacists, in order to ensure that more patients can benefit from this improved medication therapy.

We know that SED is aware of the important role that NPs play in New York's health care system. As such, we trust that you will recommend to the Legislature that the CDTM program be extended and amended to include NPs. If you have any questions, or would like to discuss how NPs can best work with pharmacists, please contact me.

Sincerely,

Stephen Ferrara

Stephen Ferrara, DNP, RN, FNP-BC, FAANP
Executive Director

cc: Suzanne Sullivan

Dear Kim and all Respected Colleagues:

With the Collaborative Drug Therapy Management (CDTM) Bill "Sunset" quickly approaching, it is clear to me that a significantly high number of prescribing professionals other than pharmacists would welcome our expertise and CDTM in this area and the latitude to prescribe controlled substances, particularly as it relates to risk stratification, ongoing drug monitoring, and drug interactions. Clearly, the area of pain management has perhaps the most compelling data compared to any other specialty areas in terms of drug-related deaths associated with opioids. Many of these deaths are because opioids are prescribed to patients that are at high risk from certain comorbid diseases, in others it's because of drug interactions, in some because of substance abuse disorder (and other psychological comorbidities, many of which require drugs that have a very high incidence of drug interactions to some but not all opioids), other patients should be receiving opioids but are receiving a suboptimal opioid selected choice, and the list goes on.

I could spend hours trying to convince a panel of why this is an important area for pharmacists to collaborate with physicians, but from my personal experience working in pain management over more than 20 years, I can tell you that many physicians would relish the same opportunity and any help they could obtain from our therapeutic, pharmacology, and pharmacokinetic expertise.

Before continuing, I'll provide some of my background to lay the groundwork for my credibility before offering some facts and suggestions moving forward.

I am a PharmD at and employed by the Stratton VA Medical Center in Albany NY. Secondarily, I hold academic affiliations with Albany College of Pharmacy & Health Sciences (ACPHS), the University of Connecticut (UCONN) School of Pharmacy, SUNY/Buffalo College of Pharmacy, and Western New England University College of Pharmacy. My titles at the VA include Clinical Pharmacy Specialist in Pain Management and Director, PGY2 Pharmacy Pain Residency. I teach a Pain elective at ACPHS and UCONN. I am a Diplomate to the American Academy of Pain Management and a Section Editor for Pain Medicine (Opioids, Substance Abuse and Addictions Section), official journal of the American Academy of Pain Medicine. I recently was notified by the American Academy of Pain Medicine that I was selected to receive "a Presidential Commendation, in recognition of you as a voice for scientific integrity and an advocate for people in pain".

It's important that the panel understand that my prescriptive role at the VA is not because I have academic affiliations, and in fact, those privileges in no way are connected to such affiliations. I am employed by the VA and my teaching responsibilities are separate. This does need to be clarified because regulation decision-makers need to understand that academic affiliations do not make the clinician; in my case it is just the opposite. I have students because of the uniqueness of my practice, but more specifically within the borders of NY State. It is here that I wish to acknowledge that current CDTM regulations requiring an affiliation with an academic hospital are most probably unfounded, since pharmacists working in the VA and DoD nationally, internationally, and in shared international waters, have been prescribing for years with no specific academic affiliation or requirements to any college or university.

I have a unique role in that as a federally employed doctor of pharmacy, I am a pain clinician in a multidisciplinary outpatient pain clinic. I also spend three clinic days a week working in various Ambulatory Care Clinics where I see the most difficult pain patients by specific request from their primary care providers. These providers are in the vicinity should I identify a unique new medical issue that needs evaluation or immediate attention, as I have no desire to be a diagnostician beyond my scope. In that capacity I am responsible for opioid risk stratification, prescribing, laboratory testing, ordering of electrocardiograms as baseline and follow-up for patients receiving methadone for pain (as this can widen Qtc interval and is especially concerning when combined with other drugs that do the same, and unfortunately are frequently overlooked), laboratory testing (as opioids can affect the hypo-adrenal axis affecting testosterone and other hormones), urine monitoring (for compliance), serum analysis, policy updates (I-STOP), teaching, and more. I work side by side with several medical providers and collaborate routinely with our local chemistry and laboratory personnel. I also serve as a clinical pain expert on various committees for the VA system regionally and nationally, and am often called upon by internal medicine doctors and board certified pain specialists (anesthesiologists, physiatrists, neurologists) from outside the VA locally and nationwide. As a pharmacist, I therefore have a unique perspective in that I routinely see both sides of the spectrum; that is, I am a clinician with a keen understanding of a dispensing pharmacists' perspective. I am currently developing a multidisciplinary pain management course collaboratively that will include graduate level pharmacists (ACPHS), nurse practitioners (SAGE), Physician Assistants (Albany Medical College) and medical doctors (Albany Medical College).

I have been very much involved educating clinicians of all disciplines on opioid therapy nationwide. Frequently these teachings include therapy with adjuvants across many therapeutic classes including barbiturates and benzodiazepines. My focus is largely on understanding the pharmacotherapeutics of opioids, risks, benefits, appropriate risk stratification, patient selection, and appropriate monitoring, when to start opioids, and when to stop them. Recently, I founded a national multidisciplinary group, *Professionals for Rational Opioid Monitoring & Pharmacotherapy* (PROMP). This group consists of renowned physicians, psychologists, PharmDs, and NPs from all over the country.

I can go on and on, but this request is not about me at all. It is about what is right for the patients, the prescribers that care for those patients and have a high liability both legally and medically, and it's about public safety and cost containment to reduce drugs costs and emergency room visits and multiple phone calls and follow-up visits to primary care. The problems certainly are not limited to opioids, as it is also important to recognize what alternatives there are to opioids, which will work, which will not, and which present an even greater danger than opioids (for instance NSAID therapy in a patient with coronary artery disease on an angiotensin converting enzyme inhibitor that is diabetic). Pain management is a complex area that most prescribers are ill-equipped to manage alone in part because of insufficient training across all the healthcare professions, but more importantly because of the extensive time required to care for these complex issues ranging from noncompliance, patient education, FDA require risk evaluation mitigation strategies, and more. There is a lack of medical pain specialists, and those that specialize nationwide mostly offer interventional procedures and require that opioids and adjuvant medications such as anticonvulsants and norepinephrine-type antidepressants be managed by the primary care physician. I promise you, the latter are clamoring for help and now are more aware than ever of diversion

problems as these pop up daily on the new NYS I-STOP monitoring system. It really is impossible to sum this up in a single letter.

I'm going to give one example of how critical the situation can be in the case of patients that are receiving antiviral therapy for hepatitis C, and managed on methadone for pain. An article addressing this issue is attached. It outlines some very important facts. First, methadone represents 2% of all opioid RX's for managing pain, but is responsible for 30% of all opioid related deaths. Second, patients most likely to receive methadone (for any reason) are those that have hepatitis or HIV disease because of neuropathic pain syndromes. The antiretroviral therapy to treat these disorders are a nightmare in terms of drug interactions with methadone, and most often are not included in pharmacy software databases. And, these are just the drugs that can elevate methadone blood and CNS levels. There are many other drugs commonly prescribed, such a azithromycin (Zithromx) or quetiapine (Seroquel) that together with methadone could cause ventricular tachycardia and subsequent death…when these patients are evaluated by the coroner, cause of death is most often listed as "methadone overdose", when in fact it was because of significant drug interactions.

In our practice, for all patients, we require that patients complete a validated opioid risk assessment tool when receiving or being considered for chronic opioid therapy; this becomes part of the medical record. The pharmacist evaluates the score and places it in the chart, and at times uses this to guide against initiation or continuation of opioid therapy. All patients sign a controlled substance agreement consenting to close monitoring, and they are monitored by our pharmacy clinicians. It is one thing to order a urine drug screen, but quite another to accurately interpret it, as patients are equally likely to be falsely accused of not taking prescribed drugs, or taking a non-prescribed drug/substance, as they are being compliant.

I'm attaching several articles that clearly support everything I have outlined herein and my curriculum vitae. Below are a list of the services I offer and the services that should and could be offered by pharmacists if CDTM expansion included the right for pharmacists to prescribe controlled substances. Many states already allow this, and the federal government has allowed it for at least 25 years.

I propose that the NYS expand CDTM to include an allowance to prescribe controlled substances, which of course would include all controlled substances. Furthermore, I suggest that any pharmacist wishing to do this be required to show at least 8 hours of live continuing education specific to pain therapeutics. My preference is that eventually all prescribers (MD, DO, NP, PA, etc) require the same training in college and/or in practice. If this is done now for pharmacists, clearly their training for prescribing such drugs would surpass the far majority of almost all clinicians currently allowed to prescribe such therapy. I would be happy to work with any regulatory agency, recognized pharmacy society, and/or pharmacy/medical colleges to offer such training.

If I can be of further assistance or you would like this letter reformulated in an official capacity, just let me know and I'm happy to do it. Again, please see bulleted points outlined below and relevant attachments.

