



SUPPORTING PATIENT MEDICATION ADHERENCE:

Ensuring Coordination, Quality and Outcomes





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Background

America's health care crisis includes systemic issues with access, quality of care, and high cost. Medication adherence is a fundamental driver of both quality and cost as up to 187 million Americans take one or more prescription medications in the treatment of both acute and chronic diseases.¹ Significant adverse consequences can result when prescriptions are not filled or refilled, and when medications are not taken appropriately. Poor medication adherence takes its toll on the health care system through unnecessary illness, disability, premature death, and wasteful spending.² In a landmark paper, Osterberg and Blaschke showed that over 50% of prescriptions in the United States are not taken as directed³, and as a result, the total direct and indirect costs of poor medication adherence have been estimated to drive up to \$290 billion in additional health care costs per year⁴. It is documented that poor medication adherence is related to approximately 125,000 deaths per year and up to 25% of hospital and nursing home admissions annually.⁵

The literature that defines and addresses the issues of medication adherence is vast with more than 40,000 peer-reviewed papers⁶, yet the rates of poor adherence have not changed significantly over the past several decades and continues to remain at an unacceptable level. The National Priorities Partnership convened by the National Quality Forum has called the opportunity to improve patient medication adherence a \$100+ billion opportunity.⁷ This group, and other well-known consortia, have reaffirmed that medication adherence needs to be a priority for national health policy.

Recent History of National Alliances

The history of national alliances that have been assembled to focus on medication adherence and to drive national health policy is an important one. In 2007, a "National Action Plan" for medication adherence was put forward by the National Council on Patient Information and Education (NCPIE).⁸ The plan called for 10 priorities including the creation of a "National Education Campaign," and the development of education and training that would target health care professionals, medical and allied health school curriculum, as well as patients with low health literacy, all of which could help foster a multidisciplinary approach to medication adherence education and management.

In 2010, the 21st Century Intelligent Pharmacy Project published a white paper through the Center for Health Transformation that emphasized the critical role of the pharmacist on the health care team to address medication adherence.⁹ Pharmacists are well-positioned as the 'medication experts' to problem-solve, to provide behavioral support directly to patients, and to collect and interpret critical data within pharmacy IT systems. With the supply of pharmacists in the U.S. market (and graduating from U.S. pharmacy schools) remaining robust compared to the supply of primary care physicians and nurses, there is an opportunity for pharmacy-based programs to play a prominent role in the multi-disciplinary approach required to address medication adherence.¹⁰

The New England Healthcare Institute, now known as NEHI, put together a multi-disciplinary, multi-member working group

¹ The Henry J. Kaiser Family Foundation. *Prescription Drug Trends*. Kaiser Family Foundation. N.p., May 2010. Web. Feb. 2011. <http://www.kff.org/rxdrugs/upload/3057-08.pdf>.

² New England Healthcare Institute (NEHI). *Medication Adherence and Care Teams: A Call for Demonstration Projects (2010)*.

³ Osterberg, Lars, and Terrence Blaschke. "Adherence to Medication." *New England Journal of Medicine* 353.5 (2005): 487-497. Print.

⁴ Healthcare Intelligence Network. *2010 Benchmarks in Improving Medication Adherence*. HIN. N.p., May 2010. Web. Feb. 2011. http://store.hin.com/2010-Benchmarks-in-Improving-Medication-Adherence_p_4006.html#.

⁵ Fleming, William K. "Pharmacy Management Strategies for Improving Drug Adherence." *Journal of Managed Care Pharmacy*. 14.6-b Supplement (2008): n. pag. Web. Feb. 2011. http://www.amcp.org/data/jmcp/JMCPSuppB_S16-S20.pdf.

⁶ Benner, Josh. URAC-PQA Medication Adherence Summit 2011 (presentation).

⁷ National Priorities Partnership. *Compact Action Brief: Improving Patient Medication Adherence: A \$100+ Billion Opportunity*. NEHI. N.p., 19 Apr. http://www.nehi.net/publications/54/compact_action_brief_improving_patient_medication_adherence.

⁸ National Council on Patient Information and Education. *Enhancing Prescription Medicine Adherence: A National Action Plan*. NCPIE. N.p., Aug. 2007. http://www.talkaboutrx.org/documents/enhancing_prescription_medicine_adherence.pdf.

⁹ Center for Health Transformation's 21st Century Intelligent Pharmacy Project. *The 21st Century Intelligent Pharmacy Project: The Importance of Medication Adherence: Saving Lives and Saving Money by Improving Medication Adherence through a Coordinated Approach to Integrated Healthcare*. Center for Health Transformation. N.p., 2010. <http://www.healthtransformation.net/galleries/wp-HIT/White%20Paper%20on%20Medication%20Adherence.pdf>.

¹⁰ Center for Health Transformation. *The 21st Century Intelligent Pharmacy Project (2010)*, ibid.

that has been dedicated to research and strategies to improve medication adherence for patients with chronic disease. They have published multiple reports under the series entitled “Thinking Outside the Pillbox.” The first two reports focused on system-wide approaches to improving medication adherence for chronic disease patients (a 2009 report and a Roundtable Highlights). A third NEHI report was published in September 2010 that put out a call for demonstration projects that focused on medication adherence strategies delivered within care teams.¹¹ The report noted that their “Call to Action” was timely given the provisions of the Patient Protection and Affordable Care Act (PPACA) and the American Recovery and Reinvestment Act (ARRA), which could facilitate programs and demonstration projects for medication adherence strategies and pharmacy-based IT systems, particularly those deployed within care teams incorporated within patient-centered medical home (PCMH) and accountable care organization (ACO) models of care.

The National Consumers League (NCL) followed-up on the NCPIE action to develop a national education campaign with multiple public and private partners. In addition, the NCL, along with Duke University Medical Center, made a case for a “National Call to Action” in their white paper that emphasized the complexity of the medication adherence process and the need for a coordinated, multi-faceted approach.¹² This white paper was released in conjunction with the education campaign in the spring of 2011, as NCL, along with more than 100 committed partners, launched the national initiative to improve poor medication adherence entitled “Script Your Future.”

Role of Accreditation

URAC, an independent, non-profit accreditation organization, is currently the leader in the pharmacy quality management space as it offers accreditation programs for pharmacy benefit management, drug therapy management, specialty pharmacy, mail service pharmacy, and Workers’ Compensation pharmacy programs. Pharmacy quality management refers to the protection of consumers through assuring high quality pharmacy practices and effective management of medications. Through its broad-based governance structure and an

inclusive standards development process, URAC ensures that all stakeholders are represented in establishing meaningful quality standards and measures for pharmacy management as well as medication management within case management and disease management programs. In June 2011, URAC sponsored a Medication Adherence Summit in conjunction with the Pharmacy Quality Alliance (PQA), which emphasized the importance of medication adherence as a priority for national health care policy as well as the need for a national strategy that includes all stakeholders in the process. The importance of a unified measure for medication adherence was presented along with the views of key stakeholders including representatives for the consumer, pharmacist, physician, health plan, employer, researcher, and government communities.

