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Comprehensive Medication Management Programs: Description, Impacts, and Status in Southern California, 2015

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ABSTRACT

Comprehensive medication management (CMM) is an evidence-based, physician approved, pharmacist-led, preventive clinical service ensuring optimal use of medications that is effective at improving health outcomes for high-risk patients while decreasing health care costs. Pharmacist-provided medication management, such as CMM pilot programs have been successfully implemented in six health care systems within Southern California resulting in improvements in clinical, fiscal, and quality measures. Challenges to implementing CMM include a lack of: reimbursement mechanisms, alignment of financial incentives, robust electronic health information exchange, quality and outcomes tracking systems, patient and provider awareness, and adequate staffing and space.

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1. Executive Summary

In response to Governor Brown's 2012 call for improved health of Californians and the resulting Let's Get Healthy California Task Force Report (December, 2012),[1] the California Department of Public Health (CDPH) drafted the California Wellness Plan (CWP),[2] California's chronic disease prevention and health promotion plan. Goal 2 of the CWP aims for health system interventions and efforts to be linked with community programs and clinical services in order to meet the needs of populations with the largest health disparities. When used safely, appropriately, and with proper education, medications can contribute to better health and longer, improved quality of life. Healthcare models that incorporate clinical pharmacy services, such as comprehensive medication management (CMM), have been able to improve similar objectives to those under CWP Goal 2. Several national organizations have published guidance on medication therapy management (MTM)[3,4,5] and Medicare includes MTM as a Part D benefit; however, CMM,[6] which fully leverages the pharmacist's scope of practice, is not as widely known. CMM is an evidenced-based preventive clinical service demonstrated to decrease health care costs and improve chronic disease treatment outcomes by ensuring optimal prescribing, monitoring, education, and use of medications that engages physicians, pharmacists, and patients. When directed at complex high-risk patients, CMM is proven to improve: quality of life, access to other healthcare providers, patients' health literacy and decision making, physician and other non-pharmacist provider satisfaction, and continuity of care. Complex high-risk patients tend to account for the majority of healthcare costs and require significantly more time, focus, and follow-up than relatively lower-risk patients.[7] The pharmacy profession can contribute to providing high quality, high value, and patient-centered care in an interprofessional collaborative practice in health care.[8] This white paper seeks to describe the current landscape, including the delivery, use, outcomes, benefits and challenges of CMM in Southern California as of May 2015.

In 2010 CMM was first defined and described by the Patient Centered Primary Care Collaborative(PCPCC)[9] to provide a framework for a "whole-patient approach" to medication management as an integral component of patient-centered medical homes (PCMH) and coordinated care systems, including Accountable Care Organizations (ACO). CMM "is defined as the standard of care that ensures each patient's medications (whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended. CMM includes an individualized care plan that achieves the intended goals of therapy with appropriate follow-up to determine actual patient outcomes. This all occurs because the patient understands, agrees with, and actively

participates in the treatment regimen, thus optimizing each patient's medication experience and clinical outcomes." In 2012, the second edition of the PCPCC Guide to Integrating Comprehensive Medication Management to Optimize Patient Outcomes was updated to include guidelines for practice and documentation consistent with PCMH and ACO integration.[10] This has served as a quick reference to distinguish CMM levels of care from those of other MTM services such as single disease state interventions (e.g., diabetes or anticoagulation clinics) and drug only (drug silo) interventions [e.g., Medicare Part D MTM Targeted Interventions (TIPs), Comprehensive Medication Reviews (CMR) or medication reconciliation at hospital discharge].

Today's health care system is fragmented due to a lack of care coordination, poorly-integrated health information, and misaligned fiscal incentives; these derive from a payment system that is transitioning from fee-for-service to an outcomes-driven value-based design. As health care for patients with chronic disease consumes a growing proportion of overall expenditures,[11] better disease management and education are crucial. With the shortage of primary care physicians (see Appendix A) there is a need for comprehensive and collaborative health care services that meet patient care needs. Not only should health care delivery improve access to skilled professional resources, but services should be evidence-based, and result in better health outcomes.

Advances in pharmacy education, training, and credentialing uniquely position pharmacists to offer CMM as part of a quality interprofessional collaborative practice[12,13] in health care. A typical CMM program systematically identifies high-risk and/or high-cost patients for enrollment. These patients are high utilizers of medications and healthcare services and have pre-diagnosed, established chronic illnesses that are persistently not at provider and patient defined medication treatment goals. Pharmacists evaluate patients to identify barriers to treatment success including performance of point-of-care testing if indicated, measurement of vital signs, and application of basic medication-related physical assessment, all part of pharmacist education and training, and supported by California State Pharmacy Law.[14] Pharmacists formulate and implement a medication care plan aligned with the primary care provider's plan for the patient to overcome treatment-related barriers to varying degrees across the United States of America (U.S.). In California, one of six states in the nation that recognizes pharmacists as health care providers, under physician authorized collaborative practice agreements pharmacists are able to adjust medication doses, discontinue or initiate medications, order tests related to monitoring medication safety and efficacy, educate the patient and caregiver if available, and communicate all actions to the primary care provider and other healthcare team members working with the patient. This process differs between institutions and can be modified to meet the needs of each healthcare organization.

Several resources are available for developing and sustaining CMM programs (see Appendix E). CMM services are not currently reimbursed by most public or private third party payers in the U.S. (see Appendix H) since pharmacists are not recognized as providers at the Federal level; as a result, few avenues are available for pharmacists to receive payment for clinical services. Financial support for CMM programs is limited to full-risk health plans / systems such as staff model health maintenance organizations (e.g., Kaiser Permanente) and medical groups participating in "at-risk" contracts (i.e., Accountable Care Organizations and Integrated Delivery Networks). California will participate in the Medicaid Health Home State Plan Option, authorized under the Affordable Care Act Section 2703, beginning 2016 (http://www.dhcs.ca.gov/services/Pages/HealthHomesProgram.aspx).

Materials in this white paper were collected as a result of the efforts of the CWP Goal 2 CMM Statewide Implementation Work Group (see Appendix K). The following six programs in Southern California were contacted and agreed to share CMM pilot program descriptions and information (Appendix L).

University of Southern California (USC) School of Pharmacy/Alta Med Health Services

Over a three-year period, pharmacy teams enrolled more than 6,000 high-risk and/or high-cost patients. Outcomes are being evaluated in comparison to a "usual care" cohort of propensity-matched patients who received care at AltaMed locations that did not offer CMM. CMM clearly outperformed usual care in the management of common chronic conditions.[15,16] In addition, the CMM program was able to maintain treatment success over time, in large part due to "check-ins" provided every two months by the pharmacy technicians for discharged patients. An average of 10 medication-related problems were identified and resolved for each enrolled patient. Preliminary return on investment analysis suggests that the program costs are outweighed by cost savings in Altamed. The CMM program using pharmacy technicians was associated with a 50 percent increase in daily patient visits.

Greater Newport Physicians Ambulatory Care Clinics

On average, ACTIVE Diabetes Program participants were able to meet their diabetes treatment goals within the first 180 days of enrollment. They were also able to meet quality measure goals for blood pressure control, high cholesterol, and nephropathy screening.

As a result of the pharmacist-led Anticoagulation Center, there were 53 percent fewer inpatient admissions and 41 percent fewer emergency department visits.

The 30-day readmission rate for Special Care Center participating seniors was 60 percent lower than the national average.

Additionally, all three programs had high-marks in patient satisfaction. When compared to a cohort of diabetes patients with hemoglobin A1c baseline above 8%, medical costs for ACTIVE program participants was approximately $1200 less per patient per year. When accounting for program costs, the savings are approximately $100 per patient per year but do not include pay for performance payments associated with improved outcome metrics.

University of California San Diego Health System

Based on a small pilot, the annualized cost avoidance with the Transitions of Care program (i.e. inpatient and outpatient) was $503,278. When compared to patients that did not receive Transition of Care services, enrolled patients were 18.9 percent less likely to be readmitted within 30 days. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Patient Satisfaction Score on the question "When I left the hospital I knew the purpose of each medication" improved to the 92nd percentile since initiation of the Transition of Care program from a baseline of 85th percentile. Within the first year of the Community-based Care Transitions Program, patient readmissions decreased dramatically by approximately 30% for the Medicare fee-for-service population to a rate of 10.4 percent.

GEMCare Medical Group, Inc.

Pharmacy services within the medical group initially included a MTM program, which successfully generated over $600,000 in medication cost savings in 305 patients seen over 12-months (July 1st 2009 through June 30th, 2010), reduced hospitalizations by 20 percent, and simultaneously demonstrated high physician and patient satisfaction.

Following the integration of the Advance Practice Pharmacist into the Comprehensive Care Clinic additional benefits were realized. Since program inception in 2010, positive economic outcomes included an overall decreased health care cost of almost 20 percent per member per month. The hospital admission rate decreased by 38 percent, readmission rates decreased by 32 percent, and emergency department visits decreased by 29 percent (see Appendix L. 1.4 Table 1). Clinical quality measures used to assess the management of diabetes and cardiovascular disease were also improved when comparing quartile gains nominally (see Appendix L. 1.4 Table 2).

Sharp HealthCare

Heart failure patients enrolled in the Continuum of Care Network had half as many readmissions as patients that were not enrolled (12 percent vs. 24 percent, p=0.005), as did the Heart Failure Core Measure 1 Compliance Rate (delivery of heart failure specific education prior to discharge).[17] Future publications describing the cost-savings and return on investment for the Continuum of Care Network are in development. Sharp HealthCare's success at reducing hospital readmission rates have resulted in recognition through the American Heart Association Get with the Guidelines Heart Failure Gold Quality Achievement Award and the American Society of Health System Pharmacists Medication Management in Care Transitions Best Practices.

Kern Medical Center

Multiple studies have consistently demonstrated statistically significant clinical, quality and fiscal outcomes.[18,19,20] Almost half of the poorly controlled diabetic patients were able to achieve the blood glucose treatment goal. There was a 40.1 percent reduction in emergency department visits, a 22.3 percent reduction in hospitalizations overall, and a 26.1 percent reduction in length of stay if hospitalized. At the time of the study, according to the Agency for Healthcare Research and Quality estimates, the mean cost per ED visit was $1,354 and the mean cost per inpatient medicine admission was $9,500. Therefore, it was demonstrated that a clinical pharmacist working as a member of the multidisciplinary team in the Diabetes Care Clinic for 40 hours per week for a mean 272 days and mean of 5.9 visits per patient resulted in an estimated annualized cost savings of $256,518 per year.

Adoption of CMM has several challenges, including a lack of: reimbursement mechanisms, alignment of financial incentives, robust electronic health information exchange, quality and outcomes tracking systems, patient and provider awareness, and adequate staffing and space. Although evidence of benefit and best practices in CMM levels of care has been well-established for decades in California, many barriers exist to widespread deployment of CMM. As a service, CMM is inherently team-based and patient centered, and thus requires the buy-in from pharmacists, patients, other healthcare providers, and health systems. Most physicians and non-pharmacist providers are unfamiliar with the clinical role of pharmacists and how pharmacists integrate with the care team. This is less of a challenge for recent and future graduates of health profession schools since interprofessional education is now a requirement for all healthcare professional education curricula in the U.S. Probably the most common interaction between physicians / non-pharmacist providers and pharmacists are phone conversations about prescriptions such as coverage or formulary problems, which provides a very limited view of the broad scope of pharmacy practice, particularly in light of provider status being granted to pharmacists in California.

The benefits of CMM are highly valuable and include improved healthcare quality measures, better access to healthcare, time-savings to other healthcare providers, reduced drug costs, reduced adverse drug events and decreased expensive health care resource utilization (emergency or hospital delivered care). Pharmacist delivered CMM models in Southern California have demonstrated improvements in therapeutic outcomes as well as reducing health care costs. Many national organizations in health and safety including the Centers for Disease Control and Prevention,[21,22,23] the Centers for Medicare and Medicaid Services,[24] the Institute of Safe Medication Practices,[25] the Patient-Centered Primary Care Collaborative,[26] the Network for Excellence in Health Innovation,[27] and the Institute of Medicine[28] recognize that integration of clinical pharmacy services into the care team ensures optimal medication therapy for complex high-risk patients, provides patient empowerment, improves patient and primary care provider satisfaction, and improves health outcomes. As a hub of health promotion, public health departments can disseminate information about CMM services and promote its benefits to the public, other healthcare providers, health plans, Medi-Cal, and employers, thus ensuring that high risk patient access and outreach occurs. As discussed throughout this paper, opportunities to align CMM through readily accessible community pharmacies with priorities of government and private payers and providers, as well as public health, are abundant and have the potential to develop into a mutually beneficial clinical and business model, especially as the shift continues towards full risk for medical providers and value-based payments.

2. Introduction

CMM aligns well with national and state healthcare priorities. In May 2012, Governor Brown issued an executive order calling for the development of a ten-year plan to improve the wellbeing of Californians by controlling costs, improving quality, advancing health equity, and identifying obstacles to improve care.[29] In response to this request, the Let's Get Healthy California Task Force was created.

CDPH responded to the Let's Get Healthy California Task Force Report (December, 2012) by drafting the California Wellness Plan (CWP), California's chronic disease prevention and health promotion plan. CWP seeks to promote the improvement of chronic disease management, health, and wellness, while empowering communities throughout the state of California to achieve equity in health and wellness for all Californians. CWP objectives are categorized under Let's Get Healthy California (LGH) Priorities and are delineated as short-term, intermediate, and long-term objectives with performance measure targets from 2015 through 2022.[30]

Selected California Wellness Plan Goal 2 Priority and Objective Excerpts[31]

CWP Goal 2	Optimal health systems linked with community prevention
LGH Priority 2.2	**Increase Access to Primary and Specialty Care**
Objective 2.2.1I	By 2022, increase the percentage of patients receiving care in a timely manner from primary care physicians and specialists (Developmental)
LGH Priority 2.3	**Increase Coordinated Outpatient Care/Increase People Receiving Care in an Integrated System**
Objective 2.3.1L	By 2022, increase the percentage of patients whose doctor's office helps coordinate their care with other providers or services from 67 to 94 percent for children/adolescents and 75 to 94 percent for adult health maintenance organization patients (Developmental)
LGH Priority 2.6	**Increase Controlled High Blood Pressure and High Cholesterol**
Objective 2.6.2L	By 2022, increase the percentage of adults diagnosed with hypertension that have controlled high blood pressure from 79 to 87 percent for Medicare patients, 50 to 70 percent for PPO patients, and 78 to 86 percent for HMO patients
Objective 2.6.4L	By 2022, increase the percentage of adults diagnosed with high cholesterol who are managing the condition from 76 to 91 percent for Medicare patients, 50 to 70 percent for PPO patients, and 78 to 86 percent for HMO patients
Objective 2.6.8L	By 2020, decrease stroke mortality rate from 36.9 to 29.5 per 100,000
Objective 2.6.9L	By 2020, decrease heart disease mortality rate from 120.5 to 96.4 per 100,000
Objective 2.6.10L	By 2020, decrease heart failure mortality rate from 12.5 to 10 per 100,000
LGH Priority 2.7	**Decrease Adult and Childhood Asthma**
Objective 2.7.2L	By 2022, reduce the asthma emergency department visit rate for ages 0-17 years from 73 to 53 per 10,000
LGH Priority 2.12	**Increase Hospital Safety and Quality of Care**
Objective 2.12.1L	By 2022, decrease the 30-day All-Cause unplanned readmission rate (unadjusted) (Developmental)

Each CWP Goal has state level objectives that can be measured and reported and that serve as a guideline for efforts to make California the healthiest state in the United States of America (U.S.) by 2022.[32] Healthcare models that incorporate clinical pharmacy services, such as CMM, have been able to improve similar objectives to those in the California Wellness Plan (noted above).[33,34]

The need for increased delivery of pharmacist-led medication management services aligns with statements from reports of the Centers for Disease Control and Prevention, and Institute of Medicine.[35,36,37] These entities call for the integration of pharmacists into the care team in order to optimize patient care while lowering health care costs.[38,39,40] The CMM model rests on

the principles of the Chronic Care Model[41] (see below) which fundamentally sits at the intersection between team based care and patient centered care and the imperative to enhance patients' capacity for self-care.

Chronic Care Model[42]
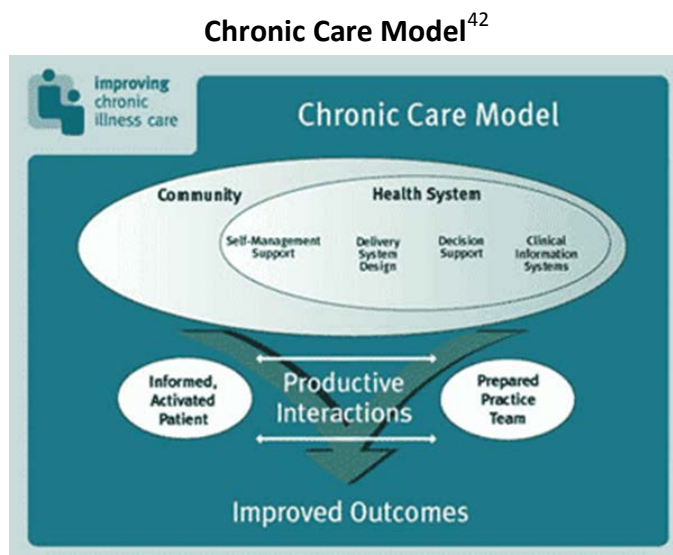
The concept of pharmacists providing more integrated team-based services is not new, as pharmacists have been operating in an integrated, clinical role in long term care facilities for nearly 30 years.[43] Large public and private health systems, including the Veterans Administration and Kaiser Permanente, commonly use clinical pharmacy services with advanced pharmacy practice activities.[44] These clinical pharmacy services go beyond the management of hypertension and diabetes.[45,46,47] In the U.S., CMM provided by pharmacists occurs in the fields of mental health, primary care, acute care, long term care, care transitions, along with single disease state MTM interventions such as anticoagulation, HIV, and others.[48,49,50,51]

The pharmacy profession can contribute to providing high quality, high value, and patient-centered care in an interprofessional collaborative practice in health care.[52] This white paper seeks to describe the current landscape, including the delivery, use, outcomes, benefits and challenges of CMM in Southern California as of May 2015.

3. Background

3.1 Prescription Drug Use is Ubiquitous

Medications are an essential element in properly managing chronic diseases.[53] Approximately 450 million prescriptions were filled in the state of California in 2014, with total prescription sales amounting to almost $ 30 billion.[54] Sixty percent of patients over 65 years of age are estimated to take 5 or more medications, while approximately 20 percent take over 10

medications at a time.[55] Suboptimal medication use (i.e., untreated indication, improper drug selection, sub-therapeutic dosage, failure to receive drugs, over dosage, adverse drug events, drug interactions, and drug use without indication) was estimated to cost as much as $290 billion per year (2008) in U.S. medical spending and contribute to as many as 1.1 million deaths.[56] With the number of Americans over 65 years of age projected to almost double and those over 85 years of age expected to triple by 2050,[57,58] the demand for provision of adequate health services and support for appropriate, effective, and safe medication use is also likely to grow.

3.2 The Burden of Chronic Disease

Chronic disease is the leading cause of death and disability among Americans and accounts for 86 cents of every health care dollar spent in 2011 in the U.S.[59,60] With nearly half the population living with at least one chronic condition, chronic diseases are responsible for almost 9 out of 10 deaths each year in the U.S.[61] Unfortunately, having multiple complex, chronic conditions is associated with polypharmacy and an increased likelihood of emergency room visits, hospitalizations, and hospital readmissions.[62]

Over 14 million individuals in California suffer from chronic illnesses.[63] Illnesses such as arthritis, asthma, cancer, depression, diabetes and heart disease top the list as the most common chronic diseases in the state. In total, California spent approximately $98 billion in 2010 in the medical treatment of these six most common chronic conditions alone. Notably, cardiovascular disease is associated with the greatest expense.[64]

Chronic disease and medication use are directly linked, as drug therapy is the evidenced-based foundation for the management of most chronic diseases.[65] Moreover, it is understood that assessing the link between the specific chronic disease and medication requires a feasible, efficient and effective manner to measure adherence to the medical regimen, be it lifestyle changes or medication-taking behavior.

3.3 Fragmented Health Care Delivery System

Inadequate care coordination and a fragmented healthcare system in the U.S. have been linked to adverse effects on cost, quality, and ultimately patient outcomes.[66] Although the U.S. Centers for Medicare and Medicaid Services (CMS) is incentivizing improvement by shifting towards value-based payment models,[67] many variables are slowing the transition, such as misaligned fiscal incentives.[68]

In addition, a shortage and misaligned distribution of primary care and specialty care physicians in many regions is leading to reduced patient access to healthcare services in California,[69,70,71,72] with 45 percent of the population residing in regions with limited primary care physicians (see

Appendix A).[73] Nationally, over 130,000 new physicians will be needed by 2025, which far exceeds the current capacity of American medical schools.[74]

Distractions and time required to navigate electronic health records may reduce the time physicians spend providing patient care services.[75,76] Collaborative team-based care is recommended by multiple government healthcare agencies as a proven solution for improving patient health outcomes while allowing physicians and other healthcare professionals more time to provide their respective services. Contrary to the perception most people have, the profession of pharmacy and training of pharmacists has evolved tremendously over the past decade. A large volume of literature evidence supports the value of healthcare systems partnering with pharmacist to improve patient care.   Although many providers are familiar with the team-based role pharmacist's play in direct patient care in hospital settings, extension of that role into ambulatory settings has not been widespread. Payment of pharmacist services has been linked to dispensing product, not recognition or payment for clinical services. However, as systems advance from fee-for-service to value based reimbursement, integration and coordination becomes critical.   For example, integration of clinical pharmacy services into the care team serving complex high-risk and/or high cost patients has proven to improve the quality of medication therapy, improve medication safety, empower patients, improve health outcome measures, reduce total cost of care, while substantially increasing patient access to care by physicians and other providers.[77,78,79,80,81,82,83,84]

3.4 Gaps in Medication-related Outcomes and Patient Safety

Medication-related outcomes in the U.S., such as healthcare quality and safety, have tremendous room for improvement.[85,86] These improvements can be realized if health systems embrace and promote innovative care models that provide adequate support for patients and other healthcare providers while simultaneously promoting proper medication use and adherence, medication safety, optimal prescribing, and care coordination (particularly during care transitions).

In 2006, an Institute of Medicine report concluded that the U.S. health care system sustains $200 billion in avoidable health care costs due to the inappropriate use of medications.[87] Ultimately, this is estimated to result in approximately 10 million unnecessary hospital admissions, 4 million emergency room visits, 78 million outpatient visits, and 246 million prescriptions that contribute to approximately 8 percent of total annual healthcare expenditures.[88]

Facts related to medication use are similarly astounding. Half of the prescription medications taken every year in the U.S. are used improperly, and 9 percent of patients who take a prescription drug seek medical attention due to medication-related complications.[89] However,

the far larger and less recognized category of medication-related problems stems from the underuse of appropriate medications to prevent and control disease.[90] Compounding the problem is the overwhelming number of available medications. Over 100,000 prescriptions and over 300,000 over-the-counter (OTC) medications are commercially available, and new products continually enter the market.[91]

The recent rapid increase in new and expensive specialty medications, including biologics, has raised significant concerns around medication dose preparation, appropriate use, administration, and adherence. These drugs are often associated with serious adverse drug reactions, require close monitoring, and sometimes require dose adjustment during treatment.[92] In addition, patients commonly administer these drug products at home, potentially increasing the risk of patient-induced errors including medication administration and storage.