Warm regards,
Jeff

For the record:

> 75% of US adults are considered to be nonadherent
Common reasons for nonadherence include forgetfulness, adverse effects, and cost of therapy
What about patients with chronic pain?
> 80% of patients age 65 and older treated by pain specialists demonstrated some degree of nonadherence
> 50% of patients treated by primary care providers demonstrated some degree of nonadherence
REF:
NCPA. http:// (http://www.ncpanet.org/pdf/reportcard/AdherenceReportCard_Full.pdf)www.ncpanet.org/pdf/reportcard/AdherenceReportCard_Full.pdf. Accessed August 1, 2013.
Markotic F et al . Pain Medicine. 2013;14: 247–256

Services Pharmacists Offer in my Practice: Medication history review and reconciliation Recommendations for initiation or modification of medication regimen Assessment of adherence to medications Behavior modification techniques and follow-up services for nonadherence Pharmacokinetic and clinical monitoring of medications Patient education regarding self-administration and monitoring of medications Monitoring for therapeutic effects, drug interactions, and adverse drug events through drug regimen review, laboratory data/vital sign assessment and patient interview Identification of and monitoring for behaviors of medication misuse, abuse, and/or addiction Assist with the development of clinical protocols to encourage the systematic approach to and use of various analgesic therapies Provide educational conferences to staff on topics related to pain pharmacotherapy Conduct academic-detailing and/or drug use evaluations Assist with quality improvement projects to improve processes related to patient care

Pain Management Competencies for Pharmacists Chronic pain syndromes Pain pharmacotherapy Interventional therapies Risk assessment and management Toxicology and urine drug screening evaluation Responsible opioid prescribing/universal precautions Behavioral interventions Motivational interviewing
Addiction medicine Inter-professional communication and collaboration Referrals

Ref: Herndon CM et al. J Pain Symptom Manage 2012; 43(5): 925-944

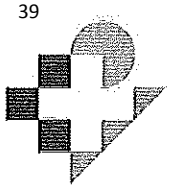
Pain Management Competencies, Core Values/Principles Advocacy Collaboration Communication Compassion Comprehensive care Cultural inclusiveness Empathy Ethical treatment Evidence-based practice Health care disparities reduction Inter-professional teamwork Patient-centered care

From: Ghassi, Dimple
Sent: Thursday, January 30, 2014 8:19 AM
To: 'pharmbd@mail.nysed.gov'
Subject: pain pharmacist

Dear Mr Mokhiber

Our Pain Management Team, led by Clinical Pharmacist Dr. Jeffrey Fudin is one of the best things that has been incorporated into VA primary care.
A multidisciplinary approach to management of chronic pain works best in patient's interest. Our Pain pharmacist, as an integral part of the team, facilitate safe prescribing and monitoring of medications. Evaluating type of pain, and prescribing medications targeting specific type of the pain while ensuring safety based on drug -drug interaction, liver and kidney function ensures proper treatment of these patients.
Pain pharmacists also evaluate /assess compliance of medications including ordering / interpreting drug levels, drug tests and possible medication and illicit drugs that can alter the drug tests. This helps to prevent drug diversion and abuse/misuse. Our Pain pharmacist and Pharmacy Resident via use of various tools help stratify patients at risk for abusing drugs and hence help physicians tailoring medications based not only on their history, type of pain but based on their risk score as well.
I highly support and recommend pain pharmacy specialist to be involved in caring for chronic pain patients here at the VA and in the community within NYS and any other states that allow collaborative prescribing and CDTM. The services provided clearly have served to improve patient care, reduce risk, reduce ER visits, and streamline care for pain patients thereby freeing up time to see other patients and for the PCP to attend to other medical issues in these various pain patients. Moreover, several of our difficult patients that require opioid therapy need a trusting working relationship with their PCP; at times, opioid issues become confrontational and the pharmacist helps us to maintain a cordial working relationship with the patients' vast medical needs while a pharmacy specialist, sometimes with a clinical psychologist, address the pain-related issue.

Thanks
Dr Ghassi
Primary care
Albany Stratton VA
518-626-6330.



The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am a Family Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", diabetes, patients who are tobacco-dependent, who have recently been discharged from the hospital and are at high risk for readmission.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

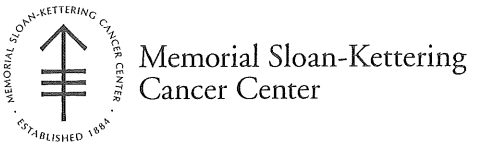
Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Olga Gibbons, M.D.
Lic # 161590

member
NewYork-Presbyterian
Healthcare System
affiliate: Weill Cornell Medical College

121 DeKalb Avenue
Brooklyn, NY 11201
718.250.8000
www.tbh.org



Sergio Giralt, MD
Chief Attending
Adult BMT Service, Department of Medicine

January 30, 2014

Lawrence H. Mokhiber, Executive Secretary
NY State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000

Dear Mr. Mokhiber:

Since 2008, Clinical Pharmacy Specialists have been essential members of the multidisciplinary Bone Marrow Transplant (BMT) service. Currently there are four Clinical Pharmacy Specialists dedicated to two inpatient transplant services, the outpatient transplant program, and the ambulatory clinic. As experts in drug therapy, the pharmacists perform comprehensive inpatient and outpatient clinical services, including:

- Ensure the accuracy and appropriateness of all medication orders
- Ensure adherence to institutional practice standards and guidelines
- Provide information and education to the medical service regarding safe medication use
- Provide admission and discharge medication counseling

In 2011, the BMT service was the first department at Memorial Sloan Kettering to support the Collaborative Drug Therapy Management program and grant prescribing privileges to Clinical Pharmacy Specialists. The expanded role of the pharmacists allowed for greater efficiency and accuracy in the management of drug therapy, including:

- Management and monitoring of essential medications, such as immune-suppressants and anti-infective medications
- Implementation of necessary dose adjustments in response to drug-drug interactions or changes in patient condition
- Modification of supportive care regimens for nausea, pain, and diarrhea to improve overall patient quality of life

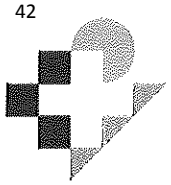
The projected growth of the BMT service will not only require additional clinical pharmacy staff, but it will also be imperative that the Clinical Pharmacy Specialists maintain their current responsibilities, particularly their collaborative prescribing privileges. The improved accuracy of medication orders by pharmacists results in decreased mediation errors, adverse drug events, and overall health care costs.

1275 York Avenue, Box 235 | New York, NY 10065
Phone: 212-639-6009 | Fax: 212-639-3861
www.mskcc.org

With the current shortage in healthcare workforce, particularly in the field of BMT, the ability of the clinical pharmacy staff to be able to prescribe medications to reduce nausea, or modify immune-suppressant orders or antibiotic orders to reduce toxicities, without having to find a physician or other healthcare provider with prescription privileges will improve patient safety and reduce patient suffering. I urge the New York Legislation to remove the sunset clause from the CDTM program and permanently make Physician-Pharmacist collaborative prescribing a law.

Sincerely,

Sergio Giralt, MD
Chief, Adult Bone Marrow Transplant Service
Memorial Sloan Kettering Cancer Center
Professor of Medicine
Weill Cornell Medical College



The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am an Internal Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", as well as asthmatics, patients who are tobacco-dependent.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

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Sincerely,

Irina Gressel, MD

member
NewYork-Presbyterian
Healthcare System
affiliate: Weill Cornell Medical College

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www.tbh.org

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of Pharmacy and Health Sciences
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718.488.0628 Fax

Office of the Dean
liu.edu

December 23, 2013

Lawrence Mokhiber
Executive Secretary
New York State Board of Pharmacy
Pharmacy Education Building, 2nd Floor West
89 Washington Avenue
Albany, New York 12234

Dear Mr. Mokhiber:

I am writing to support efforts to extend and expand the Collaborative Drug Therapy Management (CDTM) Law. CDTM has been the focus of curricular change at our College of Pharmacy in recent years. We are confident that major improvements in health care will be largely dependent on an expansion of the pharmacists role in collaboration with physicians.

CDTM is a formal partnership between a pharmacist and a physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy. Currently 46 states have authorized CDTM arrangements between pharmacists and physicians.

Working with physicians CDTM agreements can include:

- Implementing or modifying drug therapy of individual patients or groups of patients (patients with diabetes, asthma, hypertension, etc.)
- Ordering and evaluating the results of laboratory tests directly relating to drug therapy
- Administration of medications, including immunizations

The medical literature is replete with studies that demonstrate that CDTM programs improve the quality of medication therapy and improve the satisfaction of patients physicians, and pharmacists. In addition to pharmacy organizations , CDTM programs have also been supported by The American College of Physicians, The American Society of Internal Medicine and The Infectious Diseases Society of America.

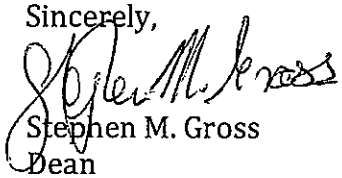
Our College has affiliations with most hospitals in the New York City area. In the teaching hospitals our faculty and students participate in CDTM programs. Clearly this should be expanded to all health care institutions and community pharmacies since it is well-accepted that CDTM can improve health care, reduce medication errors, and lower costs.

In a practical sense, we see graduating students leave New York State to practice in States where CDTM is more widely accepted, and we have difficulty in recruiting clinical faculty who might be assigned to sites where the role of the pharmacist is restricted.

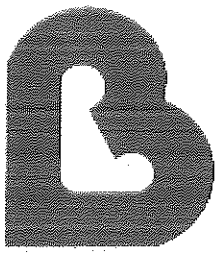
In conclusion, our curriculum has been completely revised to meet new accreditation standards that have specific requirements for students to have CDTM experiences.

Thank you for the opportunity to comment on this topic which is essential to pharmacy practice and pharmacy education.

Sincerely,



Stephen M. Gross
Dean



BRONX-LEBANON HOSPITAL CENTER
Milton Gumbs, MD
Vice President of Medical Affairs/ Medical Director

January 29, 2014

To Whom It May Concern:

As the Medical Director at Bronx Lebanon Hospital Center, I am pleased to support the Collaborative Drug Therapy Management (CDTM) at our hospital. Working with our pharmacists, many of our patients have benefited from our current CDTM program that proactively guide our patients by managing appropriate medication uses, identifying adverse events and monitoring therapeutic goals. All of this aim to improve quality of care by keeping our patients stable in the community and ultimately reduce unnecessary hospital admissions.

As of today we have implemented a Congestive Heart Failure CDTM clinic. Our pharmacists and cardiologists are working together to reduce hospital readmission. With the opening of our new ambulatory care building, we are in the process of expanding our services to the Asthma/COPD Education/management, Diabetics Management and Vaccine Clinics.