URAC has recently joined NEHI and is aligned with the “Drivers for Change” that were first articulated by NEHI in the NPP Compact Action Brief on patient medication adherence in March 2011¹³ and which are central to the “Roadmap to Improved Medication Adherence” initiative that is being unveiled by NEHI in September 2011. In the NPP Compact Action Brief, URAC is most closely aligned with the drivers for team-based care and quality measurement, as URAC has developed standards for team-based care and medication management delivered within the patient-centered health care home (PCHH). Additionally, URAC has developed quality measures for pharmacy programs, which includes measures for medication adherence that are strategically harmonized with PQA measures. The brief also identifies areas for patient care improvements that include case management, patient engagement and education, and medication management, all of which are areas where URAC actively promotes standards, measures, and educational content. NEHI’s roadmap initiative graphically highlights the complexity and growth of multiple strategies that are simultaneously addressing medication adherence. URAC aims to support the growth of these medication adherence strategies through voluntary accreditation that emphasize industry standards, best practices, and harmonized measures for outcomes.

¹¹ New England Healthcare Institute (NEHI). Medication adherence and care teams (2010), *ibid*.

¹² Bosworth, Hayden B., and The National Consumers League. *Medication Adherence: Making the Case for Increased Awareness*. *Scriptyourfuture.org*. National Consumers League, n.d. Web. July 2011. http://scriptyourfuture.org/wp-content/themes/cons/m/Script_Your_Future_Briefing_Paper.pdf.

¹³ National Priorities Partnership (Convened by the National Quality Forum). Compact Action Brief: A Roadmap for Increasing Value in Health Care. Improving Patient Medication Adherence: A \$100+ Billion Opportunity. April 2011. Produced in collaboration with NEHI. Retrieved at <http://www.nationalprioritiespartnership.org>.

White Paper Objectives

This paper is a “Call to Action” in order to ensure coordination, quality, and measurable outcomes in the dynamic and growing field of medication adherence programs. The paper will initially focus on the importance of the patient including patient behavior, decision-making processes, and relationships with key health care stakeholders. It will then highlight the important role of the pharmacist and related pharmacy programs in addressing patient adherence needs within multi-disciplinary coordinated care programs. Pharmacy quality accreditation programs, and related standards for care management programs, will be presented as a means to ensure quality and consistency within the growing field of adherence intervention. Lastly, existing health care industry programs and supportive health policy will be outlined and positioned as a foundation to build and guide successful strategies that foster multi-stakeholder approaches to medication adherence and outcomes measurement.



Section I: Patient Behavior and Relationships within the Health Care System

Patients remain at the center of all medication adherence processes; therefore, an analysis of their behavior and relationships with health care providers and within the health care system can both help define and guide solutions. The terms consumer and patient can be interchangeable but will be used more specifically in this paper to refer to the consumer as an individual in the general marketplace and to the patient as an individual that is receiving care within the health care system. The two terms can overlap when health care encompasses prevention and wellness initiatives, particularly if offered through an employer. Poor medication adherence creates a negative effect on a patient's ability to achieve their clinical goals in any setting; moreover, it has an effect on all health care stakeholders, since it increases the resources necessary to treat or control disease, frustrates provider care management plans, and can even generate financial penalties for clinicians related to outcomes, in addition to increasing costs for employers and payers.

Patient Behavior

Although poor adherence is directly linked to patient behavior, there is no definitive data that has defined a 'non-adherent' personality or revealed a relationship between adherence and the ability to follow self-care or lifestyle recommendations.¹⁴ Likewise, medication adherence has not been shown to be correlated to demographic variables such as age, gender, or race, although there is a weak relationship with lower education and income levels.¹⁵ There are many variables that can be factored into adherence behavior outside of demographic variables that have greater utility as a predictor of medication adherence behavior. Table 1 categorizes the predictive strength of consumer-related variables (and their interaction within the health care system) as they are presented in the literature. The strongest predictors of non-adherence behavior relate to the

time since initiation of a medication and the documentation of prior non-adherence.¹⁶

A key set of questions drive patient behavior research: what drives patients to not fill up to 20% of new prescriptions, and for those who do fill a new prescription, causes over 50% to discontinue their medication within the first year of therapy?¹⁷ The work of Colleen McHorney has characterized medication adherence as a rational decision-making process that is driven by patient beliefs and experiences related to their treatment and disease. Moreover, the decision to be adherent is unique for each medication, and driven by three factors: (1) the perceived need for the medication (related to their understanding of the disease and therapy); (2) the perceived concerns about the medication (related to side-effects and safety); and (3) the perceived medication affordability.¹⁸ This has implications for holistic adherence strategies to address all three factors or the entire consumer value proposition. While strategies that employ value-based insurance design (VBID) to reduce out-of-pocket medication costs have demonstrated positive trends for

Table 1 Predictive strength of consumer-related variables (from the literature)

Variables	Predictive Strength
Patient demographics (age, sex, race, etc).	Weak
Relationship between patient and providers	Moderate
Regimen characteristics	
Patient clinical status	
Patient health services use	
Health system characteristics	
Time since initiation of medication	Strong
Past non-adherence	

From Benner, Josh, URAC-PQA Medication Adherence Summit 2011 (presentation)

¹⁴ McHorney, Colleen A. "The Adherence Estimator: A Brief, Proximal Screener for Patient Propensity to Adhere to Prescription Medications for Chronic Disease". *Current Medical Research and Opinion* 25.1 (2009): 215-238. Print.

¹⁵ McHorney, Colleen A. *The Adherence Estimator* (2009), *ibid.*

¹⁶ Benner, Josh. URAC-PQA Medication Adherence Summit 2011 (presentation).

¹⁷ McHorney, Colleen A, et al. "Validity of the Adherence Estimator in the Prediction of 9-Month Persistence with Medications Prescribed for Chronic Diseases: A Prospective Analysis of Data from Pharmacy Claims". *Clinical Therapeutics* 31.11 (2009): 3584-2604. Print.

¹⁸ McHorney, *The Adherence Estimator* (2009), *ibid.*

increasing medication adherence rates^{19,20}, these strategies only address medication affordability, which applies to approximately 25% of medication adherence behavior.²¹ VBID fails to address consumer belief systems, safety concerns, or their overall commitment to each medication. Furthermore, it has been noted that poor adherence can persist even with the provision of medication at no cost (this strategy is still being studied).²² This highlights the importance of a multi-faceted approach to medication adherence and the need for strong communication and counseling to address consumer commitment to therapy.