Inappropriate medication use results in decreased patient safety and poor health outcomes, which not only nullifies the investment in costly medications but actually increases healthcare costs as patients require extra medical visits, tests, and acute care services.[93,94]

3.5 Pharmacists as Providers in California: Training, Impact, and Opportunities for Spreading CMM

The training and experience of pharmacists as medication experts places them in an ideal position to provide medication management (Appendix B)[95,96,97,98] as part of a team-based health care delivery model. Accreditation standards for pharmacy schools have changed dramatically over the past several decades, particularly in California where the practice of clinical pharmacy originated including the nation's first Doctor of Pharmacy program (1950) and first clinical pharmacy program (1968, see https://pharmacyschool.usc.edu/about/facts/history/). A Bachelor of Science degree in Pharmacy is no longer available, as accreditation standards now mandate the Doctor of Pharmacy degree. Pharmacy students receive practice-based training during all four years of school, and patient evaluation skills including assessment and test ordering are integrated into both case conferences and experiential training (see California Licensed Pharmacists Scope of Practice box below).[99] Required practice-based rotations for pharmacy students include both hospital-based and ambulatory / primary care clinical practice, with a wide range of subspecialty training to choose from including cardiology, nephrology, oncology, infectious disease, critical care, geriatrics, pediatrics, and psychiatry. Post-graduate education, including residencies up to 3 years in length and fellowships, is available for pharmacists who want to specialize. In addition, every healthcare profession school requires interprofessional education in their curricula including medical, nursing, dentistry, pharmacy, nutrition/dietetics, physical therapy, behavioral health, and public health.[100] As a result, the Doctor of Pharmacy graduate

today is well-prepared to manage medication-related problems as a member of the healthcare team in a collaborative manner that adds value to patients, physicians and other non-pharmacist providers, and the healthcare system.

As a continually evolving workforce of 28,300 employed pharmacists as of May 2014, and 30,540 pharmacy technicians as of 2012,[101] it is essential to understand the capacity of pharmacists in California to provide high-value services to patients, physicians and other non-pharmacist providers, and the healthcare system.[102,103] Moreover, since the average American lives within 5 miles or less of the nearest community pharmacy,[104] patient access to pharmacist providers and their services is a realistic assumption. The benefit of including pharmacists as part of a team-based care model has been well described.[105,106,107,108,109,110,111] California is able to offer a unique opportunity to more fully integrate and expand pharmacists' work as medication experts;[112] although pharmacists are not federally recognized as healthcare providers, California is one of six states that have granted provider status to pharmacists.[113,114,115]

Evidence of pharmacist-delivered services that improve therapeutic outcomes exists for multiple chronic conditions including mental health, cardiovascular disease, asthma, hypertension, diabetes, and others,[116,117,118,119,120] including preventive services, such as blood pressure screenings, pulmonary function testing, cholesterol testing, and diabetes screening. The majority of this evidence was generated from integrated clinical pharmacy practices offering disease state MTM or CMM level services, i.e., physicians and other non-pharmacist providers working in the same building or suite with pharmacists and sharing the same patient health records and other clinical information. Such collaborative practices are less common in the community pharmacy setting, but many examples of successful, high-impact programs exist in California among both independent and chain pharmacies. Very importantly, pharmacists in the community setting are highly accessible and practice in a variety of locations, both urban and rural, throughout the state.[121,122]

Services already available in community pharmacies include furnishing travel medications, hormonal contraceptives, smoking cessation products, as well as independently administering vaccinations to patients over three years of age and performing health screenings such as blood pressure, blood sugar, hemoglobin A1c (HgbA1c), cholesterol, bone density, and others.[123] Previous to 2013, pharmacists could only

> **California Licensed Pharmacist's Scope of Practice:**
> Pharmacists are authorized to administer drugs; furnish travel medications, hormonal-contraceptive and nicotine replacement products for smoking cessation; and independently administer vaccinations to patients over three years of age.

provide clinical services at maximum scope (e.g., perform medication-related patient assessments, order and interpret drug-related tests, initiate / adjust / discontinue medication therapy under collaborative practice agreements) in hospitals and other locations that provided medical care (community clinics, medical groups, etc.). With the creation of the Advanced Practice Pharmacist (APP) category in 2013, pharmacists can now provide this full scope of services outside of traditional healthcare settings such as community pharmacies. As a result, health plans and providers in California have an opportunity to develop collaborative practice agreements with community pharmacists to offer CMM for patients with complex medication-related needs in team-based care to ensure optimal results from medication therapy.[124,125,126]

To be sure, pharmacists have professional liability insurance. The majority of pharmacists receive insurance from their place of employment, although pharmacists can choose to purchase supplemental policies.[127] In situations where healthcare entities do not employ pharmacists, but are instead collaborating with pharmacists to provide comprehensive medication management (e.g., with a retail chain pharmacy or video telehealth medication management service), contracts should be written in a manner which provides maximum liability protection to the applicable entities by clarifying the roles and responsibilities of the pharmacists and all other parties involved. An example of a legal agreement between a provider entity and a pharmacist group providing comprehensive medication management is available in Appendix E. It is important to note that the nature of comprehensive medication management, with its emphasis on identifying and resolving or avoiding medication-related problems including adverse drug events and potential adverse drug events, should in fact reduce liability to the organization.

3.6 Traditional Pharmacist Role vs. Medication Therapy Management vs. Comprehensive Medication Management

Traditional Pharmacist Role

Pharmacists practicing in a community pharmacy setting provide easy public access.[128] Traditionally, an emphasis has been placed on the dispensing role of pharmacy practice.[129] In this role, pharmacists are responsible for ensuring that the medication supplied is safe, dispensed and correct as prescribed for each patient; therapeutic range drug dosing is determined while minimizing drug-drug interactions.[130] Other traditional duties include the preparation and compounding of medications, dispensing prescriptions, counseling, and providing over-the-counter treatment recommendations for minor ailments. While pharmacists' roles have expanded over time to include more direct patient care activities, the clinical expertise of pharmacists is often underutilized. A major reason for limited pharmacist engagement is the fact that the community practice business model is driven by prescription volume, i.e., number of prescriptions filled. Dispensing fees are intended to cover basic

counseling services from pharmacists, but fees are minimal (as low as a few dollars) and continue to diminish, limiting the amount of time that pharmacists can provide clinical services. Another barrier to expanded clinical services in community pharmacies is the limited awareness of the value of these services on the part of physicians and other non-pharmacists providers, as well as patients. Also, community pharmacists have not had access to clinical records of patients, making determinations of appropriateness of a particular medication or combination of medications to optimize therapeutic outcomes impossible. Clearly health-related outcomes will improve through optimal medication use; community pharmacists are in an ideal position to leverage their expertise and offer CMM programs to patients across California in a shift to a full range of services, from dispensing to clinical roles. Partnerships between pharmacy organizations, healthcare provider groups, health plans, colleges of pharmacy, patient advocacy groups, and government organizations are needed to develop a consistent message and information about the value of CMM (as the ability of pharmacists that are trained, willing and able to deliver and document CMM services in collaborative practice arrangements is expanded) to raise public awareness and demand.

Medication Therapy Management

Medication Therapy Management (MTM) is one example of a program offered through community pharmacies with a payment structure for clinical service provision. In 2003, with the passage of the federal Medicare Prescription Drug, Improvement, and Modernization Act, Medication Therapy Management (MTM) became a required service for Medicare providers to offer to Medicare beneficiaries under the Part D benefit. MTM is defined as a distinct service or group of services that optimize medication-related outcomes and encompass a broad range of activities, but at minimum should include medication reconciliation.[131] The consensus definition of MTM has been well defined (see Appendix C).[132,133,134] Although delivery of MTM services leverages pharmacists' training and expertise, the impact of MTM has been limited for several reasons. As with Medicare Part D MTM

Key Considerations for CMM Implementation and Sustainment (Adapted from the HRSA Patient and Safety and Clinical Pharmacy Services Collaborative and ref 71, PCPCC paper)

- Identify physician-champion(s) and secure commitment from senior leadership for needed space, supplies, technical support, electronic health record access, and support staff
- Develop systematic process for enrollment of high-risk and/or high- cost population in alignment with incentives and quality measures from the partnering organization
- Define utilization, clinical, humanistic, economic outcomes/targets
- Establish collaborative practice agreement and protocols
- Conduct rapid cycle improvement process (e.g., Plan-Do-Study-Act)
- Ensure quality and efficiency of care delivery before going to full scale
- Aggregate quality, safety, satisfaction, and cost data regularly to demonstrate program value and sustainability

services, only knowledge of the medications prescribed is required, not the clinical status of the patient (such as current blood pressure, blood sugar/HgbA1C levels, etc.). Therefore, only drug-drug interactions, duplicative therapy, potentially inappropriate drugs for certain age groups (Beer's criteria), or opportunities for generic substitution and education about the drugs currently used could be addressed. Without knowledge of the clinical goals of therapy and current gaps in care, a patient could have a comprehensive medication review and still not have reached any clinical goals of therapy to control high blood pressure, diabetes, cholesterol, or asthma, for example. This led the Medicare Payment and Advisory Commission (MedPAC) to recommend against expansion of MTM services under Part D.[135] In 2014 MedPAC wrote- "After seven years, it may be time to question whether MTM programs offered through Prescription Drug Plans (PDPs) – without the cooperation and coordination of a beneficiary's care team – have the capacity to significantly improve beneficiaries' drug regimens." They went on to say- "better medication management might be achieved through programs offered by ACOs, medical homes, and other team-based delivery models."

In addition to Medicare Part D CMRs, many MTM interventions focus on specific potential adverse drug events (e.g., high risk medications; drug-drug, drug-disease, food-drug, or activity-drug interactions) and provide payment for providers including pharmacists who indicate that they have addressed the specific issue, as opposed to having the provider and/or pharmacist conduct a comprehensive evaluation and follow-up with patients to ensure that all medication-related problems identified are resolved. In addition, the billing / payment process for MTM is complex and not in line with the workflow of pharmacies, limiting pharmacist engagement.

Unlike Comprehensive Medication Management (CMM), Medicare Part D CMRs and some disease state MTM programs do not require formal collaboration between the pharmacist and prescriber through the development of a collaborative practice agreement and medication management protocols.[136] As a result, MTM has a tendency to be less integrated with medical practices, and without the clinical information - of limited value. Finally, MTM services eligibility is defined by each Medicare Health Plan provider. See table of MTM resources in Appendix C.

Comprehensive Medication Management (CMM)
CMM is an evidence-based and patient-centered[137] service shown to reduce the burden of chronic disease while lowering health care costs (see Appendix D).[138,139,140] The goal of CMM is to assess each patient's medication regimen while enrolled in a CMM program to ensure all medications (including prescription, nonprescription, alternative, herbal, traditional, and nutritional supplements) are appropriate, effective for the medical condition being treated, safe with the patient's comorbidities and other medications, and convenient for the patient.[141] Further, in CMM, it is essential that the patient understands, agrees with, and actively

participates in his/her treatment, which is consistent with the Chronic Care Model discussed previously.[142]

The practice of CMM is broad-ranging across institutions/transitions in care, but is consistent in the process. For example, a care team approach utilizes a pharmacy team to monitor a patient in the hospital and, upon discharge, transitions the patient to a pharmacist in a primary care clinic or community pharmacy. CMM often includes prescriptive authority for pharmacists through collaborative practice agreements with physician entities.[143] The key is the physician remains the leader of the healthcare team and can grant any level of scope of practice to pharmacists in a collaborative practice agreement. For more information and resources related to CMM delivery, including a sample collaborative practice agreement, please see Appendix E.

Delivery of CMM can begin with a disease-specific request (e.g., with physician referral and/or approval a pharmacist manages medications for poorly controlled diabetes), but to be CMM it must by definition use a "whole-patient" approach looking at all diseases and medications and efforts to achieve provider and patient defined medication therapeutic goals. Although follow-up including drug therapy problem recognition and prioritization can be staged, beginning with high-risk and/or high-cost populations based first on control of a particular disease, it does not then ignore the co-morbidities or other gaps in care. If the services do remain disease focused, such as high blood pressure, diabetes and, or anticoagulation (e.g., INR) control, these are then disease specific MTM services, not CMM services.   The Veterans Administration represents a good example of movement from disease state management for their clinical pharmacist services to CMM through broadening of their limited (disease specific) scope of practice (SOP) collaborative practice agreements to over 3000 pharmacists with general and broad SOP's in ambulatory care settings.[144]

The differences between CMM and MTM may appear subtle, but they are significant. CMM is more comprehensive than MTM in that CMM evaluates all medications and all medical conditions, requires a collaborative practice agreement, and includes follow-up care to ensure resolution of medication-related problems and attainment of treatment goals.[145] In a sense, MTM can be thought of as siloed and episodic resulting from "fee for service" approaches while CMM is aligned with value-/outcome-based medication management program evolution. The following table summarizes similarities and differences between Medicare Part D MTM Comprehensive Medication Reviews (CMRs),[146] Disease State MTM interventions (dsMTM), and Comprehensive Medication Management (CMM). Note that the elements listed only pertain to medications related to the disease state such as the blood pressure medications in a hypertension clinic or medications related to coagulation in an INR clinic for dsMTM, whereas all medications and conditions are considered in CMM.

**Medication Therapy Management Comprehensive Medication Review (CMR) vs.
Disease State Medication Therapy Management (dsMTM) vs.
Comprehensive Medication Management (CMM)[147,148]**

Service Component / Element	CMRs	dsMTM	CMM
1. Conduct a comprehensive medication therapy review to identify all medications currently being taken	✔	✔	✔
2. Evaluate patient to clarify or confirm medication-related problems including basic assessment, point-of-care testing, ordering medication-related tests, etc.		✔	✔
3. Assessment of clinical status for ALL medications and medical conditions problems as opposed to select medications or conditions			✔
4. Develop an individualized medication care plan to resolve medication-related problems and ensure successful attainment of treatment goals		✔	✔
5. Add, substitute, discontinue, or modify medications/doses as needed or recommend changes, depending on state-specific scope of practice laws and in collaboration with health care team		✔	✔
6. Eligibility is determined by an anticipated annual drug spend minimum of $3138 (2015) and a minimum number of drugs and conditions. No clinical data is necessary. Absent clinical data, drug therapy problems are found only related to potential drug-drug interactions, duplicative therapy, opportunities for less expensive alternatives, and suggested inappropriate medications based on age (Beers criteria).	✔		
7. Generate a personal medication record, a complete record of all medications (prescription and nonprescription), herbal products, nutraceuticals, etc.	✔	✔	✔
8. Document care delivered, including progress towards treatment goals, and communicate details to primary care provider and other relevant healthcare team members in a timely manner		✔	✔
9. A standardized CMR format of information is given to the patient and may be faxed/transmitted to a provider- no follow-up is required to see if recommendations were followed.	✔		
10. Ensure that care is coordinated with all other team members within the broad range of services being provided to the patient		✔	✔
11. Provide follow-up care, according to individual patient needs, to determine actual outcomes from medication therapy and ensure that treatment-related goals are being achieved		✔	✔
12. Requires formal collaborative practice agreement between pharmacist and physician			✔

4. Implementation

4.1 Practice Development, Support, and Spread

Several resources are available for developing and sustaining CMM programs.

The Patient Centered Primary Care Collaborative (PCPCC) developed a simple but complete CMM resource guide that includes information about benefits and outcomes, implementation considerations, and payment and coverage (summarized in Appendix E).[149] The Alliance for Integrated Medication Management (medsmatter.org) is continuing the work of the U.S. Health Resources and Services Administration (HRSA) Patient Safety and Clinical Pharmacy Services Collaborative (http://www.hrsa.gov/publichealth/clinical/patientsafety/pspc4_overview.pdf) that began in 2006 by offering tools, resources, and training on strategic implementation and advancement of CMM based on best practices across the nation.

California schools of pharmacy can offer expertise and consultation on the development of CMM programs (see Appendix F). For example, the University of Southern California (USC) School of Pharmacy has developed a replicable Ten-step Comprehensive Medication Management Implementation Process and an online pharmacist competency development program, both of which are based on a recently completed Centers for Medicare and Medicaid Services Center for Innovation grant (see Appendix G). In addition, pharmacy schools may be able to develop rotations and/or opportunities for pharmacy residents and students to help develop and spread new programs. The infrastructure for CMM delivery is dependent upon having a large pool of qualified pharmacists, and the APP designation is accelerating training and certification of pharmacists, as well as the formation of networks for contracting with health plans and health systems.

4.2 Cost of Implementation

Cost of the workforce and reimbursement for service are two components to consider when implementing and sustaining a fully integrated CMM program. Workforce costs can include annual base salaries for pharmacists, pharmacy residents and clinical pharmacy technicians, depending on the pharmacy team composition. Having the three professional levels appropriately managed and coordinating as a team has been shown to increase the capacity to reach high-risk patients and maximizes positive health outcomes at lower costs. The annual base salary for pharmacy residents is approximately half, and that of clinical pharmacy technicians is approximately one-third the salary of a licensed pharmacist. Clinical pharmacy technicians and other health team members can manage the multiple daily patient care functions (e.g., clerical, phone calls, reminders, check-ins) that do not require a Doctor of Pharmacy degree to perform (see Appendix L. 1.1). In the USC CMMI-funded study, clinical

pharmacy technicians allowed the pharmacy team to provide CMM to 50% more patients per day (see Appendix L).

As with any service, CMM spread and sustainability is dependent on reimbursement. While MTM has reimbursement mechanisms, CMM services are not currently reimbursed by most public or private third party payers in the U.S. (see Appendix H) since pharmacists are not recognized as providers at the Federal level; as a result, few avenues are available for pharmacists to receive payment for clinical services. However, the eventual shift towards valued-based payment systems will require interventions that have demonstrated a positive return on investment, and a substantial body of published research and reports indicates that CMM programs more than compensate for their own costs by improving health outcomes in high-risk patients and preventing costly hospitalizations. Until that shift occurs, financial support for CMM programs is limited to full-risk health plans / systems such as staff model health maintenance organizations (e.g., Kaiser Permanente) and medical groups participating in "at-risk" contracts (i.e., Accountable Care Organizations and Integrated Delivery Networks).

California will participate in the Medicaid Health Home State Plan Option, authorized under the Affordable Care Act Section 2703, beginning 2016 (http://www.dhcs.ca.gov/services/Pages/HealthHomesProgram.aspx). This is a capitated medical home program that will provide supplemental coordinated services for Medi-Cal patients who are high utilizers of the healthcare system. The Health Homes program must provide six core services:
- o Comprehensive care management,
- o Care coordination (physical health, behavioral health, community-based LTSS),
- o Health promotion,
- o Comprehensive transitional care,
- o Individual and family support,
- o Referral to community and social support services,

Few details are available as of September 2015 (no stakeholder meetings have been scheduled since July 23, 2015), but the program offers pharmacists an opportunity to provide CMM for patients with complex medication-related needs in a value-based setting. The Health Homes program is a potential engagement platform for community pharmacists. The impact of the profession of pharmacy on population health will largely depend on the involvement of community pharmacists optimizing medication use through CMM in collaboration with health systems, health plans, and other health system and community organizations and partners.

4.3 Target Population

Clearly CMM is most valuable to patients who are at high-risk of harm from suboptimal medication therapy. Patient populations for which CMM has proven to be beneficial include patients who frequently utilize acute care resources, patients with chronic conditions who persistently fail to meet National Quality Forum (NQF) targets, and patients with comorbidities associated with poor medication-related outcomes (see Appendix J).[150,151,152,153]

Each health systems should consider the unique characteristics of their patient population when identifying CMM program candidates. An analysis of health system data that includes acute care utilization, NQF measures, diagnoses, medications, and test results can help clarify the greatest medication-related gaps where CMM can be targeted. CMM programs have demonstrated improvements in health care quality and resource utilization among a variety of patient populations (Medicare, Medicaid, uninsured) with diabetes, asthma, hypertension, heart failure, and dyslipidemia.[154,155,156,157,158]

4.4 Healthcare Quality and Safety Measures

Identification of appropriate outcome measures for quality improvement and program assessment are necessary to ensure that CMM is meeting program goals. Outcome measures can assess the program's ability to meet patients' needs and evaluate impact on health outcome resource utilization and net costs/savings. The ability of CMM and other clinical pharmacy services to improve patient outcomes and provide system-wide benefits has been well described.[159]

Healthcare quality measures are tools that help quantify health care processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals of the National Quality Strategy. Quality measures approved by the National Quality Forum form the foundation for many national quality initiatives and are used to monitor progress on quality improvement interventions. They also serve to describe benchmark improvements upon which programs can identify opportunities to refine intervention strategies.[160]

Many quality measures assess the appropriate management of chronic disease and are dependent on optimal medication use.[161] For example, approximately half of the quality measures in the Medicare Advantage Star Rating programs can be influenced by medication therapy management.[162] Measures such as control of blood pressure, control of blood sugar, and medication adherence are directly related to appropriate and consistent medication use and can be positively influenced by CMM.

Other quality measure sets, such as the Healthcare Effectiveness Data and Information Set (HEDIS) and the Physician Quality Reporting System (PQRS), are similar.[163,164] Additionally, 18 (and some argue as many as 22) of the 33 Medicare Shared Savings Program ACO quality metrics[165] are directly or indirectly dependent on appropriate medication use. CMM aligns well with quality improvement initiatives to achieve the national goals of better care, better health and affordable cost. In addition, since many medication-related quality measures are incorporated into "pay for performance" programs, CMM has the potential to help healthcare providers maximize performance-based payments.

While no national standard exists for quantifying medication-related problems, including medication safety, the USC School of Pharmacy developed a tool for categorizing medication-related problems identified and resolved for the HRSA Patient Safety and Clinical Pharmacy Services Collaborative (see Section 6.1). The tool is shared across the nation by Quality Improvement Programs and has become a common method for aggregating medication-related problems identified and resolved. In addition, the University of Minnesota through their pharmaceutical care research developed a taxonomy of drug therapy problems which is well established and was first published in a textbook in 1998; Pharmaceutical Care - The Patient-Centered Approach to Medication Management (2012)[166] continues to serve as a guide for many students and practitioners of CMM across the country.