CDTM is a practice model that has over a decade of experience in serving the public health interest and this model has demonstrated effectiveness in helping our patients with today's powerful, potent, complex and multi-regimented medications that need greater safety and efficacy monitoring. This is largely an unmet need in our health care delivery system that Bronx Lebanon Hospital Center has put in place to serve and benefit the health care of our community.

In closing, with the obvious and significant values of CDTM, I support the elimination of the CDTM New York State sunset clause and make a request for a permanent practice standard like many other states.

Best regards,

Milton Gumbs, MD
Vice President of Medical Affairs/ Medical Director
Bronx Lebanon Hospital Center
1650 Grand Concourse
Bronx NY 10457
Phone: (718) 901-8712
Fax: (718) 901-8799

From: "Hampton, Robin" <Robin.Hampton@va.gov>
To: "'pharmbd@mail.nysed.gov'" <pharmbd@mail.nysed.gov>
CC: "Fudin, Jeffrey" <Jeffrey.Fudin2@va.gov>
Date: 1/29/2014 8:58 AM
Subject: Integrated Clincal Pharmacy Pain Management Services at the Albany VA

Lawrence H. Mokhiber,

Executive Secretary NY State Education Department Office of the Professions State Board of Pharmacy

89 Washington Avenue

Albany, New York 12234-1000

Dear Mr Mokhiber
Dr. Fudin has asked me to contact you directly to comment on my experiences using the integrated clinical pharmacy pain management services here at the Albany and the VA Medical Center.
I recently started working at this facility in September 2013. Since that time, I have assumed primary care responsibilities for several patients in our Infectious Diseases clinic who have multiple medical issues, psychiatric issues, and, more specifically, chronic pain issues. These patients are very challenging to manage from a clinical and psychiatric perspective. As one may anticipate, they are on multiple medications. Polypharmacy is the rule.
With the help of Dr. Atkinson (PGY2 pain resident), and by extension Dr Fudin, management of these patients has been much improved. Dr. Atkinson, who attends our clinic, always finds the time to address, in a thoughtful and thorough manner, pertinent pain management and polypharmacy issues. He takes a time to educate patients (and, for that matter, clinicians) with regard to salient pharmaceutical issues at hand.
His recommendations with respect to therapeutic interventions are greatly valued by me. He is an invaluable part of the clinical team. Overall patient care is improved because of his interventions.
In summary, I think integrating clinical pharmacy pain management services into our clinic has markedly improved patient care, and has provided a valuable resource to practicing clinicians and patients alike.

Sincerely;

RW Hampton PhD MD
Infectious Diseases Staff

VA Health Care Upstate New York
Samuel S. Stratton VA Medical Center
113 Holland Avenue | Albany, NY 12208
www.albany.va.gov

January 22, 2014

Lawrence H. Mokhiber, Executive Secretary
NY State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000
pharmbd@mail.nysed.gov

Re: Clinical Pharmacy Pain Management Services

Dear Mr. Mokhiber:

The program in Neurology at the Stratton VA Medical Center has greatly benefited from the availability and expertise of Pain Pharmacy Specialists. Neurology is regularly involved in the management of chronic pain such as headache, back/neck pain as well as neuropathic pain. Our providers have regularly utilized consultation of the Pain Pharmacists to assist in managing difficult patients. The expertise has been particularly valuable when utilizing opiates.

Greater collaboration amongst diverse providers has resulted from the embedding of Pain Pharmacists in select Primary Care Clinics. The dialogue between Primary Care Providers and specialties such as Neurology on coordinated management has unquestionably increased.

We have recently benefitted from the embedding of a Pain Pharmacist in one ouf our Neurology Clinics. The Veterans have appreciated the attention and quality of care that they are being provided. Members of the Neurology Team (i.e. medical students, residents and staff physicians) are also learning better ways to manage chronic pain.

I look forward to a continued collaboration that will provide optimal care to our Veterans. Please let me know if there is additional information that you need.

Regards

Donald S. Higgins, Jr., MD
Chief, Neurology Service

From: "Kaushik, Prashant" <Prashant.Kaushik@va.gov>
To: "'pharmbd@mail.nysed.gov'" <pharmbd@mail.nysed.gov>
CC: "Fudin, Jeffrey" <Jeffrey.Fudin2@va.gov>, "'jeff@paindr.com'" <jeff@paindr.com>
Date: 1/22/2014 3:33 PM
Subject: Collaborative pain-management

Lawrence H. Mokhiber

Executive Secretary NY State Education Department Office of the Professions State Board of Pharmacy

89 Washington Avenue

Albany, New York 12234-1000

pharmbd@mail.nysed.gov<mailto:pharmbd@mail.nysed.gov>

Dear Mr. Mokhiber,

This is to appreciate the collaboration with our Pain Management Team here at the Albany VAMC headed by Dr. Jeffrey Fudin.

Rheumatological diseases do require help from Pain Management.

The input regarding the following aspects has definitely been very helpful:

i. Drug-interactions (especially with NSAIDs, DMARDs)

ii. Mechanism of action of DMARDs (both traditional/synthetic and biologic response modifiers)

iii. Dosage, pharmacodynamics and pharmacokinetics of DMARDs and NSAIDs

Dr. Timothy Atkinson, the Pain Management Resident has been an asset. He thoroughly researches the topics (mentioned above) and presents evidence-based data that leads to a significant improvement in the quality of health-care.

The use of opioids is limited in pure-Rheumatology, with the emphasis being on the judicious use of DMARDs.

Again, thanks and kind regards,

Prashant Kaushik MD
Rheumatology Lead Physician/Section Chief
Stratton VAMC, 113 Holland Avenue, MC 111
Albany, NY 12208

Associate Professor
Department of Internal Medicine
Albany Medical College
47 New Scotland Avenue, MC 109
Albany, NY 12208

From: PHARMBD [PHARMBD@MAIL.NYSED.GOV]
Sent: Friday, January 24, 2014 09:41
To: Leigh Briscoe-Dwyer; Kimberly Zammit
Subject: Fwd: collaborative pain management

NYS Board of Pharmacy
89 Washington Ave., 2nd Floor West
Albany, NY 12234
Phone: 518-474-3817 ext. 130
Fax: 518-473-6995
Email: pharmbd@mail.nysed.gov
Web: www.op.nysed.gov
http://www.op.nysed.gov/prof/pharm/>>> "Krastins, Michael" <Michael.Krastins@va.gov> 1/23/2014 4:27 PM >>>
Mr. Mokhiber,

I am a primary care physician at the Albany VA Medical Center. I work very closely in collaboration with the pain management pharmacists Drs. Jeffrey Fudin and Timothy Atkinson. They have seamlessly integrated themselves within the primary care practice of the management of patients with chronic pain. They are very helpful and available with collaborative drug therapy management. They will see patients and interact with the primary care providers to discuss care and make management recommendations that they help implement, in conjunction with the primary care provider. Thus, it is a very helpful team effort.

They have extensive expertise regarding opioid monitoring (UDS, serum, risk stratification and prescribing), and all other adjunctive pain medications (NSAIDs, antidepressants, anticonvulsants, and less common adjuncts), drug-drug interaction monitoring and drug-disease state monitoring that they convey during the care that they provide.

Thank you,
Michael Krastins, M.D.
Staff Physician, Primary Care
Albany VA Medical Center

Mount Sinai

Vicki LoPachin, M.D.

Chief Medical Officer
Senior Vice President

The Mount Sinai Hospital
One Gustave L. Levy Place, Box 1238
New York, NY 10029-6574

Tel: (212) 659-9072
Fax: (212) 659-9304
vicki.lopachin@mountsinai.org

March 3, 2014

Lawrence Mokhiber:
Executive Secretary, Pharmacy Board
New York State Education Department
89 Washington Av, Room 2 West
Albany, NY 12234

Dear Mr. Mokhiber;

I write this letter in support of the continuation of the Collaborative Drug Therapy Management (CDTM) Bill that was passed on February 4, 2011 in the State of New York. I firmly believe that this Bill should not be permitted to expire.

I have always been a strong advocate of placing the Pharmacist at the patient's bedside. As part of the multidisciplinary team, a Clinical Pharmacist provides insight into the management and monitoring strategies that optimize patient care and improve patient outcomes.

I can attest that the advanced training that our Pharmacists receive and use in practice is an asset. I was in favor of a CDTM Bill in New York State before the current Bill was even enacted into law. A well-trained Clinical Pharmacist working in collaboration with a Physician should be permitted through scope of practice to oversee and adjust a medication regimen and optimize the use of the prescribed medication(s) for the benefit of our patients. I personally feel that the definition of the practice of pharmacy should also be amended to accurately reflect the scope of pharmacy practice in the present day.
I am a proponent and Physician champion for Clinical Pharmacy Services at The Mount Sinai Hospital, I work closely with Dr. Joanne Meyer and Dr. Gina Caliendo are many of joint collaborations. We are currently evaluating our newest program, the Pharmacist-dosing of Vancomycin under protocol , using the collaborative drug therapy management (CDTM) guidelines. I work closely with Senior Pharmacy Leadership to advocate the continued expansion of such services, as I believe that these services are integral to providing world-class patient care.

The benefits in my opinion of the current CDTM Bill include optimizing medication regimens, optimizing monitoring, and providing appropriate patient follow-up. The benefits of this collaborative physician-pharmacist relationship at our academic medical center cannot be overstated.
In closing, I feel that our Pharmacists have earned their place in patient care, should continue to have this expanded scope in practice, and should be allowed to utilize their professional knowledge base and judgment for the care of our patients.