National Consumers League's Approach

The National Consumers League has launched a medication adherence awareness campaign entitled "Script Your Future". The nationwide campaign is aimed at improving patient commitment to medication adherence by equating improved adherence with a sense of gaining greater control and accountability for themselves and their disease. The multi-year effort focuses primarily on patients affected by diabetes, respiratory disease, and cardiovascular disease. It is a powerful campaign that educates the consumer that poor medication adherence can lead to consequences that affect their ability to take care of themselves and their loved ones, places undue emotional and financial burden on family members, and jeopardizes the ability to experience future family events and milestones. The campaign also encourages patients and health care professionals to better communicate about ways to improve medication adherence. The messages used are similar to the ones generated through motivational interviewing techniques that enable patients to realize that they are in the best position to influence the outcome of their care plan.^{23,24} Motivational interviewing techniques are also commonly used by pharmacists and taught in pharmacy schools to address medication adherence issues.

Script Your Future's more than 100 committed partner organizations, which include health care professionals, patient groups, insurers, researchers, pharmaceutical companies, employers, as well as researchers and government agencies, helped develop and implement the campaign and will expand the campaign's reach to consumers. The NCL campaign is being launched in a regionally-targeted fashion that is allowing for the careful collection of key metrics with baseline and outcomes data to assess its effectiveness.

The Role of Physicians

Physicians, particularly primary care physicians (PCPs) and other specialists that write prescriptions for chronic diseases, can play a key role in addressing medication adherence given that they represent the initiation of the prescription process and have the opportunity to develop a trusting relationship with the patient

Figure 1 Prescription process related to medication adherence from patient perspective



¹⁹ Gibson, Teresa B., et al. "A Value-Based Insurance Design Program At A Large Company Boosted Medication Adherence For Employees With Chronic Illnesses". *Health Affairs* 30.1 (2011): 109-117. Print.

²⁰ Chernew, ME, et al. "Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment". *Health Affairs* 27.1 (2008): 103-112. Print.

²¹ McHorney, *The Adherence Estimator* (2009), *ibid*.

²² Cutler, David M., and Wendy Everett. "Thinking Outside the Pillbox — Medication Adherence as a Priority for Health Care Reform". *New England Journal of Medicine* 362.17 (2010): 1553-1555. Print.

²³ National Consumers League. *Script Your Future*. N.p., Mar. 2011. Web. July 2011. <http://www.scriptyourfuture.org/hcp/index.php>.

²⁴ Borrelli, Belinda, et al. "Brief Motivational Interviewing as a Clinical Strategy to Promote Asthma Medication Adherence". *Journal of Allergy and Clinical Immunology* 120.5 (2007): 1023-1030. Print.

(figure 1). In addition, other health care practitioners, such as nurses, nurse practitioners, and physician assistants, can also prescribe certain medications, depending on the scope of practice regulations for each state. In these states, the care team related to the initiation of a prescription and handling of the prescription process can create an enhanced communication process.

Physicians, however, need to have the time and inclination to get involved in the prescription and medication adherence process. Because the mean duration of a primary medical consultation can range from 7.6 to 17.6 minutes, there is a propensity for the physician to redirect and control the conversation, and provide less time for listening, health-promotion, and medication review activities.²⁵ The average time that the physician spends discussing all aspects of a newly-prescribed medication is 49 seconds.²⁶ Studies have shown that no medication instructions are given by physicians in 19%-39% of prescriptions using survey methods and 17%-25% using observational methods.²⁷ For a new prescription, it has been documented that physicians discuss medication dosing directions in less than 60% of cases and review adverse effects in approximately 33% of cases.²⁸ Physicians can also be inconsistent in their communication when it relates to reviewing medications.²⁹ The risk for non-adherence has been documented to increase by 19% for patients that have physicians that communicate “poorly”.³⁰ In the management of diabetes, one study showed that physician communication regarding adherence was interpreted as “fussing,” “lecturing,” and “scolding” that was actually counter-productive to adherence behavior.³¹ This data highlights the opportunity to bring in other qualified members of the care team to provide support to the physician for medication communication and adherence issues.

At the same time, there is an opportunity for both early and continual physician education on communication styles and medication adherence counseling. The patient-physician relationship can cause dissatisfaction when the communication style is more paternalistic than patient-centered; in contrast, methods that use “Patient-Centered Communication” (PCC) place an emphasis on building a relationship, sharing information, and involving the patient in decisions.³² Perhaps as a result of more patient-centered communication, it has been demonstrated that “physician-connected” patients tend to have better medication adherence than patients that are only connected to a physician practice.³³ In most cases, patients also want information about their medications and feel frustrated when it is not provided.³⁴ The lack of communication around the medication adherence process can be especially damaging given that most patients do not like to communicate their true adherence behavior to physicians, and that most physicians assume that their patients are adherent without probing.³⁵

Within clinical practices, medication reconciliation is often not performed because it can be a time-consuming process. This again creates an opportunity for appropriate care team members to provide additional support. There is a strong case to be made for surrounding the physician with a care team, either physically or virtually, that can relieve the physician of the primary responsibilities related to communicating adherence needs to the patient. By expanding the role of other team members to oversee, guide, and support medication communication and adherence, physicians can spend more time on handling more complex cases in their office, and use their expertise and time more efficiently. Further, non-physician practitioners are likely to have more time to spend with patients than physicians on

²⁵ Lussier, MT, and Claude, R. “Time to Talk”. *Canadian Family Physician* 52.11 (2006): 1401-1402. Print.

²⁶ Tarn, DM., et al. “How much time does it take to prescribe a new medication?” *Patient Educ Counsel* 2008; 72:311-319.

²⁷ Tarn, DM., et al. “Physician Communication When Prescribing New Medications”. *Archives of Internal Medicine* 166 (2006): 1855-1862. Print.

²⁸ Tarn, DM., et al. Physician Communication (2006), *ibid.*

²⁹ McHorney, *The Adherence Estimator* (2009), *ibid.*

³⁰ Haskard Zolnerek, Kelly B., and M. Robin DiMatteo. “Physician Communication and Patient Adherence to Treatment: A Meta-analysis”. *Medical Care* 47 (2009): 826-34. Print.

³¹ Matthews, S M, A R Peden, and G D Rowles. “Patient-Provider Communication: Understanding Diabetes Management Among Adult Females”. *Patient Education Council* 76.1 (2009): 31-37. Print.

³² Ledford, C J, et al. “‘Practicing medicine’: patient perceptions of physician communication and the process of prescription”. *Patient Education Council* 80.3 (2010): 384-392. Print.

³³ Atlas, S J, et al. “Patient-Physician Connectedness and Quality of Primary Care”. *Annals of Internal Medicine* 150.5 (2009): 325-335. Print.