4.5 Outcomes: Return on Investment

Cost-savings attributable to CMM provide a compelling argument for program implementation (see Appendix D). Estimates of the return on investment (ROI) of medication management through the use of collaborative drug therapy management agreements are as high as $ 12 saved for every $ 1 invested (12:1), with an average of 4:1.[167,168,169]

Medical literature describing the economic benefit of incorporating clinical pharmacists in direct patient care activities is robust.[170,171,172] General estimates conclude that for every dollar invested in clinical pharmacy services, the health system, hospital, other healthcare providers, and/or health plan will benefit by four times that amount or more.[173] By incorporating coordinated and targeted quality CMM into health care delivery as part of a team based approach during critical transitions, an estimated $45.6 billion would be saved in direct health care costs in the U.S.[174] In contrast, according to the New England Healthcare Institute, omission of pharmacists from medication therapy management (outside of the traditional dispensing role) has resulted in an increase of total costs and drug-related morbidity and mortality totaling an estimated $298 billion.[175,176]

4.6 Key Roles

As previously clarified, CMM and disease state MTM programs require collaboration and communication with physicians and other members of the healthcare team, which is not required in Medicare Part D MTM CMRs. As a team-based program, CMM maintains the role of the physician as team leader, focusing on identifying and resolving medication-related problems that are best-managed by the skills unique to pharmacists. More recent healthcare professional graduates, including medicine, pharmacy, and nursing, have a better understanding of team-based care such as CMM, largely due to mandatory accreditation standards for interprofessional education as discussed in section 3.5. Health systems, physicians, pharmacists, other healthcare providers, public health, and patients all play key roles in implementation.

Role of Health Systems

As payment for healthcare services shifts towards those that provide value (good health outcomes), health systems will be incentivized to reduce hospital readmissions and improve quality measures.[177] Examples of models that align well with these health system priorities include pay for performance programs, accountable care organizations (ACOs), patient centered medical homes (PCMH), and the Medicaid Health Home Option Section 2703.[178,179,180] Integrating clinical pharmacy services with medical care, particularly CMM, helps health systems meet these goals by ensuring optimal results from medication therapy and requires engagement, support, and funding from senior leadership within each health system.[181]

Role of Health Care Providers

Physicians
The success of CMM programs hinges on support from physicians, since CMM collaborative practice agreements require physician approval and patient engagement is most effective when physicians endorse and see the program as an integral part of their practice.[182,183,184] CMM is often facilitated through collaborative practice agreements, where, under the authority of a prescriber a pharmacist is allowed to initiate, modify, monitor, and discontinue drug therapy.[185]

Physicians who wish to collaborate with a pharmacist to offer CMM are able to determine the range of clinical services that pharmacists can provide, within the scope of practice laws for each state. Generally speaking, pharmacist-provided CMM offers maximum value to physicians and patients when the targeted population for enrollment consists of high-risk and/or high-cost patients that struggle to reach provider and patient defined medication treatment goals. By having pharmacist provide CMM to these patients and carry forth evidence-based medication treatment plans, physicians have more time and capacity to see other patients and access to healthcare services improves. Furthermore, in the current shift towards value-based payment

for healthcare services, CMM helps improve pay for performance / shared savings measures (see Appendix D). For example, providing CMM to patients recently discharged from the hospital who are high-risk for readmission can reduce readmission penalties to hospitals and overall costs for health plans. In the community pharmacy setting, establishing a collaborative practice agreement between a medical group and network of pharmacies that allows pharmacists to deliver disease state MTM services and manage, for example, medication therapy for poorly-controlled hypertension patients to help improve rates of blood pressure control.

Procedurally, the physician is essential for the collaborative nature of CMM. The physician's (or medical director's) role includes signing a collaborative practice agreement granting the pharmacist a clearly defined scope of practice commensurate with state pharmacy laws; referring appropriate patients for CMM program enrollment; reviewing medication care plans; and providing input in quality assurance reviews of the pharmacist's performance. The role is the same for any collaborating physician, whether primary care or specialist.

Pharmacists

Although pharmacists have been providing disease state MTM and CMM services for decades with documented improvement in Triple Aim measures including healthcare quality, safety, cost, and satisfaction, CMM provided by pharmacists remains unfamiliar to most physicians. The following is a brief overview of the role of pharmacists in CMM, and what physicians can expect when collaborating with pharmacist providing the service.[186]

CMM requires a collaborative practice agreement with a physician, thus, the physician remains in the leadership role on the healthcare team. Group or individual physicians can decide what range of clinical privileges can be comfortably granted to pharmacists through collaborative practice agreements. For broad scope of collaborative practice agreements, CMM services can be offered, while disease specific agreements allow narrower disease state MTM services to be conducted. As the VA has found, broader scopes of practice allow for CMM and have a greater impact on both quality outcomes and overall ROI.[187] In addition to clarifying clinical privileges, collaborative practice agreements outline how and when pharmacists will communicate patient care issues with physicians and other healthcare team members. For example, most collaborative practice agreements state that pharmacists must document communication with patients, whether by phone or in person, within 24 hours of every encounter and adopt an agreed upon system for letting the physician know that CMM encounter was made; for electronic health records, this is usually a "task" or similar function that is activated.

Services performed by pharmacists delivering CMM, that can be unspecified or limited to specifics based on the comfort level of physicians, can include:

- Recruit high-risk and/or high-cost patients who would likely benefit the most from CMM program enrollment;
- During scheduled visits, evaluate patients for baseline knowledge, attitudes, beliefs and behaviors regarding medical conditions, medications, and medication use;
- Perform basic assessments including vital signs, point-of-care testing, administration of screening / monitoring tools (e.g., PHQ-2 or -9, Asthma Control Test, peak flow);
- Order tests related to monitoring the safety and/or efficacy of drug therapy;
- Engage relatives and caretakers as needed;
- Identify all medication-related barriers to attaining treatment goals, and formulate individualized plan to resolve these barriers through shared decision-making with patients;
- Consult with other members of the healthcare team and refer patients per referral criteria;
- Communicate urgent matters immediately to the primary care provider, which are defined by the collaborative practice agreement and/or specific protocols (e.g., critical blood pressures, pulse rates, plasma glucose levels); and,
- Follow up with patients, either by phone or in person, as frequently and long as necessary to ensure treatment goals are met.

Note that the focus of these plans is medication-related and are developed in alignment with the primary care team's plans.

Although not commonplace in community pharmacies, many chain independently-owned pharmacies are committing resources to foster the development of community pharmacy-based CMM. For example, Sav-on / Albertson pharmacies hire pharmacists dedicated to patient care who travel from store to store to provide MTM, CMM, and other clinical services.

Apart from life-threatening concerns, any disagreement between a pharmacist's recommendations and a physician's plan always defers to the physician's plan and will carry it forward according to the collaborative practice agreement. A common misconception is that pharmacists who are qualified to provide CMM will identify rare or theoretical medication-related problems such as drug-drug or drug-disease interactions that have minimal clinical significance, and will incorporate these into recommendations or treatment plans. A qualified CMM pharmacist, typically someone who has completed a residency or high-quality training program and has clinical experience, will only base final recommendations on sound, documented evidence. See Appendix M for CMM frequently asked questions.

Role of Local Public Health
Local public health departments are the cornerstone for identifying community needs, conducting chronic disease surveillance, and identifying the highest risk populations.[188] Local and state public health departments provide essential services to assure the conditions in which

people can be healthy.[189,190] These include population health, data collection, analysis and reports, administering programs and making policy recommendations. Through their capacity for epidemiologic surveillance, public health professionals are able to provide information about chronic disease trends in order to meet future population needs and address health disparities that exist in sub-populations.

As a hub of health promotion, public health departments can disseminate information about CMM services and promote its benefits to the public, other healthcare providers, health plans, Medi-Cal, and employers, thus ensuring that high risk patient access and outreach occurs.

Goal 2 of the California Wellness Plan 2014 aims for health system interventions and efforts to be linked with community programs and clinical services in order to meet the needs of populations with the largest health disparities. Thus, public health would have a role in assuring that the distribution of CMM programs is equitable and meets the needs of the highest-risk populations.

Federally Qualified Health Centers and rural health clinics, in partnership with local and tribal public health departments, would be ideal as early adopters of CMM programs as they serve high-risk and high-need patient populations and they have a large geographic distribution. However, the lack of federal recognition of pharmacists as healthcare providers and a clear understanding of the service expectations presents a challenge to receiving federal reimbursement for pharmacist services, such as CMM.

Role of Patients

Patients must be engaged as partners in the treatment and management of their chronic diseases to best prevent disease progression and premature death.[191] Patients want to be active decision-makers regarding the use of their medicines;[192] evidence has shown positive medication adherence enhancement when patients are actively engaged in their care.[193] Thus, addressing patients' concerns related to their "medication experience" increases the likelihood of patients using their medications optimally.[194]   A key component of CMM is increasing patient involvement in their care.[195,196] Patient feedback is crucial to ensure that pharmacists and health systems are delivering a service that is equitable, desired, appropriate, and meets patients' needs.[197] This requires a dynamic approach, in which providers and health systems incorporate patient needs and preferences into the delivery of services.

However, a major barrier to widespread adoption of pharmacist providing CMM, particularly in the community setting, is the stereotype image of pharmacists in the mind of the public. This can be overcome as physicians and other non-pharmacist providers become more familiar with the value of CMM and encourage patients to engage in the service. As more patients experience positive outcomes from CMM, their support and advocacy will help change public

expectations from community-based pharmacists. This support can be leveraged with patient advocacy groups by providers of CMM. For instance, the California Chronic Care Coalition has established CMM as a policy priority. They understand that not only is it important for medications to be accessible and affordable to patients, but appropriate use of the medications is critical to improve patient outcomes and assure patients that the medications they are using are the most effective and safe for them.

5. Case Studies of Comprehensive Medication Management Programs in Southern California

5.1 Methods

Materials in this paper were collected as a result of the efforts of the California Wellness Plan Goal 2 Comprehensive Medication Management Statewide Implementation Work Group (see Appendix K). The literature referenced in this white paper was obtained under the advisement of the workgroup. Interviews with stakeholders and informants were conducted in May 2015.

While this paper is not a formal systematic literature review, assessment of previously published systematic reviews, recent published literature, and landmark trials and reports were used to inform the concepts discussed in this paper. Additional consideration was given to current CMM programs within California health systems, as their barriers, solutions, and achievements are particularly germane.

Limitations

Case studies included in this paper were limited to existing disease state MTM and CMM programs known by the authors and considered best practices, and whose experts (see Appendix N) responded to correspondence during the compressed timeline of manuscript development. It should be noted that this report is not all-inclusive in describing successful disease state MTM and CMM programs throughout California.

5.2 Findings

Findings reported from the following CMM programs are assumed to be accurate as of May 2015. Furthermore, it is understood that each program has completed their respective institutional review board (IRB) process; it is possible that findings reported in this report may change later when final and/or more complete individual program results are available and published by the respective CMM programs.

The programs below were contacted and agreed to share CMM pilot program descriptions and information (Appendix L):
- University of Southern California (USC) School of Pharmacy/Alta Med Health Services

- Greater Newport Physicians Ambulatory Care Clinics
- University of California San Diego Health System
- GEMCare Medical Group, Inc.
- Sharp HealthCare
- Kern Medical Center

Other CMM pilot programs that operate in Southern California but are not described in this white paper include the following:
- QueensCare Family Clinics
- Los Angeles (LA) Christian Health Centers
- LA County Department of Health Services

University of Southern California (USC) School of Pharmacy/AltaMed Health Services
USC School of Pharmacy, together with USC Schaeffer Center for Health Policy and Economics and AltaMed Health Services, received a federal $12 million Centers for Medicare and Medicaid Services Innovation Center (CMMI) grant to integrate pharmacy teams into 10 outpatient AltaMed clinics in Los Angeles County and Orange County, including 2 Programs of All-inclusive Care for the Elderly (PACE) centers. AltaMed Health Services is the largest Federally Qualified Health Center in U.S. and serves mainly Latino populations vulnerable to health disparities and access issues through a network of more than 40 clinics. An additional pharmacy team provided CMM services through video telehealth for two other AltaMed clinic locations. Each pharmacy team, consisting of a clinical pharmacist, a pharmacy resident, and a clinical pharmacy technician, delivered CMM. All pharmacists received residency training in establishing and providing CMM in safety net clinics before they were recruited.

Pharmacists provided CMM under collaborative practice agreements established between the USC School of Pharmacy and AltaMed Health Services that grant the pharmacist maximum clinical privileges including the ability to start, stop, adjust, or substitute medication therapy and order medication-related tests. As part of its CMM program, the USC School of Pharmacy created "triggers" or algorithms to identify patients at high-risk for medical and/or medication-related harm. These algorithms identified patients with poorly controlled chronic illness such as diabetes, hypertension, dyslipidemia, heart failure, and/or chronic obstructive pulmonary disease (COPD)/asthma, and patients at risk for a medication-related problem. These include those with multiple medications, those receiving high-risk medications, or those with adherence issues. In an effort to reduce hospital readmissions, pharmacy teams used emergency room and hospitalization discharge reports to identify patients who frequently or recently used those services. Once identified, the pharmacy teams were able to directly enroll

Case Studies of Comprehensive Medication Management in Southern California as of May 2015

Legend:
- ⬠ UC San Diego Health System
- ◇ GEMCare Medical Group Inc
- ▲ University of Southern California School of Pharmacy/AltaMed Health Services
- ○ Sharp HealthCare
- ☐ Greater Newport Physicians Ambulatory Care Clinics
- ★ Kern Medical Center

June 17, 2015
Chronic Disease
Control Branch
cdcb@cdph.ca.gov

This map highlights the comprehensive medication management case study locations in Southern California known to the authors.

Contact information: California Wellness Plan Goal 2 Comprehensive Medication Management Statewide Implementation Work Group

patients in the CMM program. An agreement with AltaMed Health Services was executed prior to CMM program commencement (Appendix E).

Other grant-funded activities included an expansion of training for pharmacy residents and technicians, development of an online program to train pharmacists in the competencies for CMM provision, and an evaluation of the CMM program's impact on healthcare quality, safety, total cost, and satisfaction. Three California pharmacy technician schools (East Los Angeles Occupational Center, Cerritos College, and Santa Ana College) have integrated the competencies developed in the CMMI program into their curricula; their graduates are prepared to provide high-value clinical services. For more information about the clinical pharmacy technician curriculum, please contact Dr. Steven Chen at chens@usc.edu.

Results

Over a three-year period, pharmacy teams enrolled more than 6,000 high-risk and/or high-cost patients. Outcomes are being evaluated in comparison to a "usual care" cohort of propensity-matched patients who received care at AltaMed locations that did not offer CMM. CMM clearly outperformed usual care in the management of common chronic conditions.[198,199] In addition, the CMM program was able to maintain treatment success over time, in large part due to "check-ins" provided every two months by the pharmacy technicians for discharged patients. An average of 10 medication-related problems were identified and resolved for each enrolled patient. Preliminary return on investment analysis suggests that the program costs are outweighed by cost savings in Altamed. This is of value to organizations that are at full risk for healthcare costs (i.e., capitation). The CMM program using pharmacy technicians developed through this grant was associated with a 50 percent increase in daily patient visits. Since AltaMed was able to provide supplemental medical assistant support, no different than the level of service for any healthcare provider, the increase in patient volume was not overwhelming to the system. Patient and other healthcare provider satisfaction with CMM, measured with validated surveys, was also outstanding.

For more information on the USC California School of Pharmacy/AltaMed Health Services CMM Program please see Appendix L. 1.1.

Greater Newport Physicians Ambulatory Care Clinics[200]

Greater Newport Physicians (GNP) is an Independent Practice Association (IPA) comprised of 130 Primary Care Physicians and over 400 Specialists. GNP Cares for 80,000 managed care lives and is a partner of MemorialCare Health System and MemorialCare Medical Foundation which include multiple outpatient clinics, urgent care facilities, ambulatory surgery centers and six not-for-profit hospitals. Clinical pharmacy services originated from the desire of GNP Primary Care Physicians to incorporate a pharmacist in the management of patients on high risk medications.

Currently, there are three separate programs that integrate pharmacist-led medication management into the care team.

One is the ACTIVE Diabetes Program, which is GNP's solution to care for patients with poorly controlled diabetes that are not meeting their treatment goals through traditional methods. The CMM program utilizes a multidisciplinary team approach in which pharmacists counsel patients on medications, perform a medication review, and adjust medication therapy, according to protocol. In addition to the pharmacists (who are Certified Diabetes Educators or CDE's), the patient is also seen by a registered dietitian (CDE) and a clinical social worker to address complex diet and psychosocial aspects of diabetes management.

The GNP Anticoagulation Center is an MTM program. In the Anticoagulation Center, pharmacists meet directly with patients to evaluate their medications and provide extensive education on blood thinner therapy. The pharmacist orders labs and adjusts the patient's anticoagulation therapy based on the established collaborative agreement.

Although not technically CMM, the pharmacist is also part of the multidisciplinary team in the post-discharge clinic known as the Special Care Center; the pharmacist is responsible for a medication review and reconciliation. Pharmacists within the Special Care Center collaborate with other team members including a hospitalist, a registered nurse case manager, and a clinical social worker.

Results

On average, ACTIVE Diabetes Program participants were able to meet their diabetes treatment goals within the first 180 days of enrollment. They were also able to meet quality measure goals for blood pressure control, high cholesterol, and nephropathy screening.

As a result of the pharmacist-led Anticoagulation Center, there were 53 percent fewer inpatient admissions and 41 percent fewer emergency department visits.

The 30-day readmission rate for Special Care Center participating seniors was 60 percent lower than the national average.

Additionally, all three programs had high-marks in patient satisfaction. When compared to a cohort of diabetes patients with hemoglobin A1c baseline above 8%, medical costs for ACTIVE program participants was approximately $1200 less per patient per year. When accounting for program costs, the savings are approximately $100 per patient per year but do not include pay for performance payments associated with improved outcome metrics.

For more information on the Greater Newport Physicians Ambulatory Care Clinics please see Appendix L. 1.2.

University of California San Diego Health System[201]

The University of California San Diego (UCSD) Health System represents the only academic health system in its region, with a network of more than 850 physicians. In 2014, the UCSD Health System was recognized in the *U.S. News & World Report's* annual "America's Best Hospitals" issue and has received recognition both locally and nationally for providing exceptional care.

In the fall of 2011, a CMM program was implemented at UCSD to help high-risk patients transition smoothly from the hospital to the outpatient setting, improve health outcomes, and reduce 30-day readmissions. The initial high-risk patient population selected was heart failure patients. The program was titled The Transition of Care Program. The Transition of Care Program included pharmacists operating within the hospital as well as in outpatient hospital-based ambulatory care and medical group clinics within the UCSD Health System.

The UCSD Health System Transition of Care program utilized CMM throughout implementation. The transition of care model is comprehensive and unique as the pharmacist will interact regularly with the patient from the day of admission to approximately 30 days post discharge. The Transition of Care program services were provided by board certified clinical pharmacists and included: admission medication reconciliation, medication management during admission, discharge medication reconciliation, discharge counseling, and extensive post discharge follow-up including phone calls and clinic visits.

The UCSD Health System also participates in the Community-Based Care Transitions Program, which targets high-risk Medicare fee-for-service patients. Patients enrolled in this program receive similar pharmacist services as patients enrolled in the Transition of Care Program.

Results

Based on a small pilot, the annualized cost avoidance with the Transitions of Care program (i.e. inpatient and outpatient) was $503,278. When compared to patients that did not receive Transition of Care services, enrolled patients were 18.9 percent less likely to be readmitted within 30 days. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Patient Satisfaction Score on the question "When I left the hospital I knew the purpose of each medication" improved to the 92nd percentile since initiation of the Transition of Care program from a baseline of 85th percentile. Within the first year of the Community-based Care Transitions Program, patient readmissions decreased dramatically by approximately 30% for the Medicare FFS population to a rate of 10.4 percent.

For more information on the University of California San Diego Health System CMM Program, please see Appendix L. 1.3.

GEMCare Medical Group[202]

GEMCare Health Plan and Medical Associate's Comprehensive Care Center is a recognized Patient Centered Medical Home (PCMH) by the National Committee for Quality Assurance (NCQA). The Comprehensive Care Center is unique as an APP with full prescriptive authority was integrated into the collaborative multidisciplinary team to provide patient "centric" Chronic Disease Therapy Management.

This triple board certified pharmacist with ten-years of advanced clinical pharmacy practice experience works with pharmacy residents and students within the clinic. Through a collaborative practice agreement between the pharmacist and the physician working in the clinic, and approved by the medical group (GEMCare Medical Associates), the pharmacist is granted a broad scope of practice. The pharmacist manages a wide range of chronic and acute conditions including, diabetes, chronic obstructive pulmonary disease, and heart failure, as well as patients on high-risk medications. Chronic disease therapy management, including CMM, is provided by the pharmacist. Additionally, the pharmacist provides Transition of Care services for Medicare Advantage members.

Face-to-face interaction between the pharmacist and patient is dependent on the acuteness and level of care needed. The more uncontrolled the disease the more often the patient is seen. These appointments can occur as frequently as every two weeks until disease is controlled, or at minimum every six months.

Results

Pharmacy services within the medical group initially included a MTM program, which successfully generated over $600,000 in medication cost savings in 305 patients seen over 12-months (July 1st 2009 through June 30th, 2010), reduced hospitalizations by 20 percent, and simultaneously demonstrated high physician and patient satisfaction.

Following the integration of the APP into the Comprehensive Care Clinic additional benefits were realized. Since program inception in 2010, positive economic outcomes included an overall decreased health care cost of almost 20 percent per member per month. The hospital admission rate decreased by 38 percent, readmission rates decreased by 32 percent, and emergency department visits decreased by 29 percent (see Appendix L. 1.4 Table 1). Clinical quality measures used to assess the management of diabetes and cardiovascular disease were also improved when comparing quartile gains nominally (see Appendix L. 1.4 Table 2). The Comprehensive Care Clinic Patient Satisfaction Survey yielded high marks for access to care, patient centeredness, team support, and willingness to refer (see Appendix L. 1.4 Table 3).

For more information on the GEMCare Medical Group CMM Program, please see Appendix L. 1.4.

Sharp HealthCare[203]

In 2011 Sharp Healthcare was among the 32 Pioneer Accountable Care Organizations (ACOs) in the country. Due to the ACO designation, Sharp Memorial Hospital and Touro University California College of Pharmacy developed and implemented a post graduate year 2 (PGY2) Specialty Residency in Transitions of Care, called the Continuum of Care Network. In 2013, the Network was expanded with the establishment of a full time pharmacist faculty that taught pharmacy students CMM theory and practice.

Since its inception, the focus of the Continuum of Care Network has been to provide CMM for heart failure patients and accept physician referrals for complex high-risk patients with the goal of improving health and reducing hospital readmission rates. The Continuum of Care Network has incorporated CMM services in other areas/sites: geriatric trauma, inpatient psychiatry, skilled nursing facilities, and home health. In August 2015, the Continuum of Care Network will start CMM for chronic obstructive pulmonary disease patients at Sharp Memorial Hospital. Two other CMM programs have been developed at Sharp Memorial Hospital. In October 2014, Sharp Healthcare became one of seventy two participating sites nationwide implementing the Community-Based Care Transitions Program. This allowed for expansion of CMM at three of Sharp's acute care facilities. In addition, the "Meds to You" program was created in June 2015 to ensure patients received prescription medications prior to discharge.

Results

Heart failure patients enrolled in the Continuum of Care Network had half as many readmissions as patients that were not enrolled (12 percent vs. 24 percent, p=0.005), as did the Heart Failure Core Measure 1 Compliance Rate (delivery of heart failure specific education prior to discharge).[204] Future publications describing the cost-savings and return on investment for the Continuum of Care Network are in development. Sharp HealthCare's success at reducing hospital readmission rates have resulted in recognition through the American Heart Association Get with the Guidelines Heart Failure Gold Quality Achievement Award and the American Society of Health System Pharmacists Medication Management in Care Transitions Best Practices.