Sincerely,

Vicki LoPachin
CMO
Chief Medical Officer
Senior Vice President Office for Excellence in Patient Care

From: "Lukaszewicz, John E" <John.Lukaszewicz@va.gov>
To: "pharmbd@mail.nysed.gov" <pharmbd@mail.nysed.gov>
CC: "jeff@paindr.com" <jeff@paindr.com>, "Fudin, Jeffrey" <Jeffrey.Fudin2@va.gov>, "Arredondo, Tracy M" <Tracy.Arredondo@va.gov>, "Cottrell, Jean" <Jean.Cottrell@va.gov>
Date: 1/24/2014 3:13 PM
Subject: community Based Outpatient Clinic Pain Team Support

Dear Mr. Lawrence H. Mokhiber,

As a provider at the Glens Falls VA Community Based Primary Care Clinic I have had the pleasure of working with the Pain Management Team from the Albany Stratton VA Medical Center headed by Dr. Jeffrey Fudin providing face to face and chart review encounters with our mutual VA patients over the last several weeks. These once monthly visits and continuous phone, email, and chart encounters by the Pain Management Team have been a tremendous help not only in tailoring the pain treatment of our patients but also an educational benefit for me and the other providers in this clinic. Their help has been instrumental in aided us in providing more appropriate and beneficial care for our pain patients, educating patients about pain treatment, adjusting and monitoring these medications, and reducing drug seeking, diversion, and inappropriate use of these controlled substances. I wholeheartedly commend and recommend these services and hope that they would become a useful part of the armamentarium for all providers who treat patients with pain.

Sincerely,

John E. Lukaszewicz, MD
Family Medicine
Glens Falls Primary Care Practice
84 Broad Street 2nd Floor
Glens Falls, New York 12801
518-798-6066

From: Mahatme, Sheran
Sent: Friday, December 13, 2013 9:06 AM
To: Fudin, Jeffrey
Subject:

Dear Jeff:
As the year comes to a close, I just wanted to provide you some feedback regarding Timothy Atkinson. As you know, he has been attending our HIV Clinics not only on Tuesday afternoon but also on Thursday mornings. It has been a true pleasure having him there. His assistance in the management of our patients, which often have multiple comorbidities, has been invaluable. Many patients have remarked how helpful he has been. In fact, one of my patients the other day who had been tapered off his prior chronic pain med, stated he was "loving the new NSAID". I believe Tim would be a great asset to the medical team here. I truly hope and wish this can be facilitated as it would be a great loss without him. Patients (and providers) have come to rely on him and the ease of access to have him as a part of our team (i.e. right there) cannot be replaced easily. I thought it important to let you know what a great job Tim is doing. Thanks.
SM

Sheran Mahatme, DO, MPH
Stratton VA Medical Center
Division of Infectious Diseases
113 Holland Avenue
Albany, NY 12208
Office: 518-626-6412
Fax: 518-626-6606
Email: Sheran.Mahatme@va.gov

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From: "Mahatme, Sheran" <Sheran.Mahatme@va.gov>
To: "'pharmbd@mail.nysed.gov'" <pharmbd@mail.nysed.gov>
CC: "Fudin, Jeffrey" <Jeffrey.Fudin2@va.gov>, "'jeff@paindr.com'" <jeff@paindr.com>
Date: 1/29/2014 10:03 AM
Subject: NYS Pharmacy Pain Management

Dear Mr. Mokhiber:

This letter is written in support of ensuring that clinical pharmacy pain management remains an integral part of our current medical care. As an Infectious Diseases physician who primarily provides care to HIV infected individuals, the presence of a pharmacist remains a critical component in optimizing the health of this population. We often take a multidisciplinary approach to our patients which not only includes medical physicians but also pharmacists, dietitians, mental health providers, nursing, and case managers or social workers.

Upon my arrival to New York, I was a bit disheartened to learn that we did not have all these components at our institution due to limited resources. However, over the last six months or so, we have been most fortunate to have been able to work with a dedicated clinical pharmacy pain provider. Pain management in the realm of HIV can be a significant burden. In fact, it is known that the prevalence of chronic pain is higher in HIV patients and can be attributed to a number of different causes including but not limited to HIV itself, comorbid conditions such as advanced arthritis or neuropathy, and drugs used for the treatment of HIV. There is also a relationship between chronic pain and mental health (e.g. depression and functional decline) which is concerning, particularly in our Veteran population which can be vulnerable. A significant amount of time must be spent with patients to address this problem, but often, medical providers do not have the training, expertise, nor time to do such.

Collaborating relatively recently with our clinical pharmacy pain management service has provided an enormous amount of help. Not only are patients seen right away rather than perhaps waiting for an appointment which could be delayed (e.g. weeks to months), but cases can be discussed together to determine the necessity of certain medications and to review potential drug-drug interactions, while still providing realistic outcomes for the patient at hand to assist with his/her pain issue. In addition, attention can be drawn to contributing factors for chronic pain and ways to modify them which may not necessarily require pharmacological interventions. This all goes in hand of being able to provide the best care to our patients. With this service, our clinic patients now "expect" to see our pain management specialist at their routine visits. We have been successful in tapering some individuals off of unnecessary drugs and even providing alternatives to others. Close follow-up by our pain specialist through phone calls, individual follow-ups, and routine lab monitoring has been helpful in adjusting medication dosing, assessing the well-being of our patients, and importantly, providing continuity of care.

In conclusion, having a clinical pain management pharmacist remains a great asset to the medical team. It would be a significant loss for our patients and providers if this service was not provided on a routine basis. I would urge that the New York State Board of Pharmacy support the expansion of pharmacists in critical areas of need such as pain management. Thank you for your consideration to this matter.

Respectfully,

Sheran Mahatme, DO, MPH
Infectious Diseases Medical Subspecialty Director
Assistant Professor of Medicine
Stratton VA Medical Center
Section of Infectious Diseases
113 Holland Avenue
Albany, NY 12208

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North Shore LIJ
North Shore-Long Island Jewish Health System

400 Community Drive
Manhasset, NY 11030
Tel (516) 562 4280
Fax (516) 562 2626

Department of Medicine

February 10, 2014

Lawrence Mokhibir
Executive Secretary, NYS Board of Pharmacy
89 Washington Avenue
Albany, New York 12234

Dear Mr. Mokhibir:

I am writing to strongly support the continuation and expansion of the 2011 Collaborative Drug Therapy Management Law (S.3292/A.6448) that allows pharmacists to prescribe and manage medications under a collaborative practice agreement with physicians.

As the Medical Director of the Center for AIDS Research and Treatment at the North Shore University Hospital, the largest provider of care to people living with HIV and AIDS on Long Island, I recognize the great challenges that patients face in maintaining adherence to antiretroviral therapy without interruption. I have had the great pleasure to collaborate with Loyce Mol PharmD with whom I work as a team to support our patients. Dr. Mol consults with our patients to educate them on side effects, potential drug interactions, deal with access issues, proper dosing, and food restrictions. She provides practical support to maintain adherence with therapy by arranging home delivery, filling up pill boxes, setting electronic reminders, and being readily available to answer questions. Dr. Mol is a great partner in managing our complex patients because she spends time listening to them, learns their barriers to treatment and addresses them. She has provided invaluable service by reviewing the patient's medication profile, including prescriptions from outside providers, which may avert potential drug interactions which are common with antiretroviral therapy. Dr. Mol develops an individualized plan for each patient that accounts for their medication regimen, beliefs, concurrent medications, dietary concerns, support systems, language and cultural issues.

We have also treated, and plan to expand, treatment of HIV and hepatitis C co-infected patients, who face many challenges in achieving success. Dr. Mol's support has contributed greatly to maintain our co-infected patients on therapy and allowed us to achieve sustained virologic response rates that are superior to the statewide average. Loyce builds a therapeutic relationship that bridges the patient and medical provider and which has been of inestimable value to us. The success of our collaborative practice agreement has greatly exceeded our expectations. The contribution of the clinical pharmacist to our practice has

completed the multi-disciplinary team which includes Case Managers, Dietician, Health Educators and Social Workers. The Collaborating Pharmacist has become an essential part of managing any person with chronic illness. Each member of the team has been critically important for our patients to be successful.

The 2011 Collaborative Drug Management law should be extended indefinitely and should be expanded for all medical practices.

Sincerely,

Joseph P. McGowan, MD, FACP, FIDSA, AAHIVS
Medical Director, Center for AIDS Research and Treatment

NYU School of Medicine
NYU LANGONE MEDICAL CENTER

LEWIS S. NELSON, MD
Professor & Vice-Chair for Academic Affairs
Director, Fellowship in Medical Toxicology
Department of Emergency Medicine
New York City Poison Control Center

January 28, 2014

To Whom It May Concern:

I am writing a letter of strong support for the reapproval of the CDTM legislation that fosters collaboration between pharmacists and physicians. In my experience as chair of both the Pharmacy and Therapeutics (P&T) and the Medication Safety (MSC) committees, these joint efforts have been critical to ensuring the safe and effective use of medications within our medical center.

Pharmacists play a formative role in our deliberations about formulary requests to the P&T committee. The pharmacy perspective is integrated with that of the physicians on the committee in the decision about formulary admission or dismissal. The insight provided by the pharmacy about the risks and benefits of any new or existing medication carries significant weight. Every new medication that is reviewed undergoes an proactive internal pharmacy review for potential safety issues which informs the medical decision-making by the committee. Issues evaluated include look-alike and sound-alike naming, potential for ordering and administration confusion (such as oral liquid formulations being given intravenously), and off-label uses that may lead to clinical complications once available in the medical center.

There is no question that in either crafting a medication-related policy or investigating an adverse event, having the broad perspective offered through this collaborate effort has improved patient care. For example, the pharmacy co-chair of the P&T committee reviews with the committee the need for stocking several medications within the same class (e.g., statins). Following this review and discussion with various clinical services, we are generally able to limit the formulary within certain classes to a small number of, and in many cases a single, medication. This carries many benefits in efficiency and simultaneously reduces the likelihood of certain types of medication errors.