³⁴ McHorney, *The Adherence Estimator* (2009), *ibid.*

³⁵ McHorney, Colleen. URAC-PQA Medication Adherence Summit 2011 (presentation).

issues related to medication adherence. Telephonic-based case management, disease management, and pharmacy-based medication management are examples of programmatic support for the physician and care team. There are also advantages to bringing pharmacy services directly onsite to a medical clinic. For example, it has been demonstrated that integrated primary care and pharmacy services at worksite clinics can increase medication adherence by 9-10%.³⁶

Care Team Challenges

Even within a care team environment, challenges remain to implementing effective patient medication reviews and adherence processes. Difficulties in effective patient targeting and coordination of personnel stem from a lack of supporting prescription data and the ability to identify at-risk patients. Care teams rarely have access to objective evidence of non-adherent behavior and there are very few predictive tools that are routinely administered within an office setting. There are screening tools, such as the three-item Adherence Estimator and the Patient Activation Measure (PAM), which have shown promise and are being studied at selective institutions.³⁷ A key question is whether these tools will work as well for patients refilling their medications since patient beliefs and adherence behavior can change over time.

Specific sub-populations of patients have been targeted for more intensive medication adherence support including those with behavioral health issues, patients with several co-morbidities on multiple medications (requiring poly-pharmacy management), or patients undergoing a transition of care such as discharge from a hospital or ambulatory care facility.³⁸ Research has shown that a new prescription presents a new decision-making dilemma for consumers.³⁹ Therefore, it has been reported that the best time for medication adherence interventions should target new prescriptions because it is when consumers are forming their beliefs for the medication and considering risk-benefit trade-offs.^{40,41} Oddly enough, a similar decision-making process has

not been observed when consumers purchase over-the-counter medicines and neutraceuticals. This phenomenon is counter-intuitive and needs to be studied more thoroughly to provide insight into consumer decisions as these medications can pose just as much risk but do not have the same requirement of proof to show benefit.

Care teams also don't have regular access to pharmacy data, such as the rate at which a prescription is filled and refilled, which could help address medication adherence. The use of e-Prescribing systems could help address this issue but adoption remains at sub-optimal levels. The 2010 Surescripts report shows that only 26% of office-based physicians are using e-Prescribing systems, and that 70% of those physicians use an e-Prescribing application on their EMR system.⁴² Electronic prescribing systems can be a helpful tool for managing medication adherence because it provides timely information on initial prescription fill, cost at the point of delivery, and drug-to-drug interactions. Other stakeholders in the health care system also don't have regular access to all relevant prescription data. For example, health plans do not have the systems to track initial prescription fill data from all pharmacy sources at the initiation of therapy; as a result, they focus on prescription refill data by tracking more accessible pharmacy claims. Overall, there is a need for pharmacy partners (retail, PBM, and specialty) to address the information gap through a better linkage of their pharmacy data to other health IT infrastructure, including the provision of routine measures of medication adherence.

Role of Stakeholder Incentives

Health care quality control and incentive systems can play an important role in changing the behavior of and better coordinating stakeholders in the approach to medication adherence. Physicians, in particular, tend to respond to incentives that can continue to drive the adoption of e-Prescribing systems and link reimbursement to better medication adherence and clinical outcomes. Payers, who have traditionally managed

³⁶ Sherman, Bruce W. "Impact of Workplace Health Services on Adherence to Chronic Medications". *American Journal of Managed Care* 15.7 (2009): e53-e59. Print.

³⁷ New England Health Institute (NEHI), Medication Adherence and Care Teams (2010), *ibid.*

³⁸ New England Health Institute (NEHI), Medication Adherence and Care Teams (2010), *ibid.*

³⁹ McHorney, *The Adherence Estimator* (2009), *ibid.*

⁴⁰ McHorney, *The Adherence Estimator* (2009), *ibid.*

⁴¹ New England Healthcare Institute (NEHI), Medication Adherence and Care Teams (2010), *ibid.*

⁴² Surescripts. *The National Progress Report on E-Prescribing and Interoperable Healthcare*. Surescripts. N.p., 2010. Web. July 2011. <http://www.surescripts.com/pdfs/national-progress-report.pdf>.

pharmacy costs as a line item, are now more commonly linking medication adherence solutions to clinical outcomes. Employers, who have traditionally equated medication adherence strategies to older “poly-pharmacy” populations, are now focusing more on their younger employees and measuring productivity, absenteeism, and presenteeism metrics.

The most effective incentive-based programs for physicians and care teams related to medication adherence may reside within patient-centered medical homes and accountable care organizations. In these models, incentives are provided to encourage both improved quality outcomes and lower cost, both of which are key downstream outcomes of successful adherence strategies. NEHI has suggested that a multi-component adherence strategy should incorporate patient identification, medication management, cost barrier reduction, and provider incentives along with patient education and engagement tactics.⁴³ Medication adherence should be seen as a critical path to better patient outcomes. All strategies and multi-disciplinary interventions need to employ a patient-centric design to be effective.

Section II: The Critical Role of Pharmacists in Ensuring Quality of Medication Use

The pharmacist plays an essential role as the medication expert. Extensively trained in the pharmacology and pharmacokinetics of medication, as well as in the preparation and appropriate use of medications, the pharmacist has the advanced clinical training to expertly counsel patients and manage the medication therapy of chronic health conditions. With recent trends driven by an aging population, increases in chronic disease resource utilization and health care reform, pharmacists have become even more relevant to the optimization of health care delivery in the U.S. Pharmacists in the community setting have increasingly provided clinical services related to medications. These services are often referred to as “medication therapy management (MTM) services”.

Medication Therapy Management

The American Pharmacists Association (APhA) MTM Services working group defines MTM as a set of services that optimize therapeutic outcomes for individual patients.⁴⁴ These services usually coincide with the provision of medication but can also be related to general patient care. The set of MTM services outlined in table 2, which is not meant to be comprehensive, can be provided by the pharmacist alone or occur within a partnership between the pharmacist, the patient and their caregivers, to promote the safe and effective use of medications. Services that support medication adherence are increasingly becoming a part of MTM programs. The Academy of Managed Care Pharmacy

Table 2 MTM Services from the American Pharmacists Association Services Working Group⁴⁷