For more information on Sharp HealthCare CMM program, please see Appendix L. 1.5.

Kern Medical Center[205]

Kern Medical Center, a county-owned level 2 trauma center and safety net/teaching hospital, has relied upon APPs for many years. A partnership between Kern Health Systems and Kern Medical Center created a multidisciplinary community Diabetes Care Clinic. Increasing health equity, clinical quality improvement, coordination of care, community support and optimizing population health prevention and promotion is the focus of the Diabetes Care Clinic. The Diabetes Care Clinics' multidisciplinary team includes an endocrinologist, pharmacist, nurse

practitioner, registered dietitian, psychologist, and pharmacy and medical residents. Pharmacists in the Diabetes Care Clinic have full prescriptive authority, including initiating, discontinuing, and adjusting medications, for patients with diabetes, hypertension, dyslipidemia and diabetic neuropathy through the use of a collaborative practice agreement. The Diabetes Care Clinic is unique in that it fully leverages the training and expertise of the APPs. In addition to full prescriptive authority, pharmacists perform medication-related patient assessments, order lab tests and exams, and refer patients to primary care providers and specialists. All pharmacists within the program have completed residency and many have obtained additional certifications, including three pharmacists credentialed as Certified Diabetes Educators (CDE).

The Diabetes Care Clinic accepts referrals from other healthcare providers in the surrounding federally qualified health centers for medication management by the pharmacists. A local Medi-Cal managed health care insurance plan has contracted with Kern Medical Center to provide these services to their membership. Kern Medical Center received the California Society of Health System-Pharmacists 2014 Innovative Practice Award and the 2009 Clinical Systems Development Award from the Safety Net Institute and California Association of Public Hospitals which were featured in several newspaper and journal articles.

Results

Multiple studies have consistently demonstrated statistically significant clinical, quality and fiscal outcomes.[206,207,208] Almost half of the poorly controlled diabetic patients were able to achieve the blood glucose treatment goal. There was a 40.1 percent reduction in emergency department visits, a 22.3 percent reduction in hospitalizations overall, and a 26.1 percent reduction in length of stay if hospitalized. At the time of the study, according to the Agency for Healthcare Research and Quality estimates, the mean cost per ED visit was $1,354 and the mean cost per inpatient medicine admission was $9,500. Therefore, it was demonstrated that a clinical pharmacist working as a member of the multidisciplinary team in the Diabetes Care Clinic for 40 hours per week for a mean 272 days and mean of 5.9 visits per patient resulted in an estimated annualized cost savings of $256,518 per year.

The Diabetes Care Clinic routinely has high scores for patient satisfaction at the Kern Medical Center.

For more information on Kern Medical Center Diabetes Care Clinic, please see Appendix L. 1.6.

6. Challenges of Comprehensive Medication Management Implementation

6.1 Reimbursement

Currently, provision of CMM does not require recognition of pharmacists as a healthcare provider. CMM is typically conducted within a collaborative model of care with collaborative practice agreements that give pharmacists the necessary prescriptive authority to conduct the services (see Appendix E).[209]

The delivery of proven preventive services like CMM to high risk patient populations increases when appropriate reimbursements for provision of those services are in place.[210] To ensure delivery of these services, pharmacists must first be broadly recognized by payers as healthcare providers.[211,212] Clinical pharmacy services are excluded from Medicare Part B and are only narrowly covered under the Medicare Part D MTM provision.[213] Some CMM and MTM programs seek reimbursement through Medicare Part D and other methods (see Appendix H).[214,215]

California legislation has expanded pharmacists' scope of practice; however, the legislation does not provide the terminology necessary to allow billing and ensure reimbursement.[216] In addition, California provider status legislation for pharmacists does not extend into California Federally-Qualified Health Centers, which fall under Federal requirements. Until risk in California shifts to medical groups / providers, alternative methods are needed to fund CMM services. For 340B entities, contracts with pharmacies could include a share of the 340B contribution to provide clearly-defined CMM services. Medical groups that are pursuing medical home recognition should consider paying for CMM services since they are fully aligned with medical home standards. Value-based care models, including PCMH, ACO, and the Medicaid Health Home Option, should consider engagement of CMM since ROI evaluations have proven to be highly positive.

6.2 Communication and Transparency of Health Information

Health information must be both accessible and useable. The provision of CMM requires timely and complete data at the time of the service; data that goes beyond prescription information.[217,218] Patient medical records, which provide key information including lab results, past medical history, procedures (scheduled and historical), etc., are critical for effective CMM. Inability to access appropriate and adequate patient information diminishes the pharmacists' capacity to provide effective interventions.[219,220] Electronic medical records and integrated health information exchange are the most effective and efficient as they allow the rapid communication of CMM interventions between providers while simultaneously tracking quality

measures for reporting and quality improvement. This is particularly critical in CMM collaborations with community pharmacy; pharmacists will not be able to make sound recommendations or treatment changes without health information and test results and timely communication with the physician and broader care team.

6.3 Tracking Outcomes

Measurement of outcomes is essential for assessing program success in managing chronic disease effectively and efficiently.[221] Programs piloting CMM should consider the following outcomes:

- Intermediate outcomes (laboratory measures, number of medication adverse events, treatment goals achieved);
- Patient-centered outcomes (disease-specific outcomes, mortality, patient satisfaction, quality of life); and,
- Resource utilization outcomes (health care cost and utilization).[222]

To demonstrate the effectiveness of CMM and promote implementation, financially viable models of delivery must be highlighted.[223] However, most studies fail to evaluate the cost of providing clinical pharmacy services, including CMM, and omit economic evaluations of their program.[224] Some programs cite challenges in tracking and standardizing financial success.[225] Because CMM is often included with other system-wide changes or integrated into routine medical care, it can be difficult to isolate, assess, and evaluate the impact of CMM.

6.4 Patient Participation

Patients' commitment to manage their chronic conditions requires both motivation and engagement. Although patient engagement in CMM has not been directly examined, results measuring patient satisfaction following CMM are generally positive (see Section 6 Case Studies of CMM). For comparison, unfortunately, less than 25 percent of eligible patients participate in Medicare Part D MTM CMR.[226] However the value of Medicare Part D MTM is limited for patients since the clinical data is not available to Medicare Part D plans. At the end of a well conducted CMR, the patient's medications still may be inappropriate in addressing their clinical goals of therapy and not effective (e.g., high blood pressure or diabetes not controlled) or safe given a patients clinical parameters such as liver or kidney disease. It is unclear if lack of patient engagement stems from a failure of the MTM programs to meet patient needs, lack of patient interest, lack of patient awareness, or other causes.

Patient willingness to use CMM or other pharmacist-provided medication management services relies on patients' perceived value of the service and its ability to increase their knowledge.[227] Additionally, patients consider the capability of the service to address their concerns.[228]

Studies suggest a comprehensive approach focused on the patients "medication experience," and a systematic approach to find and resolve medication related problems that are preventing them from reaching their personal and clinical goals of therapy, such as in CMM, is critical to assisting patients to manage their chronic diseases while acknowledging and supporting their role.[229]

6.5 Awareness

Leadership of health care organizations (including physicians) and the public are often unfamiliar with pharmacist-provided medication management services like CMM.[230,231,232] Pharmacy practice is typically perceived as dispensation of medications. Generally consumers are unaware of the direct patient care responsibilities of pharmacists practicing under collaborative practice agreements, which have been in place in California for nearly half a century.[233]

Some physicians express concern about integrating pharmacists into the clinic workflow and payment scheme.[234] One California case study describes a lack of acceptance of integrating pharmacists by other healthcare providers.[235] Many programs in California highlighted the need for physician buy-in prior to integration of pharmacy services. Successful programs in California have cited physician champions as a key component of their success.[236] Often times, physicians and other providers are unaware of the extensive training pharmacists undergo to manage complex drug therapies. This training includes post-graduate residencies (up to 3 years), fellowships, dual degrees, and patient care experiences during every year of pharmacy school (see Appendix B).

6.6 Staffing and Space

CMM can be complex and resource intensive.[237] Delivery of these services requires adequate staff and space to ensure privacy. Some pharmacists working in a community setting are the only pharmacist in their pharmacy; therefore adoption of CMM presents a challenge. Pharmacists working in clinical settings, community settings, hospitals, and other health care facilities describe a lack of space with adequate privacy to conduct CMM.[238,239]

As discussed in Section 3, CMM can be most efficiently delivered by a combination of clinical / APPs, resident pharmacists, and clinical pharmacy technicians. Residents (approximately half of a pharmacist's salary) can contribute nearly as much as a clinical pharmacist, and clinical pharmacy technicians (approximately one-third of a pharmacist's salary) manage responsibilities that do not require a Doctor of Pharmacy degree, enabling pharmacists to manage 50 percent more patients (see Appendix L, 1.1). Healthcare organizations interested in adding pharmacy residents can partner with schools of pharmacy to become a part of their

accredited residency programs; otherwise, the healthcare organization would need to accredit their residency program independently, which is no simple process.

6.7 Pharmacist Time

CMM services must be separate and distinct from the preparation and dispensing of prescriptions (e.g., programs integrated into medical groups, community clinics, staff model HMOs, etc.), to allow pharmacist time allocated towards providing direct patient care. However, the amount of pharmacist resources that can be allocated to CMM services is limited by reimbursement, and typically only health systems at full risk are able to offer broader and more in-depth CMM programming.

In the community pharmacy setting, pharmacist workload and incentives are typically centered on prescription volume. Demanding additional services to existing processes and workflow, such as CMM, can seem daunting and is often perceived as an insurmountable barrier by community-based pharmacists; this is particularly true for pharmacies that are one-pharmacist operations. However, adjustments in pharmacy workflow and resource allocation can be made to accommodate CMM, as has been demonstrated by many independent and chain pharmacies locally and nationally. As dispensing functions shift to automation and technicians, as more demand and payment for CMM services increase, community/ambulatory pharmacist services will likely see a shift and an opportunity.

7. Conclusion

Significant benefits in health outcomes and cost savings have been described with the integration of CMM for the care of complex high-risk and/or high-cost patients in Southern California Case Studies. Stakeholders, including members of the California Department of Public Health, Centers for Disease Control and Prevention, Institute of Safe Medical Practices, and Institute of Medicine, have acknowledged the positive impact of integration of pharmacist-provided medication management, like CMM, on medication-related health outcomes.

As a service, CMM is inherently team-based and patient centered, and thus requires the buy-in from pharmacists, patients, other healthcare providers, and health systems. Adoption of CMM has several challenges, including a lack of: reimbursement mechanisms, alignment of financial incentives, robust electronic health information exchange, quality and outcomes tracking systems, patient and provider awareness, and adequate staffing and space.

The benefits of CMM are highly valuable and include improved patient health outcomes, improved healthcare quality measures, better access to healthcare, time-savings to other healthcare providers, reduced drug costs, reduced adverse drug events and decreased

expensive health care resource utilization (emergency or hospital delivered care). Pharmacist delivered CMM models in Southern California have demonstrated improvements in therapeutic outcomes as well as reducing health care costs. As discussed throughout this paper, opportunities to align CMM through readily accessible community pharmacies with priorities of government and private payers and providers, as well as public health, are abundant and have the potential to develop into a mutually beneficial clinical and business model, especially as the shift continues towards full risk for medical providers and value-based payments.

8. Appendices

A. Map of Primary Care Shortage in California

B. Pharmacist Education, Training and Scope

C. Medication Therapy Management Resources

D. Evidence of Cost-Savings and Cost Containment from Comprehensive Medication Management Services

E. Comprehensive Medication Management Resources and Sample Collaborative Practice Agreement Between Physicians and Pharmacists

F. California Schools of Pharmacy

G. University of Southern California/ AltaMed Health Services "Change Package"

H. Methods for Reimbursement of Medication Management Services

I. Sample Project Evaluation Tool (Logic Model)

J. Targeting Comprehensive Medication Management: Patient Identification Algorithm

K. California Wellness Plan Goal 2 Comprehensive Medication Management Statewide Implementation Work Group 2015-2016

L. Additional Case Study Information

M. Comprehensive Medication Management Frequently Asked Questions

N. Acknowledgements – Experts Consulted

O. Definitions

P. Acronyms

Q. References

Appendix A. Map of Primary Care Shortage in California[240]

California Primary Care Shortage Areas

Legend:
- Primary Care Shortage Area
- No Designation

The California Primary Care Shortage Areas correspond to the 2010 U.S. Census and uses two criteria: percent of population below 100% federal poverty level and primary care physician to population ratio. Data used include Claritas 2010 population estimates and infoUSA 2010 Physicians.

OSHPD Healthcare Workforce Development Division
GIS Layers

January 2012

0 12.5 25   50 Miles

Appendix B. Pharmacist Education, Training, and Scope

Pharmacists receive training focused on pharmacotherapy, medication use, and integration of evidence-based medicine with the goal of promoting safe and appropriate use of medications.[241] Pharmacists practice in a variety of settings including: community pharmacies, outpatient (ambulatory) clinics, physician offices, hospitals/inpatient facilities, long-term-care facilities, and skilled-nursing facilities, and others. [242]

In California, pharmacists have practiced with an expanded role since the 1970s within health care facilities throughout the state.[243] Since 1996, California pharmacists practicing in medical clinics (with residency training or appropriate clinical experience) have been able to legally adjust patient medications (AB 2802).[244] Both public and private integrated systems, including Kaiser Permanente and the Department of Veterans Affairs, are well known for leveraging the skills of clinical pharmacists to provide direct patient care services including medication-related patient assessment, medication management, laboratory monitoring, patient education, and counseling.[245, 246]

California is a leader in promoting pharmacists to practice with an expanded scope.[247] As of January 1, 2014 pharmacists' scope of practice was expanded to participate in direct patient care.[248] The passage of SB 493 (Hernandez), which was approved in 2013, created a new category of licensed pharmacist known as an APP. APPs are able to initiate, modify, and discontinue drug therapy, order laboratory tests, and refer patients to other providers under an established protocol. Further, under SB 493, all licensed pharmacists that have completed additional training are authorized to administer drugs; furnish travel medications, hormonal-contraceptive and nicotine replacement products for smoking cessation; and independently administer vaccinations to patients over 3 years old.[249,250]

In accordance with the shift of pharmacy practice towards the delivery of more clinical, direct patient care services U.S. pharmacy schools have shifted pharmacy education to support pharmacists to move into these roles.[251] Pharmacists now obtain a minimum of six years of training. More recent graduates of pharmacy school obtain a doctorate of pharmacy with an increased emphasis on direct patient care services. All practicing pharmacists have a bachelor's degree at a minimum. All pharmacy graduates are required to take the North American Pharmacist Licensure Examination (NAPLEX), a national, comprehensive, standardized competency exam to receive their pharmacy license.

Training may also include post-graduate training, including residency and/or fellowship, as well as certification in a specialty area.[252] Residencies are one to two years in length and are accredited by American Society of Health-System Pharmacists (ASHP). Pharmacists may seek additional certifications in a wide variety of specialties. Board Certification Specialties include:

psychiatric pharmacist (BCPP), ambulatory care pharmacist (BCACP), nutrition support pharmacist (BCNSP), oncology pharmacist (BCOP), and pharmacotherapy specialist (BCPS).

Generally, the provision of CMM is a primary responsibility for ambulatory care pharmacists.[253] Pharmacists practicing in an ambulatory care setting generally receive additional certifications and training including Certified Diabetes Educator (CDE) and/or Board Certified in Ambulatory Care Pharmacy (BCACP).

The specific statues related to pharmacy practice have been listed below.

California Business and Professions Codes:

§733, 4016.5, 4040, 4050, 4051, 4052, 4052.3, 4052.6, 4052.8, 4052.9, 4060, 4076, 4111, and 4174, 4210, and 4233

State law surrounding details related to the development of physician-pharmacist collaborative drug therapy management (i.e., Collaborative practice laws) is available in California Business and Professions Codes §4052.1 and §4052.2.

Appendix C. Medication Therapy Management Resources

Medication Therapy Management (MTM) is defined as a distinct service or group of services that optimize therapeutic outcomes for individual patients.[254] MTM services are independent of, but can occur in conjunction with the provision of a medication.[255] These services include a range from Medicare Part D MTM CMR levels of MTM to CMM.

Appendix C, Table 1. Available Medication Therapy Management Resources

Organization	Content / Resources (website)
California Society of Health System Pharmacists (CSHP)	CSHP MTM Task Force generated a MTM Resource Guide that provides information and opportunities of MTM in California. Resources on how to communicate the impact of programs are also available. (www.cshp.org/)
California Pharmacists Association (CPhA)	CPhA offers MTM training and certification programs for pharmacists. (http://cpha.com/)
American Pharmacists Association (APhA)	Since 2008, APhA has developed digests that track the implementation of MTM across the nation. These documents highlight survey responses from MTM payers and providers and discuss key developments in the use of MTM. Other resources include information on billing for MTM services, a toolkit of the core elements of MTM to assist with implementation, and an MTM certificate training program. (http://www.pharmacist.com/)
Medication Management Systems, Inc.	MMS is a spin-off company from the University of Minnesota that took the IT and services model for pharmaceutical care (CMM) level to a broad range of customers in the US and internationally including integrated delivery systems, health plans, PBMs, community pharmacists and others. With capability to deliver services or equip pharmacist with the technology, training, and quality assurance to deliver services ranging from Part D MTM to CMM (medsmanagement.com)
Mirixa **Outcomes Pharmaceutical Health Care**	Mirixa and Outcomes are comprehensive, technology-based companies that offer MTM services through community pharmacies across the nation. These companies link health plans, employers, physicians, and patients to community pharmacies in their network to deliver face-to-face MTM services, and provide computer applications for comprehensive management and documentation of services. (www.mirixa.com/ & www.getoutcomes.com)
American Colleges of Clinical Pharmacy (ACCP)	Several MTM-related commentaries, advocacy statements, and links to useful resources are available at ACCP's website. (www.accp.com)
Academy of Managed Care Pharmacy (AMCP)	AMCP offers links to many useful MTM-related documents, including CMS updates and other critical updates, through their MTM Resources page available at http://amcp.org/MTMResources/. AMCP also provides links to other useful publications related to CMM,

	including recent publications through the Journal of Managed Care & Specialty Pharmacy. (www.amcp.org)
American Society of Consultant Pharmacists (ASCP)	ASCP provides a resource center for MTM, particularly as it relates to long-term care (https://www.ascp.com/MTM). The site includes links to key MTM articles, CMS updates, and policy resources provided by other pharmacy organizations. (www.ascp.com)

*Table adapted from Medication management resource guide developed by the CSHP MTM Task Force[256]

Examples of disease state MTM services are employed in the management of several conditions including: anti-coagulation clinics, asthma, diabetes, osteoporosis, hypertension, immunizations, pharmacotherapy clinics, and others.

Appendix D. Evidence of Cost-Savings and Cost Containment from Comprehensive Medication Management Services

Appendix D, Table 1. Examples of Evidence of Cost-Savings and Containment from Pharmacist-led Medication Management[*]

Program	Cost Savings
Example of California Specific Cost Savings	
Asthma Healthy Home Benefit USC School of Pharmacy, Blue Cross, and Schering Pharmaceuticals	**$38,000 in emergency services**[Ω] **$85,000 in inpatient care**[Ω]
Greater Newport Physicians[257] Active Diabetes Program	**ROI $1200/patient/year**
Kern Medical Center[258] Pharmacist-managed diabetes mellitus clinic	**$256,500/year/pharmacist in ED/Hospitalization** **$ 3,812.40 per patient seen in clinic**[#]
Sharp HealthCare[259]	**$440,000 in patient medication costs**
USC/AltaMed Program	**$43.7 million over a 3 year period**
Example of Cost Savings Outside of California	
Asheville Project[260] Community Diabetes Care Program	**$1,200 to $1,872 per patient with diabetes**
Asheville Project[261] MTM Asthma Program	**$1,230 per patient (indirect costs)** **$725 per patient (direct costs)**
Blue Cross BlueShield MN[262]	**$3,768 in total health expenditures**
Fairview's MTM Program[263]	**$2,913,850 over 10-year period**
Pharmacist run anticoagulation clinic[264]	**$1,600 per patient per year**
Primary Care in Connecticut[265]	**$1,123 per patient on medical claims** **$472 per patient** Includes medical, hospital, and emergency services

[*]More evidence available through: The Letter to the U.S. Surgeon General[266]

[Ω]One year after enrollment

[#]Savings per patient only includes savings from readmissions and excludes additional savings from increased generic utilization and other pharmacy related measures

Appendix E. Comprehensive Medication Management Resources and Sample Collaborative Practice Agreement Between Physicians and Pharmacists

CMM is defined as an evidenced-based, multifaceted technique with the goal of assessing each patient's medication regimen to ensure all medications (including prescription, nonprescription, alternative, herbal, traditional, and nutritional supplements) are appropriate, effective for the medical condition being treated, safe with the patient's comorbidities and other medications, and convenient for the patient.[267]

Appendix E, Table 1. A Ten Step Process for Comprehensive Medication Management[268]

1. Identify patients that have not achieved clinical goals of therapy.
2. Understand the patient's personal medication experience/history and preferences /beliefs.
3. Identify actual use patterns of all medications including OTCs, bioactive supplements, and prescribed medications.
4. Assess each medication (in the following order) for appropriateness, effectiveness, safety (including drug interactions), and adherence, focused on achievement of the clinical goals for each therapy.
5. Identify all drug therapy problems (the gap between current therapy and that needed to achieve optimal clinical outcomes).
6. Develop a care plan addressing recommended steps, including therapeutic changes needed to achieve optimal outcomes.
7. Patient agrees with and understands care plan, which is communicated to the prescriber/primary care provider for his/her consent / support.
8. Document all steps and current clinical status versus goals of therapy.
9. Follow-up evaluations with the patient are critical to determine effects of changes, reassess actual outcomes, and recommend further therapeutic changes to achieve desired clinical goals/outcomes.
10. Comprehensive medical management is a reiterative process—care is coordinated with other team members and personalized (patient-unique) goals of therapy are understood by all team members.

The Patient-Centered Primary Care Collaborative has described the components of CMM delivery (see Appendix E, Table 1).[269] CMM, as a distinct process, goes beyond assessing individual patients' medication regimens. The provision of CMM requires development of a patient-centered care plan in which the patient understands and agrees to actively participate in that plan. Additionally, CMM goes beyond MTM through its use of an APP that assesses the patient's clinic status (e.g., assessing blood glucose control) for all the patient's conditions. Furthermore, follow-up in CMM is more rigorous because the pharmacist actively coordinates with the patient and other healthcare providers involved in order to reach provider and patient defined medication treatment goals.