The subsequent development of our non-formulary medication policy provided a further opportunity for mutual understanding to allow the creation of a practical solution to this common concern. Since we cannot stock all potential medications that patients may be using outside of the hospital, there is occasional need to provide patients with a medication that is not available in stock. Such requirements carry risk, since these medications are not subject to the automated adverse reaction checking that occur with formulary medications. Through our efforts and the help of the information technology group, we created a system to allow prescribers to formally request the use of a non-formulary medication and have individualized attention focused on that request by a pharmacist.

New York City Poison Control Center
455 First Avenue, Room 123, New York, NY 10016
tel: 212.447.8150 • fax: 212.447.8223
lewis.nelson@nyumc.org

Bellevue Hospital Center
South Manhattan Healthcare

Similarly, pharmacists are integral in identification and reporting of medication errors as well as in our investigation of the root-causes of such errors. They stand on equal footing with nurses and physicians in the process of constructing and implementing solutions to any related concern. For example, we have worked together on projects specifically evaluating means to mitigate patient harm related to high-risk medications, specifically opioid analgesics, hypoglycemic such as insulin, and anticoagulants such as heparin. Each of these medication classes undergoes formal assessment on a regular basis in an interdisciplinary format that relies heavily on pharmacy input. We have implemented corrective actions related to monitoring parameters for patients on opioids, those who receive insulin, and anyone with indewlling catheters who is anticoagulated.

From my perspective the collaborative relationship of pharmacists and physicians at our academic medical center cannot be overstated. It is absolutely critical to effective, efficient, and safe medication use.

Please feel free to contact me with any questions or concerns.

Lewis Nelson, M.D.

University at Buffalo
The State University of New York

School of Pharmacy and Pharmaceutical Science
Office of the Dean

RECEIVED
JAN 2 2014
BOARD OF PHARMACY

December 27, 2013

Lawrence H. Mokhiber. RPh, MS
Executive Secretary
NYS Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY 12234-1000

Dear Mr. Mokhiber:

We at the UB School of Pharmacy & Pharmaceutical Sciences wholeheartedly support the expansion of the scope of pharmacy practice in New York State to include Collaborative Drug Therapy Management (CDTM) on a permanent basis in both inpatient and outpatient settings. It is essential that our State advance our practice act in order to remain at the forefront of healthcare. Also, we must reassure our School's accreditation agencies, which expect that our students are trained in such venues and may practice in such programs upon graduation.

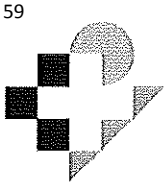
We believe that CDTM programs improve the quality of medication therapy, enhance the satisfaction of physicians, pharmacists, and patients, and result in positive therapeutic outcomes for the patients they serve. This in turn helps keep patients healthy and safe; it also reduces unnecessary health costs by minimizing improper medications, complications, and hospital admissions or readmissions.

Feel free to contact me at any time concerning this or other professional issues.

Sincerely,

James M. O'Donnell, PhD
Dean and Professor

285 Kapoor Hall, Buffalo, NY 14214-8033
Tel (716) 645-2823 Fax (716) 829-6568 Web www.pharmacy.buffalo.edu



The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am a Family Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with HIV disease/thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", asthma, diabetes, who are tobacco-dependent, who have recently been discharged from the hospital and are at high risk for readmission.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Adesuwa Okesanya, MD
Co-director of inpatient services
Family Medicine Department
Brooklyn Hospital Center

member
NewYork-Presbyterian
Healthcare System
affiliate: Weill Cornell Medical College

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From: "Pandula, Abhinetri" <Abhinetri.Pandula@va.gov>
To: "'pharmbd@mail.nysed.gov'" <pharmbd@mail.nysed.gov>
CC: "Fudin, Jeffrey" <Jeffrey.Fudin2@va.gov>
Date: 1/29/2014 8:22 AM
Subject: Multidisciplinary approach to pain

Dear Mr. Lawrence Mokhiber,

RE: The multidisciplinary approach to pain.

I am a primary care physician at the Veteran's hospital for the last two years. When I started my clinic here, I inherited a panel of 800 patients, a majority of whom were prescribed large quantities of opioids. I was not comfortable with prescribing these patient's large doses of controlled substances. A lot of these patients did not have routine opioids agreements, urine drug screens or serum quantification of their prescribed opioids. We started a multidisciplinary pain clinic involving Dr. Jeffrey Fudin and in the last 6 months Pharmacy Resident Dr. Timothy Atkinson has joined us under the mentorship of Dr. Fudin. Involving this team of providers has been an invaluable asset to my practice. We discovered that a lot of the patients were misusing the medications or were simply not taking the large amount of narcotics that were prescribed. The pharmacy team has reviewed not only narcotics but also looked extensively into drug interactions of other medications. The patients are able to understand the mechanism of action of individual drugs and are more cooperative with the treatment. The patient satisfaction has increased while the quality of care provided has also significantly improved. We are treating chronic pain with disease specific medical therapy. We focus not just on narcotics but also use SNRIs, NSAIDS, anticonvulsants, other adjuvants, iontophoresis as ordered by the pharmacist, physical, or behavioral therapy. A majority of my patients are elderly and have over 20 medications. It is very difficult for an individual provider to evaluate drug interactions in these patients with polypharmacy in a short 30 minute visit. A lot of our patients also have kidney disease and liver disease and adjusting medications for individual patient's needs is essential. Dr. Fudin and his team have been a great resource for us in this regard.

Pain should be treated with a multidisciplinary approach and after working with Dr. Fudin and his team for about two years now, I can say that this has been the best experience of my life. I have learned so much about drug quantifications and appropriateness of different types of medications. The pharmacy team has been extremely accessible to all of us. They are always eager to help with a challenging patient or a complex case at a short notice. All of the primary care physicians here at the VA have the highest regard for the pharmacy pain team and we do not want to ever lose their services. Expanding such collaboration to our medical peers with NYS would undoubtedly be a tremendous asset to medical doctors, improve pain outcomes for patients, reduce public risk, and probably in many instances aver death.

If I may be of further assistance, please doesn’t hesitate to contact me.

Sincerely,

Abhinetri Pandula, M.D.

Lifetime Health medical group

January 20, 2014

New York State Legislator:

I am writing this letter to support the Collaborative Drug Therapy Management (CDTM) law passed in 2011. I can testify to the success of Lifetime Health Medical Group as a result of pharmacist/physician collaboration. We have recently expanded our clinical pharmacy services, now covering both regions in which we are located— Buffalo and Rochester.

Due to restrictions in the current law, Lifetime Health Medical Group is not able to fully implement CDTM into practice. Yet despite these limitations our clinical pharmacist team has demonstrated an ability to make appropriate and sound drug therapy recommendations which have reduced the risk of medication misadventures, reduced unnecessary health care expenditures, and improve patient satisfaction with medical services and the overall care they receive.

Pharmacists continue to show their value for patients with chronic conditions. The 46 other states that have passed CDTM laws have reported improvements in all aspects of care. Within our own medical group, we have demonstrated that diabetic patients managed collaboratively by a clinical pharmacist and primary care physicians were significantly better controlled over patients managed by their primary care physician alone.

As health care delivery in the United States continues to evolve through models such as Accountable Care Organizations and Patient Centered Medical Homes, I believe it is in the best interest of patient care that pharmacists are recognized as an integral part of the health care team.

I ask that you consider signing A7521 into law to allow pharmacists to work to their full potential and improve health care for all New Yorkers.

Thank you for your time and attention to this important matter. Please feel free to contact me should you have additional questions.

Sincerely,

Mark F. Perry, MD
Chief Medical Officer
Lifetime Health Medical Group
120 Gardenville Parkway
West Seneca, NY 14224
Phone 716-656-4048

NYU Langone
MEDICAL CENTER

Robert A. Press, MD, PhD
Chief Medical Officer

February 3rd, 2014

Mr. Larry Mokhiber
Executive Director, Board of Pharmacy

Dear Mr. Mokhiber:

I write this letter in support of the continuation of the Collaborative Drug Therapy Management (CDTM) Bill that was passed on February 4th, 2011 in the State of New York. I firmly believe that this Bill should not be permitted to expire.

I have always been a strong advocate of placing the Pharmacist at the patient's bedside. As part of the multidisciplinary team, a Clinical Pharmacotherapist provides insight into the management and monitoring strategies that optimize patient care and improve patient outcomes. Through direct observations as an Infectious Diseases Physician and discussions with my pharmacy colleagues, I can attest that the advanced training that our Pharmacists receive and use in practice is an asset. I was in favor of a CDTM Bill in New York State before our current Bill was even enacted into law. A well-trained Clinical Pharmacotherapist working in collaboration with a Physician should be permitted through scope of practice to oversee and adjust a medication regimen and optimize the use of the prescribed medication(s) for the benefit of our patients. I personally feel that the definition of the practice of pharmacy should also be amended to accurately reflect the scope of pharmacy practice in the present day.

As a proponent and Physician champion for Clinical Pharmacy Services at NYU Langone Medical Center, I worked closely with Dr. John Papadopoulos to initiate these comprehensive services in early 2008. Since then, I have worked closely with Senior Pharmacy Leadership to advocate the continued expansion of such services, as I believe that these services are integral to providing world-class patient care. Furthermore, I was a proponent and in support of starting the Post-Graduate Year 1 and 2 Pharmacy Residency Programs. When the need for such programs was presented to me, it seemed very logical that we should have a role in furthering the post-graduate training of our pharmacists. The benefits in my opinion of the current CDTM Bill include optimizing medication regimens, optimizing monitoring, and providing appropriate patient follow-up. The benefits of this collaborative physician-pharmacist relationship at our academic medical center cannot be overstated.

In closing, I feel that our Pharmacists have earned their place in patient care, should continue to have this expanded scope in practice, and should be allowed to utilize their professional knowledge base and judgment for the care of our patients.