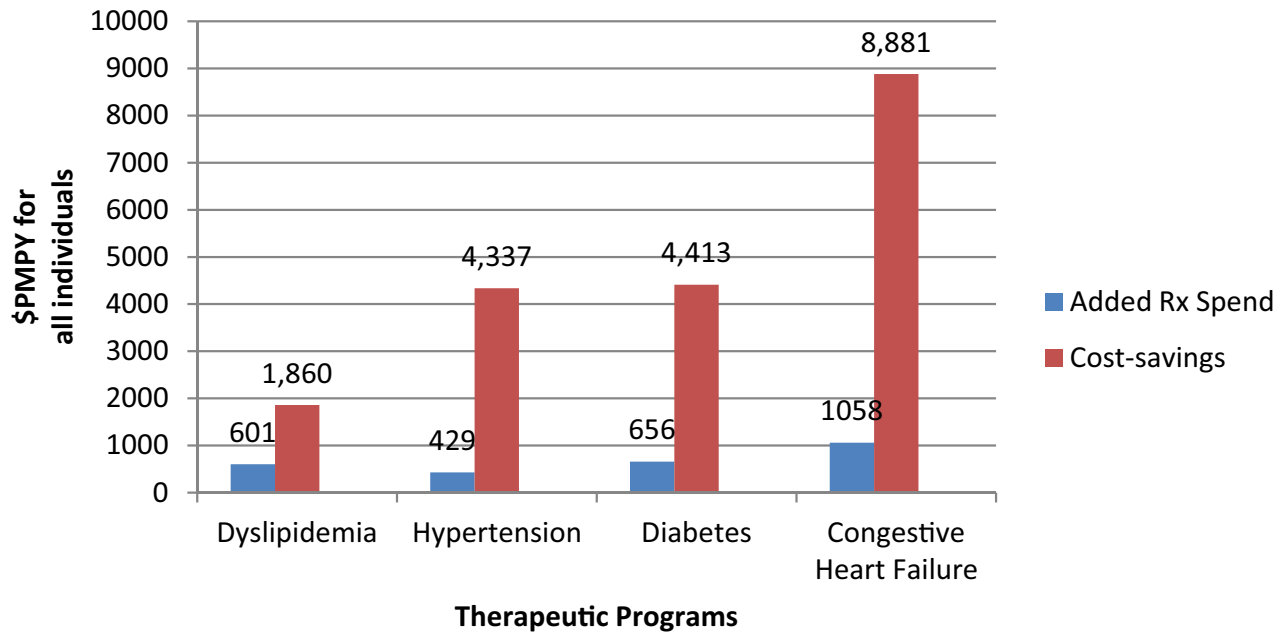
1. Performing or obtaining necessary assessments of the patient’s health status
2. Formulating a medication treatment plan
3. Selecting, initiating, modifying, or administering medication therapy
4. Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness
5. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events
6. Documenting the care delivered and communicating essential information to the patient’s other primary care providers
7. Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications
8. Providing information, support services, and resources designed to enhance patient adherence with his or her therapeutic regimens
9. Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient

⁴³ New England Healthcare Institute (NEHI), Medication Adherence and Care Teams (2010), *ibid*.

⁴⁴ APhA MTM Services Working Group. *Medication Therapy Management Services Definition and Program Criteria*. N.p., 4 May 2004. Web. July 2011. <http://www.aacp.org/resources/historicaldocuments/Documents/MTMServicesDefinitionandProgramCriteria04.pdf>.

⁴⁷ APhA MTM Services Working Group, Medication Therapy Management Services Definition (2004), *ibid*.

Figure 2 Health Care Cost-Savings from Adherence



Roebuck M et al, Health Affairs, 2010

(AMCP) has been able to develop and validate a clear definition of what specific elements would comprise a quality MTM program in the consensus document entitled “Sound Medication Therapy Management Programs” (Versions 1.0 and 2.0).^{45,46}

MTM services have demonstrated positive impact on clinical and economic outcomes. One study reported that over a seven-year period, pharmacist-initiated MTM services delivered through community pharmacies saved \$7.1 million and impacted nearly 24,000 patients.⁴⁸ A published review of clinical pharmacist’s services found that for every \$1 invested in pharmacist clinical services, nearly \$5 in cost savings was achieved.^{49,50} By boosting medication adherence, MTM can lead to an upfront increase in

medication expenditures, but it has been demonstrated that the cost-savings related to better outcomes and lower health care utilization more than offset these costs, even within different chronic disease areas (figure 2).⁵¹

With the requisite training and a proven track record for effects on quality and outcomes, pharmacists are well-positioned to continue providing patient-centered, medication management services, including those that address medication adherence. However, there can be significant variability in the way commercial MTM programs are executed and how results are measured. This has created opportunities for industry practice standardization through the validation of “Sound Medication

⁴⁵ Academy of Managed Care Pharmacy. Sound Medication Therapy Management Programs 2006 Consensus Document. JMCP Supplement April 2006; 12 (3). Retrieved at http://www.amcp.org/data/jmcp_AprilSupp06.pdf.

⁴⁶ Academy of Managed Care Pharmacy. Sound Medication Therapy Management Programs, Version 2.0 with Validation Study. JMCP Supplement January 2008; 14 (1,S-b). Retrieved at http://www.amcp.org/data/jmcp/JMCPSuppB_Jan08.pdf.

⁴⁸ Barnett, MJ. Frank, J. Wehring, H. Newland, B. VonMuenser, S. Kumbera, P, et al. Analysis of Pharmacist-Provided Medication Therapy Management (MTM) Services in Community Pharmacies Over 7 Years. *Journal of Managed Care Pharmacy*. 2009; 15(1): 18-31.

⁴⁹ Perez, A. Hoffman, JM. Meek, PD, Touchette, DR. Vermeulen, LC, et al. Economic Evaluation of Clinical Pharmacy Services 2001-2005. *Pharmacotherapy*. 2008;28(11):285e-323e.

⁵⁰ American Pharmacists Association. *Improving Medication Use: Lowering Health Care Costs*. July 2, 2009. Retrieved at <http://www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=20163&TEMPLATE=/CM/ContentDisplay.cfm>.

⁵¹ Roebuck, M Christopher, et al. *Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending*. *Health Affairs*. N.p., Jan. 2011. Web. July 2011. <http://content.healthaffairs.org/content/30/1/91.abstract>.

Therapy Management” practices⁵² as well as the harmonization of performance measures. The next section presents some best MTM practices, some of which have also been recognized by the 21st Century Intelligent Pharmacy Project.⁵³

One example of an innovative and highly functional set of MTM services is provided by Mirixa Corporation, which was founded in 2006 by the National Community Pharmacists Association (NCPA). It has positioned community pharmacists to deliver a wide range of technology-enabled, medication-related services, including medication therapy management and adherence support. Mirixa provides targeted care services to pharmacy benefit management (PBM) organizations, health plans, pharmacies, and employers through their large pharmacy-based patient care network. This network includes more than 40,000 pharmacies that deliver patient care services through a technology platform, MirixaPro™, which helps to identify at-risk patients, pull-through safety and efficacy issues, and encourages standardized care. Mirixa has primarily shared its results by providing summaries of best practices and success stories on their website, www.mirixa.com, particularly for administering adherence programs. Their client research has found that MTM and adherence programs can be most effective when delivered by a pharmacist rather than a health care professional or a call center. Mirixa has also engaged in academic partnerships and international collaborations. Similar MTM services are also provided by other organizations such as Outcomes Pharmaceutical and PharmMD.