The use of collaborative practice agreements and protocols are essential for the implementation of CMM. Examples of collaborative practice agreements and protocols

specifically for the provision of CMM within the confines of California law have been developed. General templates for protocol development are available through the Million Hearts Initiative.[270] To receive information about the USC/AltaMed collaborative practice agreements and protocols developed under the USC/AltaMed CMMI grant, please contact:

> Steven Chen, PharmD, FASHP, FCSHP, FNAP
> Associate Professor and Chair, Titus Family Department of Clinical Pharmacy and Pharmaceutical Economics & Policy
> William A. Heeres and Josephine A. Heeres Endowed Chair in Community Pharmacy
> Hygeia Centennial Chair in Clinical Pharmacy
> University of Southern California chens@usc.edu (323) 442-1393

Appendix E, Table 2. Comprehensive Medication Management Resources

Organization	Content / Resources (website)
Alliance for Integrated Medication Management[271]	Non-profit organization that supports the integration of team-based medication management services that reach high-risk, high-cost patient populations with chronic diseases. Resources include a national summary of medication management success and impact, links to recent publications on medication management, and other educational bulletins on improving medication use in high risk populations. (http://medsmatter.org/)
Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists[272]	CDC endorsed resource guide focused on the role of pharmacists in team-based care. Provides description of the evidence supporting increased utilization of pharmacists, overview of scope at the federal and state level, examples of MTM programs in state health departments, and strategies for working with pharmacists.
Collaborative Drug Therapy Management and Comprehensive Medication Management[273]	ACCP resource describing the facilitation of CMM through the use of collaborative drug therapy management.
Improving Patient and Health System Outcomes through Advanced Pharmacy Practice[274]	Report submitted to the U.S. Surgeon General to provide health system leadership with an evidence-based, comprehensive resource describing the multi-dimensional benefits of clinical pharmacy services. The report is outlined by four focus points on describing the rationale of increasing the integration of pharmacists in to health care delivery.
National Center for Chronic Disease Prevention and Health Promotion[275]	Descriptive guide defining terms, supporting the role of pharmacists and their role in collaborative drug therapy management through CMM, and providing an overview of state health departments that have incorporated programs.
Patient-Centered Primary Care Collaborative[276]	As part of the Medication Management Task Force, this resource guide served to promote the appropriate use of medications via this comprehensive guide outlining the rationale for including CMM in to patient-centered care models.

SAMPLE 1: **Clinical Pharmacist Collaborative Practice Agreement**[277]

The Pharmacy Practice Act allows pharmacists to practice under a Collaborative Practice Agreement with individual physicians. Pharmacists may participate in the practice of managing and modifying drug therapy on a according to a written protocol between the specific pharmacist and the individual physician(s) who is/are responsible for the patient's care and authorized to prescribe drugs.

By signing this document, the named physicians agree that the named pharmacist may enter into a Collaborative Practice for their patients. As Medical Director and Residency Director of the clinic, all faculty and staff physicians, nurse practitioners, and resident physicians fall under this agreement.

COLLABORATIVE AGREEMENT APPROVED BY:

PHARMACIST CLINICIAN:

_____
[INSERT PHARMACIST NAME] R.Ph., Pharm.D.

PHYSICIAN:

_____   _____
Medical Director, MD   Residency Director, MD

DATE OF IMPLEMENTATION:

DATES ANNUAL REVIEW COMPLETED:

Collaborative Practice Agreement

Purpose/Background

In order to enhance collaborative patient care, clinical pharmacists will be given authority to order labs; refill medications; and initiate, modify, or discontinue treatment when appropriate.

Policy

The clinical pharmacists, any pharmacy residents, and pharmacy students completing rotations under the supervision of the clinical pharmacist, will also follow this agreement.

Organization

Guidelines for referral: The provider can refer any patient they feel would benefit from pharmacy services and document the referral in the patient chart. Patients can also self-refer if they would like to receive pharmacy services.

Clinic visits:
- ❑   Patients can be seen on the same day as the physician or on a separate day

Clinical activities provided by the clinical pharmacist under the primary care physician:
- ❑   Order labs and tests as appropriate to assessing or monitoring drug therapy
- ❑   Refill authorization
- ❑   Therapeutic interchange
- ❑   Initiate, modify, or discontinue drug therapy in accordance with clinical guidelines (Collaborative Practice Agreement Appendix A)

Documentation: All activities will be documented in the patient chart and will be given to the primary care provider for review.

Quality Improvement

Clinical activities will be reviewed from time to time by the clinical pharmacist and physician providers, and revised as needed.

Collaborative Practice Agreement
Appendix A

1. **Anticoagulation**
   - The ACCP Conference on Antithrombotic and Thrombolytic Therapy, CHEST Supplement

2. **Arthritis**
   - Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis. American Pain Society - Professional Association.

3. **Asthma**
   - National Asthma Education and Prevention Program Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma

4. **Chronic Heart Failure**
   - ACC/AHA Guideline for the Diagnosis and Management of Chronic Heart Failure in the Adult

5. **Cholesterol**
   - NCEP: Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)

6. **Diabetes**
   - American Diabetes Association Clinical Practice Guidelines, Diabetes Care

7. **Gastroesophageal Reflux Disorder**

8. **Hypertension**
   - The Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure

9. **Latent Tuberculosis**
   - Minnesota Department of Health Tuberculosis Prevention and Control Program
   - CDC

10. **Smoking Cessation:**
    - Treating Tobacco Use and Dependence. Quick Reference Guide for Clinicians. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service.

SAMPLE 2: **LEGAL AGREEMENT between entities to provide clinical pharmacy services**[278]

START-UP AGREEMENT
BETWEEN
"ZZZ Healthcare Services" (PROVIDER)
AND
"YYY" School of Pharmacy (SCHOOL)

THIS AGREEMENT ("Agreement") is entered into effective _____ (*date*) by and between ZZZ Healthcare Services (*insert name*) ("PROVIDER"), a California nonprofit public benefit corporation, and YYY (*insert name*) School of Pharmacy ("SCHOOL").

RECITALS

A.   ZZZ Healthcare Services (*insert name*) provides healthcare services at _____ (*insert number*) location(s) in/throughout the _____ (*insert name(s)*) County area(s). PROVIDER Corporation facility is located at _____ (*insert address*).

B.   YYY (*insert name*) School of Pharmacy is located at _____, California (*insert address*).

C.   PROVIDER is willing, subject to the terms and conditions set forth below, to permit SCHOOL to provide pharmacy healthcare and clinical services to patients in its clinics.

NOW THEREFORE, the parties hereto hereby agree as follows:

1.   GENERAL INFORMATION.

SCHOOL will provide the following clinical pharmacy services at the PROVIDER clinics*:

Scope of Services for SCHOOL Clinical Pharmacy Program Staff

Pharmacist and Resident Pharmacist:

Services	Specific Examples	Approximate % of time
Administration, Quality assurance	• Establish thresholds for enrolling patients into the clinical pharmacy program through IT-derived triggers of potential medication-related problems such as patients with high total medical costs and patients who are frequently hospitalized or visit the emergency room	~10%

	• Conduct quality assurance projects including medication use evaluations • Present reports that aggregate clinical, safety, and cost outcomes of patients served by clinical pharmacists for sharing with the medical staff and senior leadership	
Direct patient care & student / resident supervision	• Develop scope of practice that includes clinical privileges and protocols • Provide direct patient care to high-risk patients, prioritizing patients by risk level, using approved protocols • Work closely with the PCP and members of the healthcare team in a patient-centered manner, ensuring that patients are referred for needed services • Supervise residents and students providing patient care, education classes, and medication counseling	~70-80%
Medical staff education	• Provide drug information to health care professionals • Provide medical staff in-services (verbal or written) on a variety of drug-related topics (new drug therapies, new treatment guidelines, etc.) as needed or requested	~10%

Clinical Pharmacy Technician:

Services	Specific Examples	Approximate % of time
Administration, Quality assurance	• Assist pharmacist in scheduling and maintaining patient care workflow • Work closely with providers and support staff to ensure that a comprehensive patient/family assessment is performed including health and functional status, cognitive capacity, support systems, psychosocial functioning and financial assessment • Provide continuing support and coordination of resources for patient/family. Ensure qualified patients receive services which may include: medical care, pharmaceutical assistance, nutrition counseling, physical or occupational therapy, behavioral health services, financial resources, transportation, food assistance, child care, and oral health • Support patient and family in successfully following a comprehensive plan of care, including checking in with stable patients. • Utilize strategies to clarify and negotiate the continuing care needs within the context of health insurance benefits and limitations as well as for patients without health coverage. • Consult and collaborate with other case managers and providers to monitor patients and participate in community resource/training meetings and professional development workshops	~30%
Patient care-related activities	• Collect and evaluate clinical outcomes, financial data and resource utilization reports. • Work with IT Department on updating electronic forms and reports • If needed, recruit patients for enrollment into the PAP (Pharmacy Assistance Program), manage storage of PAP medications, and maintain reports regarding utilization and financial impact • Participate in development of disease management strategies	~70%

*All of the above services will be associated with a detailed prescriber directed protocol that follows the major requirements described in the California Business and Professions Code, Section 4052.2.

2.   TERM OF AGREEMENT.

        The term of this Agreement shall commence on the date stated above ("Commencement Date") and shall remain in effect for a period of 3 years, subject to renewal for additional one (1) year term(s) based on the written agreement of the parties unless sooner terminated in the manner set forth below. This Agreement may be terminated by either party: (a) immediately, with cause, for breach of any material term of this Agreement, upon delivery to the other party of written notice of such breach and failure by the breaching party to cure such breach within fifteen (15) days; or (b) without cause, by delivery to the other party of thirty (30) days' advance written notice, unless sooner provided for pursuant to the terms of this Agreement. This Agreement may also be terminated at any time in the event of any occurrence beyond the control of either party which makes it impractical or unreasonable for either party to continue to abide by the terms and conditions of this Agreement. If such event occurs, the party wishing to terminate this Agreement shall do so by giving written notice to the other party of its election and such termination shall be immediately effective. This agreement involves no financial consideration or obligations between SCHOOL and PROVIDER.

3.   RESPONSIBILITIES OF SCHOOL.

        (a)   SCHOOL shall submit to PROVIDER a written Program plan which includes a description of the Program, written objectives, and expected outcomes. PROVIDER will be given a copy of the written Program plan either in advance of the Commencement Date or at the time of Commencement for its approval. SCHOOL shall not modify Program objectives or the Program plan without the prior written consent of PROVIDER.

        (b)   SCHOOL shall forward to PROVIDER the insurance coverage policy for those employees from the School that will be assigned to the PROVIDER Clinics prior to the commencement of this agreement. SCHOOL shall be responsible for supplying any additional information required by PROVIDER prior to the beginning date of this Program.

        (c)   SCHOOL will provide necessary background information (e.g. C.V.'s, resumes, or other records required) on all personnel from the SCHOOL who will be involved with the PROVIDER project program.

        (d)   SCHOOL shall designate a Program Coordinator for the PROVIDER project consistent with the information in the "Project Grant."

        (e)   SCHOOL shall enforce rules and regulations governing the activities of SCHOOL personnel assigned to the PROVIDER Clinics which are mutually agreed upon by SCHOOL and PROVIDER on or before the Commencement Date.

(f)   Any students from the SCHOOL assigned to this project will be under the direct supervision of the designated SCHOOL Program Coordinator for the PROVIDER project. The SCHOOL agrees to follow, and obligates students from SCHOOL to follow, all policies and procedures established by PROVIDER regarding patient treatment and management.

(g)   SCHOOL acknowledges that all patient records maintained at or by Medical Center shall remain the sole property of PROVIDER, and all information contained in patient records shall be kept confidential by personnel assigned by the SCHOOL. Therefore, personnel assigned from the SCHOOL to PROVIDER clinics shall respect and maintain the confidentiality of all Health Information with respect to all patients of PROVIDER, including without limitation, all Health Information regarding a patient's: (1) Medical treatment and condition; (2) Psychiatric and Mental Health; and (3) Substance abuse and Chemical dependency, which the Students may receive pursuant to this Agreement. SCHOOL personnel assigned to PROVIDER clinics shall be responsible to comply with the terms and conditions of the: (i) Confidentiality of Medical Information Act of 1981, California Civil Code Section 56 et seq. (General Patient Medical Records); (ii) California Welfare & Institutions Code §5328.6 and §5328.7 (Mental Health Records); and (iii) 42 U.S.C. §§290dd–2; 42 C.F.R., Part 2, §2.31 (Alcohol and Drug Abuse Records); and (iv) Health Insurance Portability and Accountability Act of 1996, as amended from time to time, including the amendments and related laws of the Health Information Technology for Economic and Clinical Health Act, and regulations promulgated thereunder, California laws relating to the privacy of patient and individual information and other applicable laws.

(For purposes of this Section, Health Information shall include without limitation, the following patient identifiable information: 1) Name; (2) Address, including street address, city, county, zip code and equivalent geocodes; (3) Names of relatives; (4) Names of employers; (5) Date of birth; (6) Telephone numbers: (7) Facsimile number; (8) Electronic mail address; (9) Social security number; (10) Medical record number; (11) Health plan beneficiary number; (12) Account number; (13) Certificate/license number; (14) Any vehicle or other device serial number; (15) Web Universal Resource Number (WURL); (16) Internet Protocol (IP) address number; (17) Finger or Voice prints; and (18) Photographic images; and (19) Any other unique identifying number, characteristic, or code that may be available to the SCHOOL personnel which could be used, alone or in combination with other information, to identify an individual.)

(h)   The SCHOOL Pharmacy team will complete the usual health clearance process for new PROVIDER employees.

4.   RESPONSIBILITIES OF PROVIDER

(a)   PROVIDER shall accept from SCHOOL the mutually agreed upon number of Students that will work under the supervision of assigned SCHOOL faculty and others employed by the SCHOOL assigned to the PROVIDER project. All assigned students shall be covered by the SCHOOL's Insurance Certificate of Coverage for any patient liability that they may cause.

(b)   PROVIDER on any day when a SCHOOL Project Employee or Student is providing clinical pharmacy services at a PROVIDER Clinic, and an injury to a SCHOOL Project employee or Student occurs, emergency health care or first aid for accidents occurring in PROVIDER's Clinics, PROVIDER shall have no obligation to furnish medical, hospital or surgical care to any SCHOOL Project Employee or Student, except as provided herein or at law,

(c)   PROVIDER shall provide initial first aid, initial administration of testing, initial prophylactic therapy, and other emergency treatment on-site, including, but not limited to, immediate evaluation for risk of infection of SCHOOL Project Employee or Student in the event of a needlestick injury to or other exposure of Student to blood or body fluids or airborne contaminants. SCHOOL shall provide appropriate follow-up care of the SCHOOL Project Employee or Student. In the case of suspected or confirmed exposure to the human immuno-deficiency virus (HIV) or hepatitis, such initial first aid, initial administration of testing, initial prophylactic therapy, and emergency care by PROVIDER, and appropriate follow-up care by SCHOOL, shall be consistent with the current guidelines of the Centers for Disease Control and Prevention ("CDC") and the community's standard of care. Information regarding the CDC may be obtained by calling (800) 342-2437. The initial first aid, initial administration of testing, initial prophylactic therapy, and other emergency care provided by PROVIDER shall be paid for by SCHOOL. All subsequent administration of testing, prophylactic therapy, and other required care and treatment shall also be paid for by SCHOOL.

5.   STATUS OF SCHOOL AND PROVIDER

It is expressly understood and agreed that this Agreement is not intended, and shall not be construed, to create the relationship of agent, servant, employee, partnership, joint venture or association between SCHOOL and PROVIDER, but is rather an agreement by and between independent contractors, these being SCHOOL and PROVIDER.

6.   STATUS OF SCHOOL PROJECT EMPLOYEES OR STUDENTS.

It is expressly agreed and understood by SCHOOL and PROVIDER that the SCHOOL Project Employees and Students under this Program are present at PROVIDER Clinics for the provision of patient care clinical pharmacy services only, and such SCHOOL Project Employees or Students shall not be considered employees of PROVIDER for any purpose including, but not limited to, compensation for services, employees' welfare and pension benefits, fringe benefits of employment or workers' compensation insurance. SCHOOL shall ensure that each SCHOOL Project Employee and Student understand his or her status hereunder.

7.   INDEMNIFICATION & LIMITATION OF LIABILITY.

Each party hereby agrees to indemnify, hold harmless and defend the other party and the other party's officers, directors, employees, independent contractors, agents, Students and representatives insofar as it may legally do so, from and against all liability, damages, costs, (including attorneys' fees), expenses or payment of any sum or sums of money due to any person whomsoever on account of claims, suits, liens, garnishments, attachments, costs, attorneys' fees, costs of investigation and of defense (collectively "Claims") growing out of or allegedly growing out of injuries to persons, including death, or damage to property arising from any negligent act or omission of the indemnifying party or its officers, directors, employees, independent contractors, agents, Students or representatives, and for any Claims in any way attributable to employment practices or conduct or Student discipline (including, but not limited to, any practices or conduct which are or are alleged to be in violation of any statute, common law, regulation, policy, or administrative interpretation or guide concerning wage and hour practices, health and safety, workers' compensation, employment discrimination, payroll taxes, labor relations, wrongful discharge, tortious conduct, breach of the employment relationship, whether based on oral, written, or implied contract including breach of any collective bargaining contract to which such party is bound or any other aspect of employment whatsoever) or the performance of this Agreement.

Notwithstanding anything to the contrary contained herein, to the maximum extent permitted by law, in no event will either party be responsible for any incidental, consequential, indirect, special, punitive, or exemplary damages of any kind, including damages for lost goodwill, lost profits, lost business or other indirect economic damages, whether such claim is based on contract, negligence, tort (including strict liability) or other legal theory, as a result of a breach of any warranty or any other term of this Agreement, and regardless of whether a party was advised or had reason to know of the possibility of such damages in advance.

8.   INSURANCE.

(a)   SCHOOL shall maintain in full force and effect insurance coverage written by outside carrier(s) , self-insurance [under the self-insurance program administered by the Office of the California Attorney General] or a combination thereof to cover comprehensive general liability for SCHOOL's employees, agents and Students, while at PROVIDER. In the event such coverage is written by an outside carrier, it shall be maintained at levels of not less than One Million Dollars ($5,000,000) per occurrence and Five Million Dollars ($5,000,000) annual aggregate. (See attached Certificate of Coverage held by SCHOOL (*attach certificate*)).

(b)   SCHOOL shall at all times carry Workers' Compensation insurance on behalf of its employees, including its faculty, and shall indemnify and hold PROVIDER harmless from and against any and all Workers' Compensation claims filed by any SCHOOL employee from any incident occurring or arising from participation in Program.

(c)   Prior to the commencement of the term of this Agreement, SCHOOL shall submit to PROVIDER Certificate(s) of Insurance [or evidence of a funded self-insurance program], in a

form acceptable to PROVIDER, indicating that SCHOOL has adequate liability coverage and Workers' Compensation insurance. Each such insurance policy shall provide that the insurance company will not cancel nor materially modify SCHOOL's insurance policy without giving PROVIDER thirty (30) days' advance written notice. The Certificate of Insurance [or evidence of a funded self-insurance program] and any renewal or replacement thereof shall be sent to:

> ZZZ Healthcare Services (*insert name and address)*
> 1234 Main Street
> Los Angeles, CA, 90909

9.   MISCELLANEOUS.

   (a)   Notice. Any notice or other communication hereunder must be given in writing to the address set forth below and either: (i) delivered in person; (ii) sent by telefax provided that any notice so given is also mailed as provided in subsection (iv) herein; (iii) delivered by Federal Express® or similar commercial delivery service; or (iv) mailed by certified mail, postage prepaid, return receipt requested, to the party to which such notice or communication is to be given at the address set forth below. Each such notice or other communication shall be effective: (i) if given by telecommunication, when transmitted; (ii) if given by mail, three (3) days after such communication is deposited in the mail and addressed as aforesaid; (iii) if given by Federal Express® or similar commercial delivery service, three (3) business days after such communication is deposited with such service and addressed as aforesaid; and (iv) if given by any other means, when actually delivered at such address:

If to SCHOOL:	University of YYY (*insert name*) School of Pharmacy
	Address *(insert address)*
	City, State, Zip Code
	Attention: (*insert contact name*)
If to PROVIDER:	ZZZ (*insert name)*
	Address (*insert address*)
	City, State, Zip Code
	Attention: (*insert contact name*)

   (b)   Compliance with Law. SCHOOL agrees and shall notify its SCHOOL Project Employees and Students of the requirement to agree to comply with all applicable federal, state and local laws, regulations, ordinances and orders with respect to the performance of the services to be rendered in accordance to the grant.

   (d)   Governing Law. The validity, interpretation and performance of this Agreement shall be governed by and construed in accordance with the laws of the State of California. Venue shall be in _____ (*insert name(s)*) County/ies.

(e)   No Waiver. Any waiver of any agreed to terms and conditions hereof must be in writing, and signed by the parties hereto. A waiver of any of the terms and conditions hereof is not to be construed as a waiver of any other terms and conditions hereof.

(f)   Entire Agreement. This Agreement contains a full and complete expression of the rights and obligations of the parties and it shall supersede all other agreements, written or oral, heretofore made by the parties. This Agreement may be modified only in writing, signed by the parties hereto.

(g)   Interpretation. Ambiguities, if any, in this Agreement shall be reasonably construed in accordance with all relevant circumstances including, without limitation, prevailing practices in the industry of the parties in the place where the contract is to be performed and shall not be construed against either party, irrespective of which party may be deemed to have authored the ambiguous provision.

(h)   Force Majeure.

(i)   Neither party hereto shall be liable for any delay or failure in the performance of any obligation under the Agreement or for any loss or damage (including indirect or consequential damage) to the extent that such nonperformance, delay, loss or damage results from any contingency which is beyond the control of such party, provided such contingency is not caused by the fault or negligence of such party. A contingency for the purposes of this Agreement shall be Acts of God, fire, explosions, storms, wars, hostilities, blockades, public disorders, quarantine restrictions, embargoes, strikes or other labor disturbances, and compliance with any law, order or control of, or insistence by any governmental or military authority.

(ii)   The party claiming to be affected by such contingency shall give immediate notice to the other party, giving full particulars thereof, and all such contingencies shall, as far as is reasonably possible, to be remedied with all reasonable efforts and dispatch. The existence of such contingencies shall justify the suspension of performance hereunder by either party and shall extend the time for such performance for a period of delay; provided, however, that if such period of delay shall exceed sixty (60) days from the date of such notice, either party shall have the right to cancel this Agreement.

(i)   Severability. If any part of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable the remaining provisions will nevertheless continue in full force and effect.

(j)   Authority. Each party executing this Agreement hereby represents and warrants that he or she has full authority to enter into this Agreement and to bind the party upon whose behalf such individual has executed this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives as of the date first written above.