Sincerely,

Robert A Press, MD

Robert Press, MD

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MONTEFIORE MEDICAL CENTER
The University Hospital
for the Albert Einstein
College of Medicine

MONTEFIORE MEDICAL GROUP - BRONX EAST
2300 Westchester Avenue
Bronx, New York 10462
718-829-1900

DONALD RAUM, MD
Medical Director, MMG 3

November 1, 2013

To Whom It May Concern:

MONTEFIORE

I am writing this letter in support of continuation of a bill passed in 2011 as S.3292/A.6448, allowing pharmacists to prescribe and manage medications under a collaborative practice agreement with physicians. I am the Regional Director for Montefiore Medical Groups 1 & 3.

Danielle Garcia Pharm D BCPS joined our practice in June 2013. She had made an immediate impact on quality of care, reduction of medication errors, and improved health care outcomes including reduced hospital admissions, and readmissions.

Her first task has been to organize the care and monitoring of more than 500 patients who are anticoagulated with Coumadin. Anticoagulation and its complications are major causes of uncontrolled expenses, as well as inappropriate admissions and readmissions. This has also significantly improved the workflow for the nurses and physicians by locating this important care in one place and with standardized protocols for care which have the best outcomes. This has had a large effect on the improvement of anticoagulation control.

Her focus has been scheduling appointments with patients in order to ensure timely follow-up and outreach when appointments are missed, evaluating and discussing duration of therapy on anticoagulation with PCPs, as well as improving the perioperative management of anticoagulation (bridging). She is still working her way through the Coumadin List, reviewing each patient chart to determine if they're actually on warfarin or still under our care (still ~500) and has identified some patients that have been non-compliant with INR monitoring and have re-established their care.

She is also managing referrals for medication reconciliation, counseling, and patient education for those who are non-compliant, both due to financial difficulty and poly-pharmacy utilizing evidence-based guidelines when reviewing medication lists and forming care plans to optimize patient therapy and outcomes. These are collaborative with the physicians. I understand that this law, passed in 2011 is due to expire soon. It should be extended indefinitely. Dr. Garcia's contribution to patient care is invaluable. Thank you.

Donald Raum MD

Donald Raum MD
Regional Director Montefiore Medical Group 1 & 3
Montefiore Medical Center
Assistant Professor of Medicine
Albert Einstein College of Medicine, Yeshiva University

The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am the Medical Director for the Ambulatory Care Center and a General Internist at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", asthma, diabetes, who are tobacco-dependent, who have recently been discharged from the hospital and are at high risk for readmission.

The addition of pharmacists to our clinical team provides an invaluable resource to providers and patients. Our patients receive high-quality care from our pharmacists; they are oftentimes able to spend more time educating patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Tanyka Sam

Tanyka Sam, MD, MPH
Medical Director
Ambulatory Care Center

member
NewYork-Presbyterian
Healthcare System
affiliate: Weill Cornell Medical College

121 DeKalb Avenue
Brooklyn, NY 11201
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EST. 1881
Albany College of Pharmacy
AND HEALTH SCIENCES

December 18, 2013

Dear Mr. Mokhiber,

Thank you for the opportunity to provide comment about the importance of collaborative drug therapy management to pharmacy education and patient care. As you are aware, Schools/Colleges of Pharmacy are accredited by the Accreditation Council for Pharmacy Education (ACPE). The accreditation standards can be found from: https://www.acpe-accredit.org/pdf/S2007Guidelines2.0_ChangesIdentifiedInRed.pdf. The standards were revised in 2011 and some of the most significant changes include 23 mentions of the need for pharmacists and student pharmacists to practice in an "interprofessional team" and 9 mentions of "collaborative" practice. The Center for the Advancement of Pharmacy Education (CAPE, a division of the American Association of Colleges of Pharmacy) outcome statements for pharmacy education were updated and released in July 2013, and also emphasize the importance of pharmacists practicing in collaborative models within an interprofessional team. Specifically, Domain 2 of these outcomes which focus on the Essentials of Practice and Care, state that pharmacists should *adjust* care plans as appropriate.

Currently, 40 states have CDTM legislation in place and this is an expected minimum standard of modern pharmacy practice. I have frequently advised students to seek post-graduate residency training elsewhere so that they can see the most advanced practice in the United States. Training experience within a practice where the pharmacist works under a collaborative practice agreement allows student pharmacists and first-year post-graduate residents to obtain the experience necessary to provide optimal care to patients, the health care system, and are competitive in the healthcare market which increasingly has recognized the role that pharmacists have clinically in the safe and cost-effective management of drug-related problems and patient care. Within the American Society of Health-systems Pharmacy (ASHP) Accreditation Standards for PGY1 residency programs, various standards require that pharmacists have the ability to adjust care plans. Post-graduate residency training is an important component – and indeed, increasingly becoming a *requirement* – for entry-level positions for pharmacists who provide direct patient care. The literature is replete with information regarding the value that clinical pharmacists who practice under the advanced practice models contribute to safe and cost-effective patient care, most notably the Report to the U.S. Surgeon General by Admiral Scott Giberson, currently the Acting Deputy Surgeon General (attached).

Our graduates are fortunate to have opportunities to practice within the CDTM model in academic medical centers in NYS; however, most pharmacists practice and most patients who are treated in a hospital setting does not occur within these large academic medical centers, but by smaller, community-based or acute care centers

106 New Scotland Avenue, Albany, New York 12208 ▪ 518-694-7200 ▪ 1-888-203-8010 ▪ www.acphs.edu

where CDTM is currently not permitted in New York State. This limits both the high level of service, safety, and quality that pharmacists can provide in these settings, creating a disparity in care between patients who have the luxury of leaving near an academic center and the majority of patients who receive care in community-based hospitals. Additionally, this limits the clinical training site opportunities for our College in placing students on Advance Pharmacy Practice Experiences (APPE) which are a required component of final professional year (P4) of the program to meet ACPE standards and also limits the creation of high-quality post-graduate residency training programs that meet ASHP Accreditation Standards.

This is a very brief overview of the ways in which CDTM practice opportunities are important to the training and education of our student pharmacists and post-graduate residents. I am happy to provide additional information should you require it.

Regards,

Sarah L. Scarpace, PharmD, MPH, BCOP
Assistant Dean for Pharmacy Professional Affairs
Associate Professor, Pharmacy Practice
Albany College of Pharmacy and Health Sciences
106 New Scotland Avenue
Albany, NY 12208
Phone: (518) 694 – 7226
Email: sarah.scarpace@acphs.edu

Kaleida Health

RECEIVED
JAN 29 2014

D-1 Primary Medicine Center

Buffalo General Medical Center
100 High Street
Buffalo, New York 14203

Tel. (716) 859-2175
Fax· (716) 859-2891

January 24, 2014

Lawrence Mokhiber
Executive Secretary
NYS Board of Pharmacy Executive Secretary
89 Washington Ave, 2nd Floor W
Albany, NY, 12234-1000

Dear Mr. Mokhiber:

I am writing this letter in support of the continuation of a bill passed in 2011 as S.3292, allowing pharmacists to prescribe and manage mediations under a collaborative practice agreement with physicians. I am the Section Head of General Internal Medicine at the Buffalo General Medical Campus, and I have firsthand knowledge of the positive impact pharmacists have in the care of our patients.

My partners and I collaborate with Stephanie Seyse,PharmD, BCPS, FASHP, CACP Clinical Coordinator - Internal Medicine Buffalo General Medical Center, in the management of our patients' anticoagulation therapy within the Buffalo General Medical Campus, which provides care to an underserved community. The service provided by our Coumadin Clinic provides ready access to safety-enhancing services. Dr. Seyse has made a great impact on the quality of care, reduction of medication errors and improved health care outcomes including reduced hospital admissions and readmissions. Having standardized protocols for care have resulted in the best outcomes for our patients being anticoagulated. Medication counseling and patient adherence to treatment have significantly increased with our Coumadin Clinic.

Since 2003, Dr. Seyse has been an integral part of the care of our patients. Dr. Seyse and her staff see about 125 patients with an average of 15 patients per session. Their clinic is held twice weekly. Patients clearly benefit from improved safety, increased access to health care, and my colleagues and I greatly appreciate the ability to consult Dr. Seyse and her team on complex medication cases and drug-drug interactions, both in our outpatient setting and on the inpatient service. Dr. Seyse has earned several awards and most recently the Western New York Residency Preceptor of the Year award. Despite her many achievements, Dr. Seyse is quick to point out that this is the role pharmacists in collaborative practice agreements are designed to fill.

January 24, 2014
Page 2

I understand that the 2011 Collaborative Drug Therapy Management law is due to expire soon. It should be extended indefinitely. Dr. Seyse and her team's contribution to our patients and their care has been invaluable and we need to keep and extend their presence in our facility.

Sincerely,

Richard Schifeling MD, FACP
Section Head, General Internal Medicine, Buffalo General Hospital
Associate Program Director
SUNY at Buffalo Internal Medicine Residency Program
Associate Professor of Medicine, SUNY at Buffalo School of Medicine

CapitalCare
Medical Group, LLC

Louis S. Snitkoff, MD, FACP

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Department of Medical Management and Compliance
Department of Ancillary Clinical Services
Chief Compliance Officer
Chief Privacy Officer
Medical Director

January 27, 2014

Mr. Lawrence H. Mokhiber
Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY 12234-1000

Dear Mr. Mokhiber:

I am pleased to write in support of expansion of Collaborative Drug Therapy Management (CDTM) in New York State (NYS).

As you know, present laws and regulations in NYS restrict this essential activity to inpatient hospital settings and hospital-based outpatient facilities. Over the past few years, there is a growing trend in ambulatory health care to "expand the patient care team." This has led to the inclusion of nurses, nurse practitioners, physician assistants, dietitians and diabetes educators as members of an integrated health care delivery team in which each participant practices to the top of his or her license and contributes care based upon his or her unique training and expertise.