The well-known Asheville Project and the subsequent Diabetes Ten City Challenge (DTCC), have become models for improving patients’ health through a collaboration of health care practitioners focused on coordinated care that features a patient self-management/pharmacist coach model. With the focus on diabetes management, community pharmacists were first educated and trained in diabetes wellness skills, and then involved in diabetic counseling to help set treatment goals and to provide information on the importance of adherence. The

Asheville Project is an example of an early patient-centered program that featured the pharmacist not only providing medication management services, but also providing more holistic diabetes care.

As the program progressed, the model expanded to incorporate other stakeholders in the coordination of care including the use of financial incentives. It therefore enhanced communication channels between patient, pharmacist, physician, diabetes educator, health system, and payer.⁵⁴ The DTCC represents an extension of this model within a public-private partnership between city governments, private employers, the APhA foundation, and pharmacists. Both the Asheville Project and the DTCC were able to show benefits in clinical outcomes related to hemoglobin A1c levels associated with diabetes control, and financial return on investment where the mean increase in medication costs was more than offset by the mean decrease in health care costs.⁵⁵

Pharmacist-led Intervention Strategies

CVS/Caremark developed the Pharmacy Advisor Program to manage costs, improve medication adherence, and to close gaps in care for members with diabetes.⁵⁶ This innovative program, which is designed for PBMs, uses pharmacy claims data to identify patients with sub-optimal pharmacy care. It is also used to identify gaps in care or medication issues from evidence-based protocols. Pharmacists can then follow-up on the identified issues, either by phone or face-to-face at one of their retail stores, based upon the preference of the patient. CVS/Caremark has focused on providing additional behavioral change training to their pharmacists. New pharmacists are willing to engage consumers, but it can take additional training to go beyond traditional problem-solving and engagement proficiency to master the counseling skills necessary to change adherence behavior.

They have also focused on integrating their MTM services with their daily prescription workflow and patient service systems.

⁵² Academy of Managed Care Pharmacy. Sound Medication Therapy Management Programs, Version 2.0 with Validation Study. JMCP Supplement January 2008; 14 (1,S-b). Retrieved at http://www.amcp.org/data/jmcp/JMCPSuppB_Jan08.pdf.

⁵³ Center for Health Transformation, 21st Century Intelligent Pharmacy Project (2011), *ibid*.

⁵⁴ Center for Health Transformation, 21st Century Intelligent Pharmacy Project (2010), *ibid*.

⁵⁵ Center for Health Transformation, 21st Century Intelligent Pharmacy Project (2010), *ibid*.

⁵⁶ CVS Caremark. “CVS Caremark Launches Program to Help Pharmacy Benefit Management Clients Improve Diabetes Care”. N.p., 11 May 2010. Web. July 2011. <http://info.cvscaremark.com/newsroom/press-releases/cvs-caremark-launches-program-help-pharmacy-benefit-management-clients-impro>.

In effect, they are scaling their MTM services to achieve standardization and to avoid the variability that can occur within the MTM services industry. Finally, CVS/Caremark has partnered with Harvard Medical School and Brigham & Women's Hospital to support outcomes research focused on medication adherence. One study from this academic collaboration, which used a systematic literature review of randomized controlled studies, found that pharmacists engaged directly with patients at a pharmacy are the most effective health care providers at influencing positive adherence behavior.⁵⁷ Similar programs are also provided by other PBM and pharmacy chain organizations.

Another innovative strategy is from Pleio Health Support Systems which began to create a solution to medication adherence issues in 2006 by working closely with chain pharmacies, pharmaceutical manufacturers, and technology and database providers to build a platform that integrates a myriad of medication adherence and patient support services. Through their GoodStart™ platform, patients are engaged in phone and in-person pharmacist encounters designed to identify the patient's needs, to develop an action plan and then to provide ongoing feedback and encouragement. It is a platform that has integrated a variety of adherence tactics for the consumer that present a process to guide and build adherence over time. Their strategies include prescription refill trend analysis, management of adherence protocols, execution of programmable text and voice messaging, and live patient contact services.

The website emphasizes the importance of driving good adherence for a new medication within the first 100 days by providing: "...a practical adherence support system for patients in the early adoption stage of a new medicine (the first 100 days). It provides enrolled patients with answers, encouragement, reminders, and peer support, when they need it, how they want it, (and) in their language" (www.pleio.com). Pleio has collected controlled data from pharmacies in North Carolina, Virginia, and Maryland, as well as three pharmacy chains in Canada that demonstrate improved adherence.

There is a need for continuous innovation in pharmacy-based programs for medication adherence. For example, there are

opportunities for pharmacies to address the complexity of filling prescriptions for patients that take multiple medications. Synchronization strategies would allow these "poly-pharmacy" patients to better coordinate their refill schedules. Currently, the average statin-user for dyslipidemia takes 11 medications, makes five pharmacy visits over a three month period, and synchronizes half of their refills. The same study showed that 10% of statin-users, which may represent a common Medicare sub-population, take 23 or more medications, make 11 or more pharmacy visits to two or more pharmacies over 90 days, have four or more prescribers, and only synchronize 10% of their refills.⁵⁸ Anecdotal reports from refill synchronization programs indicate that they hold great promise for improvements in medication adherence. In addition to synchronization approaches, there are opportunities for pharmacies to focus on medication management for all types of transitions of care as well as to explore risk-sharing and pay-for-performance strategies.

Currently, pharmacies and PBMs use a plethora of innovative automated methods to address medication adherence including therapeutic exchange programs, 90 day fills, mail order service and auto-refills. Care must be taken to preserve the balance between programs that maintain consumer engagement versus automated methods that can lead to stockpiling and reduced engagement. While pharmacist participation in the MTM benefit for reimbursement of their services has been increasing over time,⁵⁹ there are still other opportunities to make pharmacists even more effective within the care team environment such as granting privileges for laboratory monitoring services and ensuring that prescriptions have a diagnosis code. Two-way electronic communications between pharmacists and physicians is often impeded by information technology systems that do not interface; solutions that are targeted at enhancing the exchange of clinical and medication information is crucial to improved patient care.

Building a Pharmacy-Driven Quality Improvement Cycle

Continuous quality improvement (CQI) is contingent on the availability of performance data to regularly assess how well the process of care is functioning. To build a CQI model for medication adherence, there will need to be standardized

⁵⁷ Cutrona, S L, et al. "Physician Effectiveness in Interventions to Improve Cardiovascular Medication Adherence: A Systematic Review". *Journal of General Internal Medicine* 25.10 (2010): 1090-6.

⁵⁸ Choudhry, Niteesh K, et al. "The Implications of Therapeutic Complexity on Adherence to Cardiovascular Medications". *Archives of Internal Medicine* 171.9 (2011): 814-822. Print.