PROVIDER: ZZZ CORP. *(insert name)*

By: _____
       Signature

_____
       Printed Name

_____
       Title

_____
       Date

SCHOOL: UNIVERSITY OF YYY SCHOOL OF PHARMACY (*insert name*)

By: _____
       Signature

_____
       Printed Name

_____
       Title

_____
       Date

Appendix F. California Schools of Pharmacy

American University of Health Sciences School of Pharmacy
http://www.auhs.edu/school-of-pharmacy/

California Northstate University College of Pharmacy
http://pharmacy.cnsu.edu/

California Health Sciences College of Pharmacy
http://chsu.org

Chapman University School of Pharmacy
http://www.chapman.edu/pharmacy/index.aspx

Keck Graduate Institute (KGI) School of Pharmacy
http://pharmacy.kgi.edu/

Loma Linda University School of Pharmacy
http://www.llu.edu/pharmacy/index.page

Marshall B. Ketchum University College of Pharmacy
http://www.ketchum.edu

University of the Pacific Thomas J. Long School of Pharmacy and Health Sciences
http://www.pacific.edu/Academics/Schools-and-Colleges/Thomas-J-Long-School-of-Pharmacy-and-Health-Sciences/Academics/Doctor-of-Pharmacy.html

Touro University California School of Pharmacy
http://cop.tu.edu/

University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences
http://pharmacy.ucsd.edu/

University of California San Francisco School of Pharmacy
http://pharmacy.ucsf.edu/

University of Southern California School of Pharmacy
http://pharmacyschool.usc.edu/

Western University of Health Sciences
http://www.westernu.edu/pharmacy/

West Coast University School of Pharmacy
http://pharmacy.westcoastuniversity.edu/

Appendix G. University of Southern California/AltaMed Health Services "Change Package"

Although the University of Southern California (USC) School of Pharmacy has decades of experience with integrated clinical pharmacy services, many new lessons were learned in initiating and managing the Health Care Innovation Award (HCIA), particularly because of the changing health care landscape and unique attributes of their large safety net partner. The lessons learned from both USC's experience and the HCIA program are described in the CMMI HCIA Program Replication Guide, abbreviated "Change Package." Components of the "Change Package" can be applied to any patient population (e.g., safety net, Medicaid, commercial, Medicare) or practice setting.

To receive information about the CMMI HCIA Program Replication Guide, please contact:

> Steven Chen, PharmD, FASHP, FCSHP, FNAP
> Associate Professor and Chair
> Titus Family Department of Clinical Pharmacy and Pharmaceutical Economics & Policy
> William A. Heeres and Josephine A. Heeres Endowed Chair in Community Pharmacy
> Hygeia Centennial Chair in Clinical Pharmacy
> University of Southern California
> chens@usc.edu
> (323) 442-1393

Appendix H. Methods for Reimbursement of Medication Management Services

Medicare

Medicare is administered by the Centers for Medicare and Medicaid Services (CMS). Federally recognized health care providers who may bill Medicare Part B for patient care services are outlined by the Social Security Act. According to the Social Security Act, pharmacists can provide the following: immunization, durable medical equipment, diabetes education services, and Medication Therapy Management services.[279]

Support of pharmacist-delivered direct patient care, such as CMM, would be achieved through the recognition of pharmacists as health care providers under the Social Security Act Title 18, Part E, Section 1861 "Pharmacists; Pharmacist-Delivered Patient Care Services."[280] Nationally, there is a 2015-2016 Congressional campaign to recognize pharmacists as health care providers with the introduction of HR 592 (Guthrie) and S 314 (Grassley) "Pharmacy and Medically Underserved Areas Enhancement Act" which amends title XVIII of the Social Security Act to provide Medicare coverage of pharmacist services."[281,282]

Medicare recognizes pharmacist-led medication management services as part of the Medicare Part D benefit.[283] For this service, Current Procedural Terminology (CPT) codes are used are classified in to three categories: "initial", "follow up," and "additional" each in 15 minute increments (Appendix I, Table 1).[284] However, this model of compensation has been described as inadequate and poorly aligned to CMM.[285] Furthermore, Revenue Value Units (RVUs), a standard metric used to determine reimbursement rates for physicians, are usually not assigned to these codes by payers. Often, time taken by pharmacists to complete CMM (including preparation for the consultation, delivery of the service, and follow up for the intervention) is much greater than the amount allocated for typical "MTM" reimbursement.[286]

Appendix I, Table 1. Medicare Code Model for Medication Therapy Management Services[287]

Code	Service
99605	Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention if provided; initial 15 minutes, new patient
99606	Initial 15 minutes, established patient
99607	Each additional 15 minutes (Used in conjunction with 99605, 99606)

In addition, 2015 updates from CMS regarding the physician fee schedule clarify that, under chronic care management (CCM) and transitional care management (TCM), physicians can bill Medicare for unsupervised after-hours services provided by nonphysicians (https://www.federalregister.gov/articles/2015/07/15/2015-16875/medicare-program-

revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions#h-160).
Furthermore, the nonphysician provider of these services does not need to be a direct
employee of the medical practice in order to bill incident to a physician's care. Currently the
application of these rules varies state to state and practice to practice depending on
interpretation by states, compliance officers, and plans. Another method of billing Medicare
for CMM is Medicare Annual Wellness Visits (AWV, https://www.cms.gov/Outreach-and-
Education/Medicare-Learning-Network-
MLN/MLNProducts/Downloads/AWV_Chart_ICN905706.pdf), where pharmacists can be
integrated into healthcare teams providing this service. However, CCM, TCM, and AWV require
that pharmacists providing and billing for services be physically integrated into medical
practices, limiting the expansion potential and excluding community pharmacies.

Medicaid

Medicaid, known as Medi-Cal in the state of California, is also administered by CMS. As of
2015, fifteen states offer Medicaid reimbursement for clinical pharmacy services.[288] Examples
of state reimbursement systems can be found through Minnesota and Mississippi.[289] Medi-Cal
does not reimburse for pharmacist-provided direct patient care at this time.

Third Party Payers

Third-party payers can independently choose to provide reimbursement for CMM.[290] Typically,
reimbursement will be through either a fee-for-service or a capitation based model. However,
service delivery and coverage will likely vary between payers. Billing for CMM or MTM services
is often attempted through the use of prior authorizations and each payer must be contacted to
determine which CPT code the provider should use. Reimbursement rates will also vary
between providers.

Federally Qualified Health Centers

Federally, pharmacists are not recognized as health care providers; therefore pharmacists are
not able to bill for clinical pharmacy services, including CMM, conducted in federally qualified
health centers. Promising changes are occurring on a national level. Two bills introduced in
both chambers of Congress in early 2015, HR 592 (Guthrie) and S 314 (Grassley), support the
reimbursement of pharmacists by including pharmacists as health care providers under
Medicare Part B.[291] This change in classification requires an amendment of title XVIII of the
Social Security Act to include clinical pharmacist services with those covered by Medicare Part
B.[292]

Alternative Reimbursement Strategies

Indirect third-party billing for CMM services in outpatient prospective payment systems can
also be done using Ambulatory Payment Classification (APC) codes through collaborative

practice agreements.[293] In this case, CMM services fall under "technical/facility fee" or a "professional fee" and payments are made to the physician. To bill for this service, utilize APC codes 600, 601, and 602.[294]

"Incident to" physician services are sometimes used in physician officers to charge for non-physician services. [295] However, these fall under strict criteria and offer a low level of reimbursement (CPT code 99211).[296]

Through the use of Clinical Laboratory Improvement Amendments (CLIA) waived labs, pharmacists are able to provide and receive reimbursement for basic screening services.[297] These include low complexity laboratory tests, including finger sticks for blood glucose or INR. This allows the request for reimbursement of laboratory tests through various payers including Medicare and Medicaid.

Appendix I. Sample Project Evaluation Tool (Logic Model)

The images displayed on pages 67 and 68 can be combined to create a graphic display of a sample Logic Model (see below Appendix I, Figure 1). This model can serve as a template for program planning and evaluation.

Appendix I, Figure 1. Sample Project Evaluation Tool (Logic Model)

Assumption

Comprehensive Medication Management is an evidenced-based service shown to reduce the impact of chronic disease while leading to cost-savings

Underlying Problems/Issues

- Medication use is prolific but medication-related outcomes are often suboptimal
- Over 14 million Californians suffer from chronic diseases
- Medications are a fundamental component of chronic disease management
- Forty-five percent of Californians live in a primary care shortage region
- Providers have less time to address complex patients with multiple chronic conditions

Intended Results

Impact

Promote safe, effective, and appropriate medication use

Demonstrate cost savings (ROI)

Improve institutions' performance on quality measures

Increase patient access to healthcare services

Promote collaborative and multi-disciplinary healthcare delivery

Outcomes

Enroll 6,000 high-risk patients over 3 years

Expand network to include 10 dedicated clinics

Develop well trained clinical pharmacy team at each clinic (pharmacist, pharmacy resident and clinical pharmacy technician)

Decrease annual hospital readmission and acute care utilization of enrollees

Comprehensive Medication Management

Personalize patients' medication regimen based on their medication experience

Coordinate medications from different providers

Optimization of drug-disease state management

Planned Work

Activities

Secure program funding; Seek opportunities for sustained funding (ie. capitation payments, grant funding)

Define program evaluation, metrics and quality improvement measures; Create an evaluation plan

Engage key decision makers (hospital + facility executives)

Partner with physician champions

Resources/Inputs

Supplemental program funding

Outcomes & quality measures aligned with health system priorities

Endorsement from health system leadership and physicians

Physician buy-in

Increase capacity to deliver primary and specialty care

Provide sustainable improvements in patient outcomes

Promote patient empowerment

Provide comprehensive, coordinated care to complex patients

Increase percentage of enrolled patients meeting NQF endorsed chronic disease measures within 6 months

Decrease 30-day inpatient readmission and emergency department visits to at or below national average

Achieve patient and provider satisfaction scores of at least 4.5/5

Challenges

- Inadequate pharmacist and clinical pharmacy team reimbursement infrastructure
- Communication & transparency of health information
- Insufficient outcomes tracking
- Maintenance of sustained patient participation
- Consumer and physician awareness of clinical pharmacy practice
- Adequate support staff and space with privacy to provide CMM
- Pharmacist time and workflow adaptability

Establish access to the electronic health record beyond medication-related information

Create collaborative practice agreement

Hiring staff (pharmacist, clinical pharmacy technician, medical assistant); Demonstration of CMM competency

Develop algorithm or integrated referral system to systematically identify high-risk patients

Design and implement referral system, clinic workflow, and follow-up; Schedule regular leadership and team meetings to identify and address problem areas

Design and implement a public relations campaign

Health information exchange

Collaborative practice agreement

Defined and trained clinical pharmacy team

Surveillance system to identify high-risk patients

Developed and dynamic clinic workflow

Disseminate success of outcomes (qualitative and quantitative results)

Environmental Considerations

- Institutional and community support of pharmacist-delivered services
- Integrated electronic health system

Appendix J. Targeting Comprehensive Medication Management: Patient Identification Algorithm

The integrated algorithm used to systematically identify high-risk and/or high-cost patients developed through the USC/AltaMed CMMI grant has been provided for this manuscript.

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Appendix K. California Wellness Plan Goal 2 Comprehensive Medication Management Statewide Implementation Work Group 2015-2016

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Appendix L. Additional Case Study Information

Appendix L. 1.1 University of Southern California (USC) School of Pharmacy/ AltaMed Health Services

USC School of Pharmacy was awarded $12 million by the Centers for Medicare and Medicaid Services Innovation Center (CMMI) to evaluate the impact of clinical pharmacy services on the Triple Aim measures of health care quality, individual care experience, and overall health care costs over three years.

USC School of Pharmacy partnered with USC Schaeffer Center for Health Policy and Economics to implement clinical pharmacy services at ten large clinics centralized in Los Angeles and Orange County and operated by AltaMed Health Services. AltaMed Health Services is the largest Federally Qualified Health Center in U.S. and serves mainly Latino populations vulnerable to health disparities and access issues through a network of more than 40 clinics. AltaMed services include primary care, dental, pediatric, women's health, HIV, and Program of All-Inclusive Care for the Elderly (PACE). Of 10 clinics with integrated clinical pharmacy services, two are PACE clinics that enroll high risk elderly patients eligible for nursing homes. After three years, the USC School of pharmacy expanded pharmacy services to include video telehealth at two other AltaMed clinic locations.

Practice Support

Each clinical pharmacy team consists of a clinical pharmacist, a pharmacy resident, and a clinical pharmacy technician. USC School of Pharmacy employed a total of eleven pharmacists that are highly trained through pharmacy residency and qualified to provide CMM. All clinical pharmacists are residency-trained specifically in establishing and providing CMM in safety net clinics before they were recruited for the program. Most pharmacists pursued and obtained certifications, such as CDE and/or BCACP during the duration of the program.

Role of Pharmacist

Pharmacists provide CMM with full prescriptive authority under a collaborative practice agreement established between USC School of Pharmacy and AltaMed Health Services. During each patient visit, pharmacists evaluate medication therapy for its appropriateness, effectiveness, and safety as well as considering the patient's attitude and behavior toward drug treatments. Pharmacists interview patients, provide physical assessments, order and monitor laboratory tests, and identifying medication-related problems. Pharmacists are authorized to modify treatment regimens, order medications, and provide education to patients on self-management, treatment regimens, disease states, and medication adherence. Additionally, pharmacists are responsible for documenting their findings, assessments, and plans. The documentation is forwarded to patient's primary care provider for review. In the program,

pharmacists typically follow-up with patients more frequently than primary care providers. Follow-up ranges from every one to four weeks depending on the severity of conditions and until treatment goals are met.

Role of Clinical Pharmacy Technician

The USC School of Pharmacy developed specific roles for clinical pharmacy technicians in their CMM delivery model. By integrating clinical pharmacy technicians, pharmacists are able to focus on the cognitive aspects of CMM and to increase efficiency and productivity during daily patient visit. Examples of clinical pharmacy technicians' roles include obtaining the patients' medication history (including prescription, over-the-counter drugs, supplements, and herbals), providing medication adherence tools (pill boxes), actively recruiting patients for CMM, managing and scheduling patient appointments, managing a Patient Assistance Program, providing medication education reinforcement, and conducting follow-up with patients after their treatment goals have been reached. Clinical pharmacy technicians are trained using a combination of didactic and hands-on sessions, developed also by USC School of Pharmacy. A total of eleven pharmacy technicians have been training using these methods.

Target Population

In order to delivery CMM efficiently and produce the maximum impact, USC School of Pharmacy created strategies to target high-risk and/or high-cost patient populations for CMM by developing patient identification algorithms (see Appendix J). These algorithms are created to identify patients with poorly controlled chronic diseases such as diabetes, hypertension, dyslipidemia, heart failure, and/or COPD/asthma, and patients who may be at risk for a drug-related problem such as those with multiple medications, those receiving high-risk medications, or those with adherence problems. These algorithms are embedded into the electronic medical record to generate monthly reports, which are reviewed by the clinical pharmacy technicians. Emergency or hospitalization discharge reports are also used to identify high-risk patients with potentially preventable admissions. Additionally, patients are referred for CMM services by other health care providers.

Results

The outcome measures on the impact of pharmacy-led CMM include medication-related quality of care, medication safety, acute care utilization, medical, lab, and pharmacy expenditures, patient access to health care services, and patient and physician satisfaction. Over a three year period, more than 6000 high-risk patients with uncontrolled chronic diseases and frequent use of hospital and emergency care have been enrolled in CMM. Patient enrolled in CMM were compared to a control group. The control group was selected from AltaMed clinics that do not have integrated clinical pharmacy teams.

In all patients with uncontrolled diabetes (NQF endorsed measure of hemoglobin A1c >9 percent) clinical pharmacy teams improved hemoglobin A1c to below 9 percent in 64 percent of patients within 6 months of period. For comparison, the group that did not receive CMM achieved a hemoglobin A1C of < 9 percent in only 38.2 percent of patients. Future publications on diabetes, blood pressure, lipid management, and anticoagulation are currently being analyzed.[298]

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Appendix L. 1.2 Greater Newport Physicians Ambulatory Care Clinics

Greater Newport Physicians (GNP) employs 4.25 FTE Pharmacists to provide clinical pharmacy services in a Primary Care clinic setting. The development of clinical pharmacy services came from internal physician support as network-physicians desired to incorporate pharmacist-specific expertise in the management of patients on anticoagulants. Eventually, the use of clinical pharmacy services expanded to include other high risk categories and conditions. Currently, CNP has three separate programs where pharmacist-led medication management is a primary focus. The services described are not directly revenue generating, but receive funding through the physician group and have been shown to reduce hospitalizations and emergency department visits.

ACTIVE Diabetes Program

The ACTIVE Diabetes Program is GNP's solution to care for patients with poorly controlled diabetes that are not achieving their treatment goals through traditional methods. The ACTIVE Diabetes Program uses a multidisciplinary team approach. The program employs a referral based system to target patients with consistently, poorly managed diabetes and other medication issues. Clinical pharmacists, through the use of a medication management protocol, provide comprehensive and individualized care. The pharmacist is responsible for

performing the medication review and adjusting medication therapy. Key components of the ACTIVE Diabetes Program include multidisciplinary evaluation, individualized management plans, patient empowerment and goal setting, and follow-up.

The pharmacist works in collaboration with a registered dietitian who assists the patient in developing and following an appropriate meal plan and a social worker who addresses psycho-social issues that may impact their disease. Communication between the team and the primary care physician (and Endocrinologist, if involved) occurs after each visit.

Results

The ACTIVE Diabetes patient population observed an average HgbA1c level drop from 9.8 percent to 7.7 percent in the first 180 days of participation. And while this is a striking achievement, it is important to note the initial entry criteria was targeted at patients with HgbA1c > 9 (representing enrollment of only the most poorly controlled patients). Post intervention results for this population exceed the Integrated Healthcare Association (IHA) 90th percentile for multiple diabetic care measures and this exceeds what most organizations achieve when well controlled patients are included. Advances in blood pressure and cholesterol control were also observed. Blood pressure control and cholesterol control in this population also exceeded IHA 90th percentile results. Clinical improvements included 77 percent of patients reaching low-density lipoprotein (LDL) of under 100 (compared to 63 percent at baseline) and 92 percent of patients reaching a blood pressure under 140/90 (compared to 88 percent at baseline).

Patient satisfaction ratings with all ACTIVE team members were 4.6 out of a 5-point scale. Ultimately, a return on investment demonstrated positive results, with an estimated savings of $90/patient/year when compared to other poorly controlled diabetic patients (i.e., medical cost savings=$1,200/patient/year minus ACTIVE Diabetes program costs=$1,110/patient/year).

Anticoagulation Center

Anticoagulation Centers play an important role in managed care as they reduce emergency department visits, inpatient admissions and readmissions. Additionally, the Anticoagulation Centers coordinate care between all specialties. Care coordination is critically important given the unpredictability of how patients may respond to treatment with anticoagulants. GNP utilizes the expertise of ambulatory care trained clinical pharmacists with over thirty years of hands on experience in anticoagulation management. These pharmacists meet face-to-face with the patient, assessing the patient's medications and their risk of bleeding, ordering labs, and adjusting the patient's medications.

Results

Efforts of the Anticoagulation Center have led to 53 percent fewer inpatient admissions and 41 percent fewer emergency department visits for anticoagulation-related events compared to a

cardiology-managed cohort. Both physician and patient satisfaction were high (4.77 and 4.9 out of 5.0 points).

Special Care Center

In the post discharge clinic, known as the Special Care Center, the pharmacist is an integral part of a multidisciplinary team and is responsible for the medication review and medication reconciliation from all the patients' providers. The pharmacist collaborates with other members of the health care team including a hospitalist, a case manager, and a clinical social worker. Common medication related issues addressed by the pharmacist include duplications of therapy, omissions of therapy, incorrect doses, and drug interactions that might have resulted in readmission or other complications.

Results

Special Care Center pharmacists have demonstrated their efficacy in preventing medication errors. Through the use of pharmacist-led medication reconciliation, the Special Care Center identified a 68 percent discrepancy rate between the discharge medication list and what the patient was actually taking. A quarter of senior patients were taking medications to be avoided in the elderly. Almost 20 percent of patient reviewed had medication regimens with actual drug-drug interactions and 51 percent requiring intervention were for high-risk medications (i.e., antiplatelets, anticoagulants, and insulin). The 30-day readmission rate for participating seniors is 60 percent lower than the national average. Overall, patient satisfaction scores averaged 4.85 out of 5.0 points.

Appendix L. 1.3 University of California San Diego Health System

Practice Support

At UCSD there is a total of 5.5 full-time-equivalent (FTE) pharmacist support for the pharmacist-managed Transitions of Care (TOC) program. The program also includes two post-graduate-year-two (PGY2) pharmacy Transitions of Care residents that were established as part of the first nationally accredited ASHP PGY2 Residency in Transitions of Care. In addition, post-graduate-year-one (PGY1) pharmacy residents specializing in acute and ambulatory care delivery and pharmacy students support the TOC program. All pharmacists in the TOC program are residency trained and are BCPS or BCACP certified.

Target Population

Patients are identified through two mechanisms. The first mechanism uses the pharmacist to identify and classify patients as high-risk based on specific characteristics (Appendix L. 1.3. Table 1). These patients are automatically enrolled in the program once identified by the pharmacist. The second mechanism is through the CCTP program. The CCTP program targets high-risk Medicare fee-for-service patients only. Patients are identified by a transition nurse

specialist and referred for a pharmacy intervention if they are on eight or more chronic medications and/or on a high-risk medication. Additionally, physicians can refer patients to the program if they deem a patient high risk.

Appendix L. 1.3 Table 1. Pharmacist-Managed Transitions of Care Program Target Patient Populations

High Risk Disease States	Risk Factors

• Heart failure
 • Solid organ transplant
 • Human immunodeficiency virus (HIV)
 • Acute thrombosis/Deep Vein Thrombosis /Pulmonary Embolism
 • Bone marrow transplant
 • Diabetes
 • COPD/Asthma
 • Chronic kidney disease
 • Acute kidney injury
 • Pneumonia
	• **Polypharmacy**
	   o More than 8 medications
	 • **High risk medication use**
	   o Insulin
	   o Oral hypoglycemic agents
	   o Warfarin
	   o Other anticoagulants
	   o Antiplatelet agents
	   o Anticonvulsants

Medication Reconciliation and Comprehensive Medication Management Delivery
Upon admission, medication reconciliation is performed and the patient is screened for non-adherence or other medication-related issues. During the patient interview, the outpatient/dispensing pharmacy and primary caregiver is identified to aid in patient acquisition of medications and medication education at discharge. Further, during the patient interview, the pharmacist assesses if the patient has barriers to medication use, for example, medication access (insurance issues) or health literacy.

The pharmacist medication management intervention continues throughout admission, at discharge, discharge counseling and post discharge. During the admission, the pharmacist is involved in interdisciplinary rounds to advocate for appropriate, safe, and effective medication use. The pharmacist also makes initial efforts to educate the patient/caregiver on anticipated discharge medications.

The post-discharge, follow-up care is comprised of a phone call within 72 hours and/or clinic visit within 7 days of discharge. The UCSD Health System transitions of care model is comprehensive and unique in that the pharmacist will continually follow the patient from the day of admission to approximately 30 days post discharge. Select patients are followed past the 30 day-mark based on the discretion of the pharmacist. Physicians can also request additional or closer follow up post discharge.

Health Information Exchange

Communication with patients includes telephone calls and clinic visits as mentioned above. Patients are given a dedicated phone number for the TOC pharmacist for any medication issues or concerns. All patient interactions are documented by the pharmacist, whereby communication to other healthcare providers occurs through the electronic medical record. If the patient does not routinely have their care provided within the UCSD system, progress notes are faxed to the primary care or other appropriate provider.