As part of a recent collaboration with one of our regional payers, CapitalCare Medical Group (CapitalCare) experienced the benefits of having a clinical pharmacist embedded in two of our primary care offices. This individual provided invaluable insights and much needed professional services to our patients and practitioners. However, due to current laws and regulations, she was unable to engage in CDTM.

CapitalCare is a large, multispecialty physician group practice with 28 offices located throughout the Capital District. We have approximately 120 prescribing practitioners who provide care to more than 150,000 active patients, from newborns to the oldest old. Expansion of CDTM would enable these patients to benefit from the expertise of a pharmacist with respect to medication management in their primary care setting where, arguably, coordination and management of care can be done most effectively and efficiently.

Please feel free to contact me if I may provide additional information.

Yours truly,

Louis S. Snitkoff, MD, FACP

D'Youville COLLEGE
320 Porter Avenue
Buffalo New York 14201-1084

NOV 21 2013
STATE BOARD OF PHARMACY

November 15, 2013

Lawrence H Mokhiber
Executive Secretary, NYS Board of Pharmacy
Executive Secretary, NYS Board of Midwifery
89 Washington Avenue
Education Building, 2 West
Albany, New York 12334

Dear Mr. Mokhiber,

I am writing to support the continuance of New York's Collaborative Drug Therapy Management (CDTM) law and provide some insight into the impact of the law on our teaching and practice missions.

As you know, every school of pharmacy's curriculum must provide at least 1700 hours of introductory and advanced practice experience. These experiences are intended to connect classroom learning to clinical practice in order to produce graduates capable of participating in an interdisciplinary patient-centered model of health care

Our best clinical sites provide opportunities for our faculty and preceptors to practice in a contemporary model of care. Our clinical faculty members serve as role models, and their sites provide opportunities for students to develop expertise in managing patients' medication therapies. Unfortunately, the number of ambulatory sites in New York where pharmacy is practiced at this level is limited by the state's practice model. We have placed faculty members at two sites that qualify as "teaching hospitals" according to article 28 of the New York Public Health Law.

The clinical faculty members who practice at ambulatory sites affiliated with teaching hospitals have made an impact on the quality of care for their patients. Michael Cimino has been practicing as a clinical pharmacist in New York for more than 30 years. We recruited him to our faculty to create a practice site at the Roswell Park Cancer Institute Over a typical three week period he reports that he monitors 85 to 90 patients receiving tacrolimus to prevent rejection of their transplanted bone marrows and makes recommendations to change therapy in 30 to 40 patients for a variety of problems (including optimal treatment of graft versus host disease, pain management, blood pressure control, prevention or management of adverse drug events, appetite stimulation, glucose control, and infection prevention). He reports that his ability to manage patients has been limited by the language in the New York act which precludes pharmacists from being categorized as "practitioners".

Michael MacEvoy practices at an outpatient site affiliated with the Catholic Medical Partners, a nationally recognized example of a high performing health system. He works closely with physicians managing diabetic patients and reports that he and his pharmacy colleagues have improved care for over 200 patients followed during the 2011-12 year. The improvements included reductions in LDL cholesterol, blood pressure, weight, and improvements in glucose control measured by hemoglobin A1C levels.

(716) 829 8000
fax (716 829 7790

www.dyc.edu

2011-12 Catholic Medical Partners Clinic Patient Summary
(N = 206)

Measure	% patient w improvement	Avg Pre*	Avg Post*	Change	% Change	% improved/at goal (goal in parentheses)**
HgbA1C	61.2	7.88	6.95	-.92	10.95	81.86 (<7)
LDL Cholesterol	47.6	94.8	74.2	-20.63	20.56	83.98 (<100)
Systolic BP	45.1	134.6	122.1	-12.48	8.93	71.72 (<130)
Triglycerides	49.3	192.6	137.3	-55.22	24.64	70.23 (<150)
BMI	43.7	35.9	33.8	-2.11	5.93	54.76 (<30)

*Data for improved patients
**Data for full sample

The remainder of our faculty members who practice in ambulatory sites practice in a consultative role because of the limits placed upon them by the practice act. Dr. PJ Pitts works with an interdisciplinary team at the Jericho Road Community Health Center. This site does not qualify as a "teaching hospital" and Dr. Pitts therefore cannot modify therapy except through a proxy. Nurse practitioners and physicians at the site contact her to help manage patients receiving anticoagulant medications. She sees the patient, writes a note, but must contact someone else to modify therapy. We recruited her to this position because of her experience with collaborative practice in her home state of Oregon but unfortunately, she cannot practice at a comparable level in New York State Our clinical faculty who practice at other ambulatory sites in the area report similar experiences.

It is unfortunate that all of our students cannot be trained at contemporary clinical sites. When available, we place students at federal facilities where pharmacists are recognized as providers and can practice drug therapy management under protocol. The Western New York Veterans Administration Medical Center provides numerous opportunities for our students to participate in a contemporary practice environment. Other students report wonderful opportunities in the Indian Health Service, another example of contemporary practice.

Students licensed as interns in other states are placed in sites where CDTM is practiced. We have placed students at sites in Ohio, California, Wisconsin, and Pennsylvania. Students can administer vaccines in some of these states, but in all, they can practice (under supervision) collaborative drug therapy management.

Because of the limits imposed by New York's practice act, we advise students seeking additional training in ambulatory settings to train in North Carolina, Minnesota, Kentucky, Iowa, or Virginia, states recognized for advanced pharmacy practice. When recruiting faculty members for ambulatory sites, we look for residents trained in these states. There are only five community pharmacy/ambulatory care residency positions in New York State. In contrast there are more than 10 positions in North Carolina and over 50 in Minnesota.

I hope that this brief summary provides some insight into the possibilities for improving care at sites where contemporary practice models are in place. Our hope is that the Assembly will remove the sunset provisions and expand the practice model to include any ambulatory site where there is a willing provider and a properly credentialed pharmacy practitioner.

Sincerely,

Gary P. Stoehr

Gary P. Stoehr, Pharm.D
Professor and Dean
D'Youville College School of Pharmacy

ST. JOHN FISHER COLLEGE

WEGMANS SCHOOL OF PHARMACY

March 25, 2014

Lawrence Mokhiber
Executive Secretary, NYS Board of Pharmacy
89 Washington Avenue
Alban, New York 12234

Dear Mr. Mokhiber:

I am writing this letter in support of continuation of a bill passed in 2011, allowing pharmacists to prescribe and manage medications under a collaborative drug therapy management (CDTM) with physicians. As the Dean of a school of pharmacy, I have several practice faculty that practice under this agreement and I have personally seen the positive impact that my faculty have in the care of patients. Having a CDTM agreement in place that allows the pharmacist to engage in such activity according to an established protocol is a great way to meet both the clinician's and the patients' needs. It allows pharmacist to make the interventions necessary to ensure the patients' care is optimized without spending additional time trying to get in contact with other care providers. The pharmacist(s) can then continue to alert the clinicians to changes made in a patients regimen as well as document it in the patient's medical record.

Equally important, we train all of our pharmacy graduates to provide this level of care to the patients they serve. As our students enter the work force they are looking for this type of practice opportunity, and when they can't find it in the state of New York my concern is that our best and brightest will leave the state to find a place where they can practice to the level they have been trained. Most other states have collaborative practice as a part of their pharmacy practice act.

CDTM is a practice model that has over a decade of experience in serving the public health interest. It has demonstrated effectiveness in helping patients manage today's powerful and complex medications that may often require additional monitoring for safety and efficacy. This is largely an unmet need in our health care delivery system that pharmacist are trained to provide and are perfectly located to provide this service to all patients.

In closing, with the obvious and significant values of CDTM, I support the elimination of the CDTM New York State sunset clause and make a request for a permanent practice standard like many other states.

Sincerely,

Scott A. Swigart, Dean, Wegmans School of Pharmacy
St. John Fisher College
sswigart@sjfc.edu
Phone: (585) 385-8201

From: **Torri, Giovanni** <Giovanni.Torri@va.gov>
Date: Thu, Jan 30, 2014 at 2:22 PM
Subject:
To: "pharmbd@mail.nysed.gov" <pharmbd@mail.nysed.gov>
Cc: "jeff@paindr.com" <jeff@paindr.com>

Mr. Mokhiber

Managing patients with chronic pain syndrome has always been a very challenging endeavor for physicians like me, whom have never received any form of training in this specialty.

Since instituting a collaborative clinic integrating clinical pharmacy pain management providers and the medical clinic at the VA, this challenging process has significantly improved In many ways; among these:

1. Personal interactive discussion between providers in decision making regarding best approach/medicines for individual patients.

2. Improved approach in treatment of patients with proper medications, being sensitive to possible medication interactions, proper monitoring of urine/blood tests to assure compliance and therapeutic levels

3. Team approach for difficult-to-manage patients, reducing both patients and providers anxieties during clinic visits

4. Personal source of teaching and information regarding a difficult clinical subject which has been previously lacking in my extensive medical training.

Therefore, it is my strong belief that integrating providers with clinical pharmacy pain management experience in the medical clinical setting has significantly improved our care for patients with chronic pain syndrome, at the same time educating us towards the understanding of this complex problem.

Giovanni Torri, MD

The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 31, 2014

To the Members of the New York State Legislature:

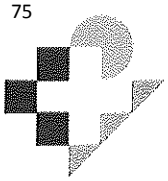
I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am a Family Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", diabetes, who are tobacco-dependent, or who have recently been discharged from the hospital and are at high risk for readmission.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Alejandra Uribe, DO
Attending Physician
The Brooklyn Hospital Center, Family Medicine Department
121 DeKalb Ave| Brooklyn, NY 11201



The Brooklyn Hospital Center

Keeping Brooklyn healthy.

January 30, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am an Intensivist /Pulmonologist and I serve as chairman of P&T committee at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with asthma in the chest clinic and critically ill patients in ICU.