⁵⁹ New England Health Institute (NEHI), Medication Adherence and Teams (2010), *ibid*.

and easily accessible measures of medication adherence. The Pharmacy Quality Alliance (PQA) is leading the industry-wide efforts towards standardization of medication adherence measures. The PQA-developed, and NQF-endorsed, measures of adherence are called the Proportion of Days Covered (PDC) measures. The PDC measures have been adopted by the Centers for Medicare & Medicaid Services (CMS) to evaluate all Medicare Part D plans and have also been recommended by CMS for use by Quality Improvement Organizations (QIOs). In October 2011, CMS will release the first set of Part D plan ratings that include the PDC medication adherence measures. URAC has partnered with PQA and incorporated the PDC measures within the URAC pharmacy quality management (PQM) accreditation programs to support the harmonization process.

The PDC measures offer an improvement over the often-used Medication Possession Ratio (MPR) metric. Although both measures are based on prescription claims data, the PDC avoids some of the common problems of MPR such as the over-estimation of adherence for patients who switch drugs or who use dual-therapy within a drug category. The PDC also captures the impact of a patient's discontinuation of a medication regimen, whereas some versions of MPR do not. Comparisons of PDC and MPR have shown that PDC tends to give a more conservative and accurate estimation of adherence for patients on complex therapy.⁶⁰

With the recent standardization of medication adherence measurement, and advances in information technologies to allow efficient calculation of PDC, the possibility of building a quality improvement model for medication adherence is quite doable. In fact, PQA has sponsored demonstration projects to show how health plans and community pharmacies can share performance information and drive improvements in medication adherence. From 2008-10, PQA sponsored several "Phase 1" demonstration projects that involved collaborations of health plans, community pharmacies, and technology vendors to calculate PDC rates for community pharmacies and provide regular updates of PDC rates to each participating pharmacy.⁶¹ The success of Phase 1 led to Phase 2 wherein a smaller set of collaborating plans and pharmacies are building adherence interventions on top of the quality measurement platform.

One of the most successful examples for this model is in Pennsylvania and includes Rite Aid Corporation, Highmark

Blue Cross Blue Shield, CECity and the University of Pittsburgh. The Pennsylvania demonstration is known as the Pharmacy Outcomes for Chronic Medication Use Study (PhOCUS). The main objective of the project is to test the impact of a pharmacy-driven quality improvement model for medication adherence. In this model, Highmark calculates the adherence rates for 240 Rite Aid stores in western Pennsylvania. The study utilizes a quasi-experimental design wherein half of the Rite Aid stores are in an intervention group while the other half are in a control group. The adherence scores for every pharmacy are loaded into a web-based platform, developed and maintained by CECity, and the adherence reports are updated on a monthly basis. The Rite Aid pharmacists in the intervention group can login to the website to view the adherence rates for their stores and monitor their progress towards adherence goals. They also have access to quality improvement tools through the platform. The participating Rite Aid stores also re-designed their dispensing process to optimize pharmacist-patient interaction and to ensure that every patient on diabetes or cardiovascular medications is screened for potential non-adherence. Additional support is directed to patients who are identified as being high-risk for non-adherence or who have questions or concerns. Preliminary results from the study indicate that adherence rates are improving in the intervention pharmacies. Further analyses will determine the overall impact of the model on health care utilization, including hospitalizations, emergency department visits, medical, and drug expenditures.

Accreditation for Pharmacy Programs

URAC accreditation programs have become a trusted and independent resource for evaluating and monitoring the safety, effectiveness, and service quality of an organization. Accreditation for pharmacy quality management, which is mostly voluntary at the state level, demonstrates an organization's commitment to excellence, quality improvement, and the need to drive industry best practices. More importantly, participation in accreditation programs show a commitment to consumer protection and empowerment since these attributes are key drivers of many of the consensus-based standards developed by URAC's multi-stakeholder advisory committees. The Pharmacy Advisory Committee includes a wide diversity of stakeholders including employers, consumers, pharmacy consultants, health plans, retail pharmacy, PBM organizations, labor and large purchasing groups. URAC offers accreditation for PBM organizations,

⁶⁰ Martin et al. Contrasting measures of adherence with simple drug use, medication switching, and therapeutic duplication. *Ann Pharmacother* 2009; 43:36-44.

⁶¹ Doucette et al. Pharmacy Quality Alliance: Five Phase I demonstration projects: Descriptions and lessons learned. *J Am Pharm Assoc.* 2011;51:544-550.

specialty pharmacy, mail service pharmacy, worker's comp pharmacy, and Drug Therapy Management (DTM) for PBM's, Health Plans and other health care organizations.

In the URAC pharmacy accreditation programs, medication management, and specifically medication adherence, is prominently featured in specific standards. Drug Therapy Management (DTM) program services typically are delivered by pharmacists and other qualified health care professionals with experience and expertise in medication management. The DTM accreditation program offers a variety of standards that optimize therapeutic outcomes for consumers and patients as a result of appropriate medication therapy (table 3).

One of the mandatory DTM standards requires that the services offered through the drug therapy management program monitor and promote medication adherence. Another DTM standard addresses "a lack of adherence to medication therapy" as one of the factors used to identify at-risk individuals for participation in a drug therapy management program. There is a core standard for "health literacy" that ensures that important communications to patients, such as for medication adherence: (1) conforms to the literacy level of the patients; (2) helps patients be aware of what effect a health care decision may have for their daily lives; and (3) presents and delivers information in a way that is appropriate to the diversity of the patient population. In the Patient Centered Health Care Home (PCHCH) program, there is a standard that ensures that medication review and reconciliation is performed and documented at each patient visit, and a rationale must be provided if the care team believes that it is not indicated. Within URAC's Case Management and Disease Management accreditation programs, there are standards for medication safety and efficacy, including medication knowledge, adherence, and the need for medication reconciliation.

URAC's processes employ the development and periodic update of program standards and measures, as well as the stratification of standards and measures into mandatory and leading categories. Mandatory standards and measures are meant to represent established industry practices, while the leading standards category is meant to create a voluntary "high bar" that many organizations strive to achieve, and in the process, develop new best practices. Measures in URAC's Drug Therapy Management program include: (1) Medication Possession Ratio (MPR) soon to be replaced by Proportion Days

Table 3 URAC's DTM Accreditation Program: Highlights of Standards and Objectives

1. Promotes appropriate therapeutic outcomes for targeted consumers
2. Review of a program's principles, criteria, and consumer-centered approach.
3. Includes a drug therapy assessment, reassessment, and evidence-based research and practices
4. Monitor and promote medication adherence
5. Requires population specification, consumer identification and recruitment
6. DTM outcomes measurement and quality improvement
7. Affords participating consumer rights, shared decision-making, and education
8. Promotes medication use communication
9. Promotes coordination of care
10. Addresses the consumer communication and education materials
11. Includes program evaluation process, outcomes reporting and methodology disclosure.

Covered (PDC, mandatory); (2) Complaint response timeliness (a mandatory consumer/experience metric); (3) Overall consumer satisfaction (a mandatory consumer/satisfaction metric); (4) Call center performance (a mandatory consumer/experience metric); (5) Overall client satisfaction (a mandatory client satisfaction metric); and (6) Therapeutic outcomes (a leading metric related to clinical outcomes performance).