Results

In the heart failure population, pharmacists averaged one clinical intervention per patient. Interventions occurred 78 percent of the time during their inpatient stay while 22 percent of the interventions occurred during post discharge follow-up. The majority of the clinical interventions pertained to dose/frequency adjustment, untreated diagnosis/medication omission, and facilitation of outpatient drug therapy. The average time spent per patient performing the transitions of care workflow was 77 minutes; not including time spent rounding or coordinating with the inpatient interdisciplinary team.

Unless otherwise stated, results reported above and in Section 6.3 University of California San Diego Health System were derived from the first piloted program, focused on UCSD Health System's heart failure patient population. Collected data included clinical interventions, readmission rate information, time it took the pharmacist to perform activities, and cost avoidance associated with the clinical interventions. Of note, these clinical interventions were only collected for the pharmacist performing transition-of-care activities. Transition-of-care activities include admission medication reconciliation, discharge medication reconciliation, discharge counseling, and post-discharge follow-up.

Appendix L. 1.4 GEMCare Medical Group, Inc.

GEMCare Health Plan and GEMCare Medical Associates, both located in Bakersfield California, have utilized the expertise of Advance Practice Pharmacists (APP) for many years. In 2009, GHP worked with FrontLine Pharmacy Consulting Inc. to address their ballooning Medicare Advantage Prescription Drug pharmacy budget. FrontLine Pharmacy Consulting Inc. collaborated with GEMCare Health Plan, GEMCare Medical Associates and their pharmacy benefits manager to re-tool their formulary into a quality driven formulary and implement direct patient care activities through a Medication Therapy Management Program. The robust outcomes (ROI = 1100 percent) and patient satisfaction led to the development and integration of the APP with full prescriptive authority through a collaborative practice agreement into a Level III National Committee for Quality Assurance (NCQA) certified Patient Centered Medical Home (PCMH) known as the "Comprehensive Care Center".

The Comprehensive Care Center (CCC) was piloted in April 2010 with 30 high risk patients that were identified using a predictive modeling algorithm. The CCC has now grown to approximately 500 patients. The APP integrated into the CCC team is a triple board certified [BCPS, Certified Geriatric Pharmacist (CGP) and CDE] and residency trained pharmacist with 10 years of direct patient care experience.

A collaborative practice agreement grants the APP full prescriptive authority to manage the pharmacotherapy regimens for diabetes, hypertension, dyslipidemia, COPD, asthma, heart failure, anticoagulation, and many other conditions. GEMCare Health Plan and GEMCare Medical Associates in with collaborating with other organizations are currently expanding this mode to improve population management.

Practice Support

The multidisciplinary NCQA certified Patient Centered Medical Home with an APP includes:

- Physician (Internist and gerontologist),
- Mid-Level Provider- Nurse Practitioner (NP)
- Pharmacist Provider- Advance Practice Pharmacist (APP)
- Case Management
- Social Services
- Integrated Behavioral Health
- Medical Assistants (MA)
- Palliative Care
- Health Educator

Patient Identification and Referral

The population served include high-risk Medicare beneficiaries identified using a predictive modeling algorithm. Eligible patients are identified using predictive modeling software that assigns each patient a risk score using 200 variables collected over the previous 12-24 months.

The patient's primary care provider is contacted by the health plan and offers the clinic's services to help manage the patients. If primary care provider agrees, the case manager team then contacts the patient to schedule appointment an initial appointment. The first visit is with physician or nurse practitioner who reviews the patients past medical history along with acute conditions and properly documents their Hierarchical Condition Categories (HCC) score to initiate a care plan for the team. An appointment will be made with the APP prior to the next primary care provider visit. During their visit with the APP, the pharmacist will review and adjust the care plan as they see fit, initiate disease management and education, and schedule follow-up appointments as needed to achieve acute and chronic patient centric goals. The

patient maintains primary care provider follow-up as determined necessary by the primary care provider.

Visits and Follow up

The pharmacist is co-located with the medical doctor and nurse practitioner, with whom they share the same office and visiting rooms. Continual follow-up occurs depending on the individual patient's risk, acuteness of disease, chronic disease control and other confounding issues that may increase or decrease risk level. At a minimum the pharmacist will have face-to-face visits every 6 months. Typically, face-to-face visits account for 90 percent of the pharmacist-patient interactions. Telephone appointments are also used for managing medication-related issues and follow-up.

Payment for Services

The clinic is fully funded by the Medicare Advantage Prescription Drug plan (GEMCare), with private pay accounting for less than 10 percent of the services. Additional funding is realized through increased CMS reimbursement due to improved sickness scoring (Hierarchical Condition Categories) and the success in reaching the quality measures. The pharmacist is reimbursed directly by the Medical Group. The Medical Group is not reimbursed for pharmacist visits (i.e. CPT codes) by the health plan. The health plan does pay for the pharmacist salary indirectly through clinic funding.

Results

Initially, a Medication Therapy Management (MTM) program, provided by FrontLine Pharmacy Consulting, addressed formulary redesign and quality improvement initiatives. The MTM program successfully reduced pharmacy costs ($600,000 in medication cost savings in 305 patients) and overall health care costs (per-patient-per-month) by approximately 20 percent. Hospital admissions were reduced by nearly 40 percent, readmissions were reduced by 32 percent, and emergency room visits were reduced by approximately 30 percent. Cost savings in these three outcomes resulted in increased health plan reimbursement while simultaneously demonstrating high physician and patient satisfaction scores.

Following the integration of an APP into the Comprehensive Care Clinic the following benefits were realized.

Appendix L. 1.4 Table 1. Economic, Utilization and Medical Outcomes of Patients in the Comprehensive Care Clinic Compared to Baseline in 2013

Outcome	Result
Economic Outcomes 2013	
Overall Health Care Cost PMPM[#]	Decreased 19.16%
Utilization Outcomes	
Admissions/1000	Decreased 38%
Re-admissions/1000	Decreased 32%
Emergency department visits/1000	Decreased 29%

#PMPM= per member per month

Appendix L. 1.4 Table 2. Chronic Care Measures of Patients Managed in the Comprehensive Care Clinic in 2013

Chronic Care Measures	Quartile
HgbA1C Done	Best
HgbA1C < 9%	Best
LDL Done	Best
LDL <100 mg/dl	Middle
Microalbumin Done	Best

Appendix L. 1.4 Table 3. Comprehensive Care Clinic 2014 Patient Satisfaction Survey

Access to Care	Patient Centeredness	Team Support	Willingness to refer family or friends
4.8/5	4.8/5	4.8/5	4.9/5

Appendix L. 1.4 Table 4. Primary Care Quality Scorecards in 2013 for Patients Managed by the Comprehensive Care Clinic compared to Patients within the Health Plan Managed by their Primary Care Provider in the Independent Physician Association

	IPA[#]-Patients	CCC[*]-Patients	CCC Quartile[+]
Risk Stratification			
Average Demographic Factor[++]	0.467	0.502	Best
Average HCC[β]	0.591	1.503	Best
Average RAF[¥]	1.082	2.162	Best
Hospital Admissions			
Adjusted admissions/1000	25	181	Best
Emergency Department Visits			
Adjusted visits/1000	406	258	Best

[#] IPA = Independent Physician Association

[*] CCC= Comprehensive Care Clinic

[+]Quartile = Data values are the three points that divide the data set into four equal groups, each group comprising a quarter of the data; CCC Quartile = CCC compared to all other IPA providers (approximately 50 providers)

[++] Average Demographic Factor = Assessment of demographic factors (age, gender, etc.)

[β]HCC = Hierarchal Condition Category (disease and payment score)

[¥]RAF = Risk Adjustment Factor (sickness score)

Appendix L. 1.5 Sharp HealthCare

Sharp HealthCare is an integrated healthcare delivery system based in San Diego, California. The system includes four acute care hospitals, three specialty hospitals, two affiliated medical groups, a health plan, and extended outpatient services in a variety of areas including home healthcare and skilled nursing.

Sharp HealthCare, in collaboration with Touro University College of Pharmacy, established the Continuum of Care Network (CNN) in 2011. The CNN was Sharp Healthcare's solution to the provisions of the Patient Protection and Affordable Care Act of 2010, which called for system-wide initiatives to reduce hospital readmissions and realign payments with the quality of care delivered. The three pharmacist-led CMM programs at Sharp Memorial Hospital include: the CCN, the CCTP, and "Meds to You."

Comprehensive Medication Management Service Model

The services provided by the CMM team at Sharp Memorial Hospital (SMH) are nearly identical regardless of the program title. In general, CMM services are delivered in four stages: admission; inpatient; discharge; and post-discharge (see Appendix L. 1.5. Table 1). Each stage includes a defined set of services.

Continuum of Care Network (CNN)

The CNN at SMH was developed as a result of collaboration with Touro University College of Pharmacy. Lead by a clinical pharmacist faculty, the CNN utilizes pharmacy residents and pharmacy students to impact readmission rates at SMH. The traditional focus of the program has been in providing CMM services for heart failure patients and physician referrals.

Although still rooted in readmission reduction, published data showing the benefits of the CNN resulted in an evolution of CMM service delivery in SMH. Currently, a number of studies are underway through the CCN to better understand the patient care, medication related, and clinical characteristics that contribute to readmission. The goal is to better identify the patient population that will benefit from CMM services to have a greater impact on overall health and readmission rates. CCN is poised to expand services to target COPD patients in August of 2015 and further expansion into the trauma and psychiatric populations in 2016.

Results

Published results of pharmacist efforts as part of the CNN are available.[299] These results reflect the impact of a single pharmacist on heart failure readmission rates and improved discharge coordination and patient education.

When compared to those not enrolled, heart failure patients enrolled in the CCN had a lower all-cause 30-day readmission rate (12 percent vs. 24 percent, p=0.005). Additional results of

the study included the heart failure core measure 1 compliance rate, which requires "heart failure patients discharged home with written instructions or educational material given to patient or caregiver at discharge or during the hospital stay [to] address all of the following: discharge medications, activity level, diet, follow-up appointment, weight monitoring, and what to do if symptoms worsen." Over the course of the study the heart failure core measure 1 compliance rate improved from the 80th to the 90th percentile (p=0.004). The top three pharmacist interventions included: discharge counseling (74.1 percent); providing a MedActionPlan[TM] (68.5 percent); resolving discrepancies identified during the medication reconciliation (64.8 percent).

Appendix L. 1.5 Table 1. Sharp Memorial Hospital Comprehensive Medication Management Services Model

Stage of Care	Service Delivered
Admission	• Patient selection and enrollment • Home medication documentation
Inpatient	• Daily inpatient rounds • Inpatient medication reconciliation • Daily profile review and therapeutic recommendations • Anticipate discharge issues
Discharge	• Discharge medication reconciliation • Discharge prescription review • Bedside delivery of prescription medications • Patient education and counseling • Assist with placement and access issues
Post-discharge	• Follow-up phone call for select patients • Follow-up home visit by nursing health coach

Community-based Care Transitions Program (CCTP)

In 2014, Sharp Healthcare became one of seventy-two participating sites in the nation involved in the CCTP. CMM services for CCTP focus on high-risk Medicare fee-for-service patients. Priority is given to individuals with high-risk disease states prone to penalties, those with new unstable disease states, those with polypharmacy issues, those with high-risk medications, or those with a documented medication related admission. This program utilizes the Coleman model and involves two main interventions: a nursing health coach and CMM pharmacy services.[300]

Meds to You

The "Meds to You" program, currently in a pilot phase at Sharp Memorial Hospital, is a new medication access program being implemented at Sharp HealthCare. The intervention is

focused on acquiring and delivering prescription medications to patients upon discharge. This not only improves patients' access to medications, but is an additional opportunity to address medication-related questions with a pharmacist prior to discharge.

Resources

As the flagship facility of the Sharp Healthcare network, SMH boasts the most diverse array of Medication Management services within the health system. Currently, SMH employs a mixed funding model for providing medication management services to patients. The CCN, which focuses on heart failure patients and physician referrals, is funded through an established partnership with Touro University College of Pharmacy with one (1 FTE) Clinical Faculty and one (1 FTE) PGY2 Pharmacy Resident. The CCTP, which focuses on high-risk Medicare patients, utilizes one FTE Clinical Pharmacist. Pharmacist reimbursement in the CCTP is achieved through the CCTP grant initiative.

Clinical pharmacy technicians play an essential role in the delivery of pharmacy services, including CMM. Clinical pharmacy technicians are responsible for verifying and documenting home medications, identifying and informing front line staff of discrepancies between the inpatient orders and home medication lists, and collaborating with clinical pharmacists. Currently SMH provides funding for 3.5 FTE Clinical Pharmacy Technicians working in concert with the CMM programs. Additional technician support is provided through the Sharp Healthcare Patient Assistance Program, in which pharmacy technicians assist patients with medication access issues.

Training

All pharmacists involved in CMM at SMH are residency trained. Many pharmacists are board certified or are in the process of obtaining board certification, and the majority has extensive experience with providing inpatient clinical pharmacy services. At SMH, pharmacists providing CMM undergo a rigorous internal certification process that involves three phases. The first phase includes one-on-one training with a certified pharmacist. In the second phase, the pharmacist must demonstrate the ability to successfully discharge a predisposed number of patients. The third phase includes a three-step clinical, multimodal examination.

Pharmacy technicians also participate in an internal structured training and certification. Clinical pharmacy technicians' are periodically audited to ensure accuracy and efficiency. Additionally, ongoing medication education is provided to the technicians by pharmacists to enhance knowledge and improve accuracy of home medication documentation.

Health Information Exchange

Sharp HealthCare utilizes an integrated electronic medical record that allows for instantaneous communication between services throughout the health system. All inpatient CMM services at

SMH rely heavily on in-person, verbal communication between the various healthcare providers and the patients at bedside. Telephonic communication is often used as an alternative. In addition, written health information and education is provided to the patient at discharge. Additionally, each patient's primary care provider receives an electronic and written summary of the inpatient course post-discharge.

Patient Identification

Patient identification methods vary depending on the program. For the CCN, heart failure patients are identified via an integrated, automated screening tool that utilizes clinical and medication-related variables. This tool was developed through a collaboration of clinical pharmacists and information technology specialists and has replaced the original method that used nursing notifications. Due to the diverse patient population, CCTP patients are identified via a nursing health coach. The nursing health coach refers patients to the pharmacist for CMM services. The "Meds to You" program is still refining the patient identification process, however, initial identification has been performed via a customized patient list developed within the electronic medical record.

Appendix L. 1.6 Kern County Medical Center

On June 3, 2009 Kern Medical Center partnered with Kern Health Systems, a local private insurance company, to develop a multidisciplinary diabetes clinic to meet the overwhelming need for diabetes management within the county. The Kern Medical Center Diabetes Care Clinic utilizes a multi-disciplinary approach to diabetes care. Providers include an endocrinologist; a clinical pharmacist; a nurse practitioner; a registered dietitian; a psychologist; resident physicians and pharmacists. As Kern Medical Center was the only public diabetes clinic in the Kern County, the issue of access to care for the diabetic population was at a critical level. Further, Kern Health Systems was facing a clinical crisis, as many of its patients with diabetes were not well controlled leading to higher downstream costs and poor patient outcomes.

Establishment of the Diabetes Care Clinic has allowed APPs to become the main providers of specialty diabetes care to the Kern County's safety-net and Medi-Cal patients in recent years. The impact of the clinical pharmacists providing direct patient care as mid-level practitioners led to Kern Medical Center winning the 2009 California Health Care Safety Net Institute Quality Leadership Award and the California Society of Health System-Pharmacists 2014 Innovative Practice Award.

In addition to the pharmacist-led Diabetes Care Clinic, Kern Medical Center pharmacy clinics also provide care for other specialty services including: anticoagulation, blood pressure, oncology, pharmacotherapy and refill support, and smoking cessation.

Practice Support

The Kern Medical Center pharmacist-led Diabetes Care Clinic fully leverages the training and expertise of the APPs. Through the use of collaborative practice agreements spanning all providers within the Kern Medical Center facility, APPs have full prescriptive authority to start, stop and adjust medications for diabetes, hypertension, dyslipidemia and diabetic neuropathy. Additionally, pharmacists have the authority to perform patient assessments (foot exams, vitals, etc.), order lab tests, order exams and refer to primary care providers and specialists.

In addition to the APPs the program heavily relies upon pharmacy residents and interns to participate in the provision of care. Throughout the course of the program a core multi-disciplinary team was involved. The general composition of the Diabetes Care Clinic team included:

- One endocrinologist (2006 to 2012)
- Six Advanced Practice Pharmacists
- One Nurse Practitioner
- One Pharmacy Resident
- Two Intern Pharmacists
- Clinic staff including an intake clerk, medical assistants, and registered nurses

Patient Identification and Referral

Through the use of separate collaborative practice agreements, the health plan gives network providers the ability to refer patients for collaborative management through APPs. In addition to provider referrals, patients are able to self-refer of obtain "walk-in" appointments. Additional referrals occur through a screening process of patients in both the hospital and emergency departments.

Visits and Follow up

Patients in the Diabetes Care Clinic are treated for diabetes and its co-morbidities (hypertension, dyslipidemia, and diabetic neuropathy) according to an established protocol. Medications are initiated, adjusted and discontinued in accordance with individual patient needs and the most current evidence. Patients systematically receive verbal and written education through intentionally designed curricula regarding their disease state, healthy lifestyle choices (exercise, diet, foot care, etc.), and medication management. Routine foot exams, vital signs and laboratory testing for all outcomes and organ systems are routinely performed and monitored. Upon purchase, retinal scans will also be routinely provided in clinic. Patients are also referred to specialists as needed for annual screenings and patient care issues (i.e. podiatrist, optometrist/ophthalmologist, endocrinologist, etc.). When urgent health issues outside the scope of practice of clinical pharmacists or nurse practitioners are encountered the supervising physician is consulted.

The total Diabetes Care Clinic volume was estimated at approximately 7,000 clinic visits per year. Typically, patients averaged approximately 4 visits with the APP in the clinic per year. Phone follow-up was a major component of care delivery,

Payment for Services

At the inception of the Diabetes Care Clinic in 2009, over 50 percent of the patients were without insurance. At that time the program was funded via the county safety net program. At this time, Medi-Cal is a major insurer of Diabetes Care Clinic participants. Since Medi-Cal does not recognize pharmacists as mid-level practitioners and Medi-Cal participants securing reimbursement proves challenging.

Outcome Measures

The objective of the pharmacist-led Diabetes Care Clinic is to improve clinical, quality and fiscal outcomes in regards to diabetes and downstream medical costs. Data end points collected include clinical outcomes such as: HgbA1c, LDL, triglycerides, blood pressure, and microalbumin (creatinine). Additional quality assurance measures collected include: trends in medication prescribing, hospital admission, emergency department visits, and cost avoidance of hospitalizations and emergency department visits.

Results

For patients enrolled in the Diabetes Care Clinic from January 2005 to March 2011, patients achieved a mean HgbA1c reduction of 2.3 percent per patient.[301] After a mean treatment length of 267.8 days, 45.1 percent of patients had an HgbA1c of less than 7 percent (see Appendix L. 1.6. Figure 1). HEDIS measure specific to diabetes control was met for 64.8 percent of post-clinic patients (HgbA1c ≤ 8 percent). The mean baseline fasting blood glucose decreased from over 200 mg/dL down to less than 120 mg/dL in over half the programs patients.[302]

Appendix L. 1.6 Figure 1. Kern Medical Center Diabetes Care Clinic Pre- v. Post-Clinic Diabetes Control Results[303]
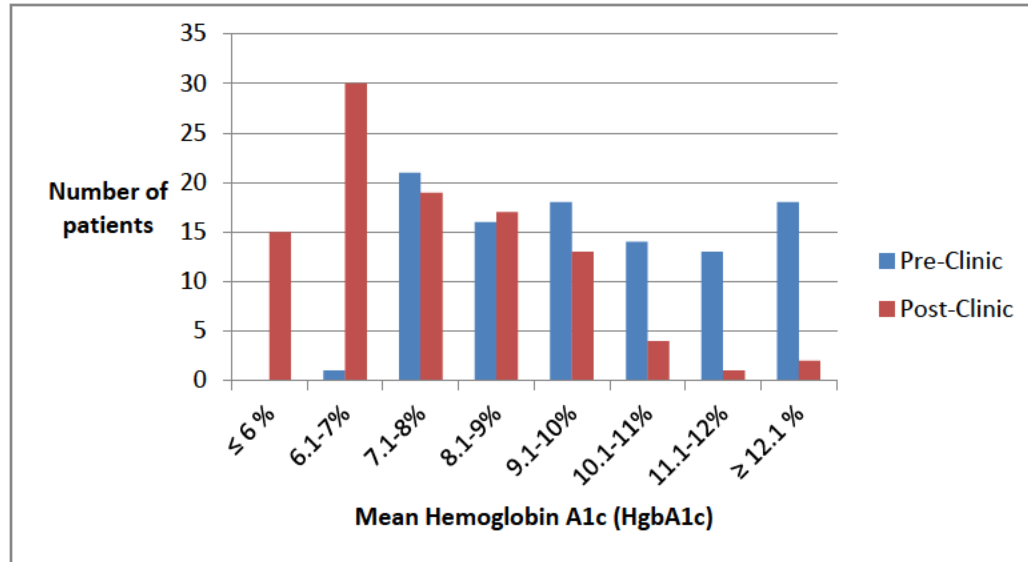
Additionally, statistically significant decreases in LDL, triglycerides, and hospitalizations and emergency department visits related to diabetes were reported. Patient enrolled in the Diabetes Care Clinic were at the blood pressure goal (< 130/80 mmHg) 50.3 percent of the time.[304]

In addition to the Diabetes Care Clinic at Kern Medical Center, pharmacist-led efforts have also led to successful clinical outcomes in other relevant measures. Within Kern Medical Center pharmacists-led services contributed to medication specific outcomes including achieving a therapeutic INR 79 percent of the time and smoking cessation quit rates at three-times the national average.

Appendix M. Comprehensive Medication Management Frequently Asked Questions

What is Comprehensive Medication Management?

Comprehensive Medication Management (CMM) is a term used by the Patient Centered Primary Care Collaborative and most pharmacy organizations to describe a patient-centered approach with integrated management services that are provided by a pharmacist as part of a health care team.

How does CMM differ from Medication Therapy Management (MTM)?

Medication Therapy Management (MTM) is the term used by the Center for Medicare and Medicaid Services (CMS) to describe the billing of medication management services, provided by a pharmacist or other professional, which ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use. MTM can be specific to certain medications or conditions, and is not necessarily a collaborative program with physicians and other healthcare professionals. Follow-up care is not essential under MTM.

CMM goes beyond MTM by taking a systematic approach to patient care, evaluating all medications and conditions, providing services collaboratively with physicians and other healthcare team members, and providing follow-up to ensure that each patient reaches individualized treatment goals.

What service does the pharmacist perform that is not already done?

Medications are first-line treatments for almost 90 percent of chronic diseases, resulting in $374 billion in U.S. spending on prescription drugs in 2013 according to IMS Health Holdings Inc. Yet according to the Institute of Medicine, for every dollar spent on prescription drugs, another dollar is spent either correcting safety problems caused by medications or managing the shortfall in health outcomes due to inappropriate or inadequate medication therapy which includes preventable hospitalizations, emergency room visits, and outpatient visits. When optimally performed for complex high-risk and/or high-cost patients, CMM ensures the safe and optimal use of all medications, from medication selection to dosing and combinations of medications, leading to attainment of provider and patient defined medication treatment goals. Pharmacists are the most uniquely qualified and specifically trained member of the healthcare team to provide CMM.