Our patients receive top quality care from our pharmacists. Our pharmacists are instrumental in providing asthma education in Chest clinic. They provide patients customized asthma action plan. They educate patients regarding the importance of accurate monitoring and recording of peak flow measurement, the correct technique of using HFA medications, indications for controller and reliever medication to maximize benefit from therapy. They do smoking cessation counseling. They are active partners in community action plan to help reduce asthma ED visits, hospitalizations and help improve quality of life of our patients with asthma. They free up our time and help us focus on patient assessment.

Our pharmacists are integral part of our ICU interdisciplinary team. Pharmacists have authored many ICU protocols. These protocols include "Pain, agitation and delirium assessment and management, "Tight Glucose control in critically ill patients", "Enteral and parenteral nutrition supplement", and "Electrolyte supplement order set". They are members of our antibiotic stewardship team.

Our pharmacists play a key role in P&T committee meetings. They provide quarterly report on medication errors and adverse drug reaction. They do root cause analyses and identify opportunities for medication safety.

Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

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member
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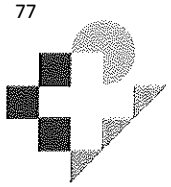
readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Viswanath Vasudevan, MD
Chair, P&T committee



The Brooklyn Hospital Center
Keeping Brooklyn healthy.

January 29, 2014

To the Members of the New York State Legislature:

I am pleased to provide this letter in support of the physician-pharmacist collaboration, known as Collaborative Drug Therapy Management (CDTM) in New York State. I am an Internal Medicine physician at The Brooklyn Hospital Center in Brooklyn, New York. I currently work with a highly skilled group of pharmacists in a CDTM practice. Our particular collaboration involves managing patients with thrombotic events, thrombophilias, and arrhythmias requiring "blood thinners", as well as asthmatics, patients who are tobacco-dependent.

Our patients receive top quality care from our pharmacists. Our pharmacists spend more time educating our patients than is typically possible with a standard physician encounter and are able to focus on drug-related issues more closely than the average physician can in the limited time of an office visit. Our pharmacists are knowledgeable and skilled in the selection of medications, as well as dosing modifications and drug-drug/drug-food interactions. I believe that all patients deserve this level of care and should be afforded the option to have a pharmacist partner with their physician for optimal care, regardless of the type of institution or clinical setting that the patient receives their care.

Our patients enjoy having a "personal pharmacist". This enhanced relationship between the physician, pharmacist, and patient has led to better outcomes, fewer adverse events, and fewer readmissions. I am hopeful that the legislature will look favorably upon the CDTM demonstration project and allow such practices to continue, flourish, and expand.

Sincerely,

Linus Yoe, MD 1/29/14

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affiliate: Weill Cornell Medical College

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January 20, 2014

Lawrence Mokhiber
Executive Secretary, NYS Board of Pharmacy
89 Washington Avenue
Albany, New York 12234

Dear Mr. Mokhiber:

I am writing this letter in support of continuation of a bill passed in 2011 as S.3292/A.6448, allowing pharmacists to prescribe and manage medications under a collaborative practice agreement with physicians. As the Medical Director of the Anticoagulation Management Service at FoxCare Cardiology, I have firsthand knowledge of the positive impact pharmacists have in the care of patients.

My colleagues and I collaborate with Amanda R. Winans, PharmD, BCPS in the management of our patients' anticoagulation therapy within the Bassett Healthcare Network. In this medically underserved area, having access to such a high level of care is an important and essential goal.

The AMS was initiated this past July, driven out of the need for high quality services to the underserved area. In this economically challenging time, justifying existing programs, let alone starting new programs is a monumental task. The institutions strong conviction that collaboration with pharmacists improves patient care led us to the decision to invest precious resources to ensure the safety of our patients.

And patients clearly benefit from and appreciate this service, which was previously unavailable. Already, the program has grown by over 50% and is poised for further growth in 2014. I am certainly pleased, as the care provided by our collaborating pharmacist is key to keeping our patients healthy and safe.

I understand that the 2011 Collaborative Drug Therapy Management law is due to expire soon. It should be extended indefinitely. Dr. Winan's contribution to our patients and their care has been invaluable and we need not only to keep Pharmacy in our clinics but to extend their presence.

Sincerely,

Jerel Zoltick, MD, FACC
AMS Medical Director
FoxCare Center Cardiology
Oneonta, New York

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Ph 1-800-BASSETT (227-7388) • **Web** www.bassett.org
Bassett Medical Center is affiliated with Columbia University

Appendix C.-Current New York State CDTM Legislation

Education Law Article 137, Pharmacy

§6801-a. Collaborative drug therapy management demonstration program.

1. As used in this section, the following terms shall have the following meanings:
    a. "Collaborative drug therapy management" shall mean the performance of services by a pharmacist relating to the review, evaluation and management of drug therapy to a patient, who is being treated by a physician for a specific disease or disease state, in accordance with a written agreement or protocol with a voluntarily participating physician and in accordance with the policies, procedures, and protocols of the facility. Such agreement or protocol as entered into by the physician and a pharmacist, may include, and shall be limited to:
        i. adjusting or managing a drug regimen of a patient, pursuant to a patient specific written order or protocol made by the patient's physician, which may include adjusting drug strength, frequency of administration or route of administration. Adjusting the drug regimen shall not include substituting or selecting a different drug which differs from that initially prescribed by the patient's physician unless such substitution is expressly authorized in the written order or protocol. The pharmacist shall be required to immediately enter into the patient record any change or changes made to the patient's drug therapy and shall use any reasonable means or method established by the facility or the department to notify any of the patient's other treating physicians with whom he or she does not have a written agreement or protocol regarding such changes. The patient's physician may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist;
        ii. evaluating and, only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, ordering clinical laboratory tests related to the drug therapy management for the specific disease or disease state specified within the protocol; and
        iii. only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, ordering or performing routine patient monitoring functions as may be necessary in the drug therapy management, including the collecting and

reviewing of patient histories, and ordering or checking patient vital signs, including pulse, temperature, blood pressure and respiration.

b. "Written agreement or protocol" shall mean a written document, pursuant to and consistent with any applicable state or federal requirements, that addresses a specific disease or disease state and that describes the nature and scope of collaborative drug therapy management to be undertaken by the pharmacist, in collaboration with the participating physician, in accordance with the provisions of this section.

c. “Physician" shall mean the physician, selected by or assigned to a patient, who has primary responsibility for the treatment and care of the patient for the disease or disease state that is the subject of the collaborative drug therapy management.

d. "Facility" shall mean a teaching hospital, including any diagnostic center, treatment center, or hospital-based outpatient department, however, for the purposes of this section, residential health care facilities and nursing homes shall be excluded. For the purposes of this section, a "teaching hospital" shall mean a hospital licensed pursuant to article twenty-eight of the public health law that is eligible to receive direct or indirect graduate medical education payments pursuant to article twenty-eight of the public health law.

2.

a. A pharmacist who meets the experience requirements of paragraph b of this subdivision and who is employed by or otherwise affiliated with a facility shall be permitted to enter into a written agreement or protocol with a physician authorizing collaborative drug therapy management, subject to the limitations set forth in this section, within the scope of such employment or affiliation.

b. A participating pharmacist must:

i.

A. have been awarded either a master of science in clinical pharmacy or a doctor of pharmacy degree;

B. maintain a current unrestricted license; and

C. have a minimum of two years experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation; or

ii.

A. have been awarded a bachelor of science in pharmacy;
B. maintain a current unrestricted license; and
C. within the last seven years, have a minimum of three years experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation.

c. Notwithstanding any provision of this section, nothing herein shall authorize the pharmacist to diagnose disease. In the event that a treating physician may disagree with the exercise of professional judgment by the pharmacist, the judgment of the treating physician shall prevail.

3. The physician who is a party to a written agreement or protocol authorizing collaborative drug therapy management shall be employed by or otherwise affiliated with the same facility with which the pharmacist is also employed or affiliated.
4. The existence of a written agreement or protocol on collaborative drug therapy management and the patient's right to choose to not participate in collaborative drug therapy management shall be disclosed to any patient who is eligible to receive collaborative drug therapy management. Collaborative drug therapy management shall not be utilized unless the patient or the patient's authorized representative consents, in writing, to such management. If the patient or the patient’s authorized representative consents, it shall be noted on the patient's medical record. If the patient or the patient's authorized representative who consented to collaborative drug therapy management chooses to no longer participate in such management, at any time, it shall be noted on the patient's medical record. In addition, the existence of the written agreement or protocol and the patient's consent to such management shall be disclosed to the patient's primary physician and any other treating physician or healthcare provider.
5. Participation in a written agreement or protocol authorizing collaborative drug therapy management shall be voluntary, and no patient, physician, pharmacist, or facility shall be required to participate.
6. Nothing in this section shall be deemed to limit the scope of practice of pharmacy nor be deemed to limit the authority of pharmacists and physicians to engage in medication management prior to the effective date of this section and to the extent authorized by law.

* NB Repealed September 14, 2014

Regulations of the Commissioner Part 63, Pharmacy

§63.10 Collaborative drug therapy management

a. Applicability. This section shall apply only to the extent that the applicable provisions in Education Law sections 6801 and 6801-a, authorizing certain pharmacists to participate in collaborative drug therapy management, have not expired or been repealed.

b. Experience requirement for participating pharmacists.

    1. As used in Education Law section 6801-a(2)(b), a year of experience shall mean not less than 1,680 hours of work as a pharmacist within a period of one calendar year.

    2. In order to be counted as a year of experience that includes clinical experience in a health facility, such experience shall include, on average, not less than 15 hours per week of clinical experience which involves consultation with physicians with respect to drug therapy, as determined by the facility that employs or is affiliated with the pharmacist.

Appendix D. Acknowledgements

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