What are common activities that pharmacists perform in the course of delivering CMM?

Under collaborative practice agreements with physicians, pharmacists commonly provide the following services when delivering CMM:

- Identify high-risk and/or high-cost patients for enrollment who have not reached chronic disease treatment goals and/or are high utilizers of acute care services
- Interview patients to understand current knowledge, attitudes, beliefs, and habits related to chronic diseases and treatments, including all medications (prescription and nonprescription)
- Evaluate each medication used by patients for appropriateness, effectiveness, safety, and adherence / proper use
- Perform basic physical assessment and vital sign measurement
- Perform point-of-care testing
- Identify all medication-related problems that prevent attainment of treatment goals
- Design a care plan specific to resolving the medication-related problems identified and attaining treatment goals, involving the patient in a shared decision-making or similar format to ensure "buy-in" / ownership for the plan
- Document all findings and actions / recommendations, and communicate activities to the primary care provider and other relevant healthcare team members (usually through the electronic medical record) within 24 hours of patient contact
- Conduct quality assurance of CMM services in partnership with collaborating physicians

Are pharmacists qualified to provide these clinical services? Are pharmacists trying to take away patient care services from physicians?

Pharmacy education has evolved drastically over the past two decades. The Doctor of Pharmacy degree is now the only degree offered by schools of pharmacy; accreditation standards mandate hands-on direct patient care training as part of the curriculum. Post-graduate residency programs, up to 3 years in duration, and fellowships are available. A national board certification for pharmacists has been established that recognizes general and specialty clinical practices.

By focusing on medication-related problems, pharmacists are addressing a gap in the delivery of healthcare that accounts for hundreds of billions of dollars wasted on preventable adverse or suboptimal treatment outcomes. When enrolling the most challenging patients with poor chronic disease control and/or frequent acute care utilization, pharmacists are able to help physicians improve healthcare quality scores, patient access, and level of practice satisfaction. CMM allows physicians to focus more on diagnosing and evaluating rather than titrating, monitoring, and adjusting treatments.

How are CMM efforts coordinated with the provider in a way that still gives the provider team leadership? When and how would the pharmacist communicate as a team member with the physician?

Because CMM requires a collaborative practice agreement with a physician, the physician remains in the leadership role on the healthcare team. Group or individual physicians can decide what range of clinical privileges can be comfortably granted to pharmacists through collaborative practice agreements. The process of CMM requires that medication-related care plans align with the primary care physician's care plan. In instances where a pharmacist and physician disagree about a treatment plan, the physician's plan is adopted unless there is absolute certainty that harm will occur to the patient. This can be articulated in the collaborative practice agreement, but a pharmacist taking the initiative to prevent medication-related harm is a professional practice obligation.

In addition to clarifying clinical privileges, collaborative practice agreements outline how and when pharmacists will communicate patient care issues with physicians and other healthcare team members. For example, most collaborative practice agreements state that pharmacists must document communication with patients, whether by phone or in person, within 24 hours of every encounter and adopt an agreed upon system for letting the physician know that CMM encounter was made; for electronic health records, this is usually a "task" or similar function that is activated.

Most community pharmacies seem very busy. How have CMM services been incorporated into the daily workload of pharmacists?

Many chain and independent pharmacies offer varying levels of CMM. Models for delivering CMM through community pharmacies include either having pharmacists on-site provide services or have designated clinical pharmacists provide the services and travel to different stores / locations depending on patient volume. Pharmacy technicians are developing a broader role that supports clinical services such as checking in patients, performing vital sign measurements and point-of-care tests, recruiting new patients, checking in with patients by phone to remind them of appointments or verifying appropriate use of a medication, etc. Having access to medical record and diagnostic test information also makes the CMM process much more efficient and effective.

Appendix N. Acknowledgements - Experts Consulted

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Appendix O. Definitions

Accountable Care Organizations (ACO)

Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care and accept collective accountability for the cost and quality of care delivered to a population of patients. The concept was formally created under the Affordable Care Act. The most significant provision includes a change in Medicare payment focusing on incentives focused on "pay-for-performance."

An ACO could take many different shapes and are formed from a variety of multidisciplinary models including: multispecialty medical groups, physician-hospital organizations (PHO), organized or integrated delivery systems, managed independent practice associations (IPAs).[305]

Acute care facility

Acute care is a branch of secondary health care where a patient receives active but short-term treatment for a severe injury or episode of illness, an urgent medical condition, or during recovery from surgery. Typically acute care facilities include a hospitals, emergency rooms.

Advanced Practice Pharmacist (APP)

Described by California Business and Professions code **§**4016.5. An Advanced Practice Pharmacist may perform patient assessments, order and interpret drug therapy-related results, refer patients to other providers, participate in the collaborative management and evaluation of diseases, and initiate, adjust, or discontinue drug therapy. Licensure issuance is still in development by the California Board of Pharmacy and is expected to begin in early 2016.

Arthritis

Arthritis is a term used to describe more than 100 rheumatic diseases and conditions that affect joints. Common symptoms of arthritis include pain, aching, stiffness, and swelling in and around the joint. Some forms of arthritis can affect multiple organs and cause widespread symptoms. The most common forms of arthritis are osteoarthritis, fibromyalgia, gout, rheumatoid arthritis, and systemic lupus erythematosus.

Asthma

Asthma is a chronic disease that affects the lungs by inflaming and narrowing the airways of the lungs. It causes wheezing, breathlessness, chest tightness, and coughing, making breathing difficult. The symptoms of asthma can lead to decreased physical activity, which increases the risk of obesity and other chronic diseases. Asthma can be managed with medications that control symptoms and avoiding "triggers." Asthma triggers are different for everyone who has asthma. Asthma triggers include tobacco smoke, dust mites, outdoor air pollution, cockroaches, pets, mold, smoke from burning wood or gas, allergies, infections like the flu, physical activity, certain medications, certain

weather conditions, certain foods, fragrances, and strong emotions that can lead to rapid breathing (hyperventilation).

California Pay for Performance (P4P)

The California P4P program is led by the Integrated Healthcare Association (IHA), an organization that publicly reports the performance of physician organizations.   The primary objectives of Value Based P4P are to reorder the priorities of the P4P Program to emphasize cost control and affordability; to continue to promote quality; to standardize health plan efficiency measures and payment methodologies; and to increase the amount of incentives available to provider organizations using a shared savings model. More information about P4P and the IHA is available at http://www.iha.org/p4p_california.html.

California Wellness Plan Goal 2: Optimal Health systems Linked with Community Prevention

To attain "The Overarching Goal of the Plan," equity in health and wellbeing, Goal 2 of the California Wellness Plan describes several Let's Get Healthy Task Force Priorities. These are described by specific objectives that are outlined in the California Wellness Plan.

Center for Medicare & Medicaid Innovation

Also known as the Innovation Center, the Center for Medicare & Medicaid Innovation (CMMI) is affiliated with the Centers for Medicare & Medicaid Services. CMMI supports the development and testing of innovative health care payment and service delivery models. Financial support is achieved through the use of grant funding.

Chronic disease

Chronic diseases are long-lasting or recurrent medical conditions that progress slowly. Chronic diseases and injury are the leading causes of death, disability, and diminished quality of life in California. Chronic diseases such as heart disease, cancer, stroke, asthma, chronic obstructive pulmonary disease, diabetes mellitus, arthritis, oral health conditions, mental health conditions, and substance use disorders are manageable. The chance of recovery (prognosis) increases when chronic diseases are detected early and controlled through clinical interventions or medical treatments and trough lifestyle changes and disease management.

Chronic Obstructive Pulmonary Disease (COPD)

This term refers to two diseases, chronic bronchitis and emphysema, both of which making breathing difficult. Symptoms of COPD include constant coughing, shortness of breath, and wheezing. COPD develops slowly and can get worse over time. When it is severe it can prevent basic tasks, such as bathing and dressing. COPD can be managed with medications that control symptoms and by avoiding triggers. COPD triggers include tobacco smoke, air pollutants, dust, and infections such as flu. Smoking is the leading cause of COPD; other risk factors include long-term exposure to air pollution, chemical fumes, second-hand smoke, or dust.

Clinical pharmacy

A health science discipline in which "pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention".[306] With in-depth knowledge of medications clinical pharmacy considers evidence-based guidelines and relevant legal, ethical, social, cultural, and economic aspects of patient care.

Collaborative Practice Agreements

Increased autonomy of pharmacists through collaborative practice agreements gives clinical pharmacists provider support to ensure pharmacists are fully capable to provide efficient and timely care. Specifically, in the use of CMM, collaborative drug therapy management agreements involve an agreement between one or more physicians and qualified clinical pharmacists who work within the context of a defined protocol that permits the clinical pharmacist to assume responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering medications; and selecting, initiating, monitoring, continuing, and adjusting drug regimens.[307]

For additional information, please see Appendix G.

Congestive heart failure (or heart failure)

Heart failure is "fluid congestion" – extra fluid- in the blood as a result of heart failure. When the heart is unable to pump enough blood through the body, certain organs and tissues, such as the kidneys do not get enough oxygen and nutrients. The kidneys do not filter as much fluid from the blood into urine, leaving extra fluid. This extra fluid builds up in the lungs, liver, and other tissues and can cause fatigue and breathing problems.

Diabetes

Diabetes is a chronic medical condition that occurs when the body cannot produce or properly use the hormone that controls blood sugar (insulin). Insulin is produced by the pancreas and travels through the bloodstream to deliver glucose to cells, so they can convert it into energy. Problems with insulin production and/or insulin use prevent blood sugar (glucose) from entering cells and being used as energy. This increases the amount of glucose in the bloodstream. Diabetes is the leading cause of blindness, amputation, and kidney failure, and also contributes to heart attacks and strokes. There are several types of diabetes:

Type 1 diabetes: previously known as juvenile diabetes, an unpreventable autoimmune chronic disease that affects the body's ability to produce enough insulin. When the body does not produce enough insulin, glucose builds up in the bloodstream instead of entering cells, this not allowing the body to use all of the glucose for energy. Insulin therapy and other treatments enable those with type 1 diabetes to manage the condition and live long, healthy lives.

Type 2 diabetes: a preventable, chronic disease characterized by elevated blood sugar (glucose) levels. It is caused when the body is unable to produce or use the hormone that controls glucose

(insulin), resulting in a build-up or sugar in the blood (hyperglycemia). Type 2 diabetes usually begins as insulin resistance. Symptoms of diabetes may take years to emerge and include fatigue, hunger, increased thirst, increased urination, infections (bladder kidney, skin, and others) that are frequent or heal slowly, blurred vision, erectile dysfunction, and pain or numbness of hands or feet.

Gestational diabetes: high blood sugar that starts or is diagnosed during pregnancy. Gestational diabetes occurs in pregnant women who have never previously had diabetes but have high than normal blood glucose levels during pregnancy. Immediately after pregnancy, 5 percent to 10 percent or women with gestational diabetes are found to have diabetes, usually type 2. Women who have had gestational diabetes have a 35 percent to 60 percent chance of developing diabetes in the 10-20 years.

Evaluate

To determine the significance, worth, value, or condition of, usually by careful appraisal and study. Evaluation is often conducted to assess effectiveness of interventions, demonstrate the need for interventions, identify ways to improve the intervention, fulfill accountability to funders and other key stakeholders, and to enhance program sustainability.

Federally qualified health center (FQHC)

All organizations receiving grants under Section 330 of the Public Health Service Act (PHS) are Federally qualified health centers (FQHCs). These facilities qualify for enhanced reimbursement from Medicare and Medicaid, as well as other benefits. To qualify to be a FQHC the population served must be in an underserved area or have specific health disparities. The FQHC must offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors.[308]

Five-Star Quality Rating System

Centers for Medicare & Medicaid Services (CMS) created the Five-Star Quality Rating System to help consumers, their families, and caregivers compare nursing homes more easily and to help identify areas about which you may want to ask questions. Separate ratings in three specific categories (health inspections, staffing, and quality measures) are also available. More information about CMS Five-Star Quality Rating System can be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/FSQRS.html.

Goal

A goal is a high-level, general statement of intent.

Health

Physical health (oral as well as medical conditions) and mental health are not just the absence of disease but the full range of health status, that is, not only morbidity and mortality, but functional status or disability, suffering, and quality of life.

Health disparities

Differences in health that are systematically associated with being socially disadvantaged (e.g., being poor, a member of a disadvantaged racial/ethnic group, and/or female), putting those disadvantaged groups at further disadvantage.

Health equity

Efforts to ensure that all people have full and equal access to opportunities that enable them to lead healthy lives. Striving to eliminate health disparities strongly associated with social disadvantage; striving for equal opportunities for all social groups to be as healthy as possible with selective focus on improving conditions for those groups who have had few opportunities, such as the poor, disadvantaged racial/ethnic groups, women, and/or persons who historically have faced more obstacles to realizing their health or human rights.

> **Determinants of equity:** social, economic, geographic, political, and physical environmental conditions that lead to the creation of a fair and just society.

Health literacy[309]

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

> **Health literacy is dependent on individual and systemic factors**: communication skills of lay persons and professionals, lay and professional knowledge of health topics, culture, demands of the healthcare and public health systems, and demands of the situation/context

> **Health literacy affects people's ability to:** navigate the healthcare system, including filling out complex forms and locating providers and services, share personal information, such as health history, with providers, engage in self-care and chronic-disease management, and understand mathematical concepts such as probability and risk

Health systems

Health system is a general term encompassing individuals involved in health care delivery, resources, and the institutions themselves. Health systems exist in a wide variety of structures throughout the U.S. and California. Goals of health systems include responsiveness to their populations expectations, delivery of quality services, robust financing, maintenance of an adequately compensated and trained workforce, and sufficient infrastructure and facilities to deliver quality medicines and health services.[310]

Healthcare Effectiveness Data and Information Set (HEDIS)

The Healthcare Effectiveness Data and Information Set (HEDIS) is a tool used by more than 90 percent of America's health plans to measure performance on important dimensions of care and service. Altogether, HEDIS consists of 81 measures across 5 domains of care. HEDIS 2015 measures related to CMM include the requirement for medication review for elderly adults.[311]

Heart disease

Heart disease is all diseases of the heart and blood vessels. Numerous conditions fall under this term, such as coronary artery disease, high cholesterol and high triglycerides (hyperlipidemia), high blood pressure (hypertension), congestive heart failure, heart attack, and stroke. Heart disease is the leading cause of death in California.

Heart failure

Heart failure is a serious, chronic, and progressive condition where the heart "fails" to pump as much blood as the body needs. The heart compensates by enlarging its chambers, increasing its muscle mass, and/or pumping faster. The blood vessels may narrow to maintain blood pressure and blood is diverted away from less important tissues or organ to protect the most vital organ such as the heart and brain. Over time, symptoms such as fatigue and breathing problems may emerge. Heart failure can be managed with medication and lifestyle changes, such as: not smoking, losing weight or maintaining a healthy weight, tracking fluid intake, avoiding alcohol, avoiding or limiting caffeine, good nutrition, regular physical activity, and monitoring blood pressure.

Heart failure core measure 1

The Heart Failure core measure 1 compliance rate, which states that " heart failure patients discharged home with written instructions or educational material given to patient or caregiver at discharge or during the hospital stay addresses all of the following: discharge medications, activity level, diet, follow-up appointment, weight monitoring, and what to do if symptoms worsen."[312]

Hierarchical Condition Category (HCC)[313]

The Hierarchical Condition Categories were created by Medicare in 2004 as a model to adjust capitation payments to private health care plans. Payment is adjusted for the health care expenditure risk of their enrollees. Measures include 70 HCC categories, which are directly related to the diagnosis code. Patients are able to have more than one HCC category assigned to them, and categories accumulate over a 12 month period to determine the CMS reimbursement rate to the Medicare Advantage health plan. Payment includes an additive "risk adjustment factor" that is assigned to each HCC.

High blood pressure (hypertension)

There are two forces that create blood pressure: blood pumping through the arteries out of the heart and the rest periods between heartbeats. The arteries stretch as blood pressure increases, to enable blood to flow through. When blood pressure is high, too often, over time, arteries lose their elasticity, become scarred, and/or become clogged. Eventually, these problems in the arteries can result in damage to the heart tissue or heart failure.

High cholesterol and high triglycerides (hyperlipidemia)

Cholesterol and triglycerides are types of fat (lipids) in the blood. High levels of these fats can result in plaque build-up (clogs) in the arteries, which can lead to coronary artery disease. Good nutrition can physical activity increase the change of lowering the levels of these fats in the blood, which also reduces the risk of coronary artery disease.

Integrated Healthcare Association (IHA)

The Integrated Healthcare Association (IHA) is a multi-stakeholder leadership group that promotes quality improvement, accountability and affordability of health care in California. IHA is a nonprofit association working to actively convene all health care parties for cross sector collaboration on health care topics.

The IHA is responsible for collecting and reporting data results from the California Pay for Performance (P4P) program. CA P4P began in 2003, and is used to validate health plan incentive payments based upon performance against a set of quality and efficiency measures.[314]

Local Public Health Department

The agency, department, or office having primary responsibility for administration of public health services in a county.

Medication adherence[315]

Medication adherence related to any deviation from the prescribed course of medical treatment. Some indicators of poor medication adherence (nonadherence) include: patient's failure to pick up or renew prescriptions, failure to take a medication as prescribed (take medication at the right dosage at the proper interval), discontinuing (stopping) a medication that the patient should have continued to take.

Barriers to medication adherence: cost, side effects, Polypharmacy (managing multiple prescriptions), understanding of the disease, forgetfulness, cultural and other belief systems, imperfect drug regimens, individuals' ability to navigate the health care system, individuals cognitive impairments, asymptomatic condition (reduced sense of urgency due to a lack of feeling symptoms).

Medication reconciliation

According to the American Pharmacists Association, medication reconciliation is defined as "the comprehensive evaluation of a patient's medication regiment any time there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions, as well as to observe compliance and adherence patterns. This process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten or adjusted, or if the patient has added nonprescription medications to [his or her] self-care." Medication reconciliation is one component of medication management, but is also provided as a stand-alone service and can be provided by a wide range of health care practitioners.[316]

National Quality Forum (NQF)

The National Quality Forum (NQF) is a not-for-profit, nonpartisan, membership-based organization that works to catalyze improvements in health care. The organization works with public and private partners to foster quality improvement, endorse consensus standards for performance measurement, ensure that consistent and high-quality performance information is publicly available, and thereby ensure measures and meaningful and accurate.[317]

Patient Centered Medical Homes (PCMH)

The patient centered medical home is a health care delivery model structured to provide patient centered care that is coordinated and multidisciplinary. Care delivery requires an effective and well maintained relationship with the patient. Maximizing the benefits medication-related outcomes during the treatment of chronic condition is an explicit target of the PCMH delivery model.[318]

Pharmacy residency[319]

"A pharmacy residency is an organized, directed, postgraduate training program in a defined area of pharmacy practice" that is typically conducted over a one year period after the pharmacist has completed their preliminary training and graduated from an accredited college of pharmacy. Pharmacy residencies provide additional training and experiences leading to advanced practice skills and knowledge.

A second year of pharmacy residency (post-graduate-year-two), are offered to provide specialty training in areas such as psychiatry, oncology, pediatrics, or ambulatory care.

Physical activity

Bodily movement that is produced by the contraction of skeletal muscle and tat substantially increases energy expenditure, including exercise, sport, dance, and other movement forms.

Physician Quality Reporting System (Physician Quality Reporting or PQRS)

The Physician Quality Reporting System (PQRS) is a quality reporting program that encourages individual eligible professionals (EPs) and group practices to report information on the quality of care to Medicare. PQRS gives participating EPs and group practices the opportunity to assess the quality of care they provide to their patients, helping to ensure that patients get the right care at the right time.[320]

Primary care provider

The primary care provider is the health care professional mainly responsible for the care of a patient, typically in an outpatient setting.

Return on Investment (ROI)

Return on investment is a performance measure used to evaluate or compare the efficiency of a program or investment. To calculate the ROI, divide the return or benefit of the program (difference of the "gain from investment" and the "cost of investment") by the "cost of the investment."

Risk Adjustment Factor (RAF)

The Risk Adjustment Factor was established by Centers for Medicare and Medicaid Services (CMS) to pay plans for the risk of the beneficiaries they enroll. Also known as the "sickness score," RAF allows CMS to standardize the base payment bids to plans adjusted based on the differences in expected costs of the enrollees. RAF is part of the Hierarchical Condition Category (HCC) Model (described above) in the payment for beneficiaries with chronic conditions.

Stroke

A disease in which blood flow to the brain is interrupted due to narrowed or blocked blood vessels (ischemic stroke) or because a blood vessel bursts (hemorrhagic stroke). Stroke causes the part of the brain affected to start to die, potentially resulting in death or disability. Stroke is the third leading cause of death in California. Inherent risk factors for stroke include age, family history, race, or gender. Modifiable risk factors for stroke include high blood pressure, high cholesterol, tobacco use, poor nutrition, lack of regular physical activity, being overweight or obese, alcohol and other drug abuse, uncontrolled diabetes, sick-cell disease, other heart arterial diseases and disorders, and heart failure.

Telehealth

The use of electronic information and telecommunications technologies to support long-distance clinical health care, professional health-related education, public health, and health administration.

Appendix P. Acronyms

ACO	Accountable care organization
APhA	American Pharmacists Association
APP	Advanced Practice Pharmacist
ASHP	American Society of Health-System Pharmacists
BCACP	Board Certified Ambulatory Care Pharmacist
CCN	Continuum of Care Network
CCTP	Community-based Care Transitions Program
CDC	Centers for Disease Control and Prevention
CDE	Certified Diabetes Educator
CDPH	California Department of Public Health
CGP	Certified Geriatric Pharmacist
CMM	Comprehensive medication management
CMMI	Center for Medicare and Medicaid Innovation
CMR	Comprehensive Medication Review
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic Obstructive Pulmonary Disease
CWP	California Wellness Plan
dsMTM	Disease State Medication Therapy Management
FFS	Fee-for-service
FQHC	Federally qualified health center
HgbA1c	Hemoglobin A1c
HCC	Hierarchal Condition Category
HEDIS	Healthcare Effectiveness Data and Information Set
HIV	Human Immunodeficiency Virus
HRSA	United States Health Resources and Services Administration
IHA	Integrated Healthcare Association
KHS	Kern Health Systems
KMC	Kern Medical Center
LDL	Low-Density Lipoprotein
MedPAC	Medicare Payment and Advisory Commission
MTM	Medication therapy management
NQF	National Quality Forum
OTC	Over-the-counter [medications]
PCMH	Patient Centered Medical Homes
PGY2	Postgraduate year two
PQRS	Physician Quality Reporting System/ Physician Quality Reporting
RAF	Risk Adjustment Factor
ROI	Return on Investment
TIPs	Targeted Interventions
TOC	Transitions of Care
US	United States of America
USC	University of Southern California

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