Summary of Opportunity for Pharmacist and Pharmacy-based Programs

Pharmacists are essential to the care team and their participation in the medication adherence process helps empower patients to be adherent to their medication regimens. For example, CVS Caremark has shown that pharmacist outreach can increase the pick-up of prescriptions initiated by prescribers by 14%, and increase the number of patients picking-up past due prescription refills by 42%.⁶² Indeed, pharmacist-led medication adherence programs meet the optimal intervention attributes

⁶² DuPaul, Chris. PQA-URAC Medication Adherence Summit (2011), presentation.

that have been described in the literature,⁶³ which include adherence interventions that are: (1) delivered by a trusted source; (2) personalized to the patient's situation; (3) reinforce medical need and expected outcomes; (4) segment and target at-risk populations; and (5) reward/reinforce initiation and maintenance.

This section has presented several best practices where effective pharmacist-led interventions combine education, motivation, support, reminders and rewards, as well as involve collaborations with providers in a team-based approach and with other health care stakeholders at the systems level. In effect, the patient self-management/pharmacist coach model is proliferating and being buttressed within team-based coordinated care models and innovative payer incentive programs. Accreditation models for commercial programs and federal mandates for Medicare programs are requiring standardization of formats related to medication management, patient communication and reporting. To maintain quality and consistency of these programs, and their integration into the health care system, an accreditation model needs to ensure that industry standards and harmonized measures continue to drive a commitment to excellence and to continuous quality improvement.

Section III: Building on Current Programmatic and Policy Frameworks

Mining the benefits of improved medication adherence is a major theme and component of existing coordination and transition of care initiatives, the Patient Protection and Affordable Care Act (PPACA), as well as recent legislation introduced into Congress. One of the unifying concepts of these programs and provisions of law is that care should be patient-centered, closely coordinated, and overseen by a dedicated care team comprised of both primary care physicians and non-physician practitioners including pharmacists. Specific programs which employ this patient-centered approach to care coordination and improved medication adherence include health care/medical homes, case management and disease management programs, medication therapy management programs, and accountable-care organizations.

URAC's accreditation programs address these health delivery areas by offering organizations the ability to demonstrate their excellence and to maintain accreditation status.

Medication Adherence in the Health Care/ Medical Home

According to a guide from the Patient Centered Primary Care Collaborative (PCPCC), of which URAC is a member, successful integration of medication management services into a health care/medical home requires the following five key elements:⁶⁴ (1) a description of the patient's medication experience; (2) a list of medication-related problems that need to be addressed; (3) care plan goals of therapy individualized to the patient; (4) measurable outcome parameters personalized for each patient; (5) interventions personalized for each patient (inclusive of education and decision-making tools); and (6) routine follow-up evaluation of actual outcomes related to medication use. The guide also highly recommends active participation of a clinical pharmacist on the care team, as a key team specialist/consultant in the area of medication safety, efficacy, and interactions. This is particularly critical for complex patients who are taking multiple medications.

Potential weaknesses in implementing these key elements for integration are related to the need for standardized formats and the focus on process rather than counseling efforts that drive patient medication adherence behavioral change. However, accreditation and federal requirements are driving efforts towards standardization. In addition, the use of more non-physician care team members that have the skills, the time, and the patient-centered training can increase the probability of efficiently executing these processes and interventions for medication management.

URAC has differentiated its education and accreditation initiatives through its recognition of Patient Centered Health Care Home (PCHCH) programs. The Urban Institute Report notes that a "health home" refers to a more expansive version of the medical home model with the ability to deliver additional and more expansive services.⁶⁵ URAC defines a PCHCH as a quality-driven, interdisciplinary, clinician-led team approach to delivering and coordinating care that puts patients, family members, and personal caregivers at the center of all decisions concerning the

⁶³ Benner, Josh. URAC-PQA Medication Adherence Summit (2011), presentation.

⁶⁴ Patient Centered Primary Care Collaborative. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes*. PCPCC. N.p., n.d. Web. July 2011.

⁶⁵ Rother J. "A consumer perspective on physician payment reform." *Health Affairs* 2009; 28(2):w235-w237.

patient's health and wellness. To reach the widest possible number of practices, URAC's PCHCH Program has been designed to accommodate the diversity of state rules, allowing other qualified non-physician practitioners to serve on a care team, subject to state scope of practice requirements. The ability for more staff to be involved in the prescription, counseling and monitoring processes fosters a stronger total team approach to medication adherence. Principles and standards related to practice-based team care, coordinated care, patient self-management, patient-centered care, shared decision-making, cultural competency, and quality measurement, all support an enhanced and well-coordinated approach to medication adherence.

PharmMD, a pharmacist-led medication therapy management organization, in its white paper entitled *Medication Homes Play Vital Role in the ACO*⁶⁶, argues for the establishment of "medication homes" within Accountable Care Organizations (ACOs), claiming that it can be the first component of an ACO to show improvement in clinical outcomes and cost-savings. The article states that a medication home should provide a "complete source for each patient's health and pharmaceutical records, which can be updated and shared real-time with other providers." The medication home concept features pharmacists and information technology as the key connectors and enablers for success. It empowers pharmacists to work directly with patients at multiple points and to keep providers on the care team up to date. It also depends on integrated IT systems to connect the clinical settings and care management programs, including case management, disease management, and medication therapy management. Although the medication home is conceptually an early driver of health care efficiency in an ACO, the cost and set-up time for the integrated systems component could represent a barrier to various partnership models, particularly for smaller groups in less sophisticated care team settings.

Aligning to a National Roadmap

A national roadmap for medication adherence strategies could illustrate opportunities for better coordination and alignment among the multiple stakeholders driving growth of adherence programs and innovative solutions. NEHI has developed a '*Patient Medication Adherence Roadmap*' to represent the multiplicity and complexity of market-based solutions and supportive public policies, and provide an opportunity to visually connect solutions

and policies to actual interventions in the field. The roadmap defines 7 pertinent trends or "mega-drivers" of medication adherence strategy including: (1) Health information technology such as electronic medical records, e-Prescribing, health information exchanges and reminder technologies; (2) Emerging care coordination models, including models for physician, hospital and pharmacy practices; (3) Payment innovations including new payment models, value-based purchasing, and manufacturer-sponsored incentives; (4) Quality improvement standards and measures, most particularly standards and measures on medication use and management among physician, hospital and pharmacy practices; (5) Patient engagement tools and interventions, including incentives offered through benefit design, and services for patient education, activation or motivation; (6) Product innovation; and (7) Research to identify best practices, especially practices that can be scaled up within increasingly complex health care practices and delivery systems.

Numerous market trends and policy initiatives falling within these "mega-trends" can and should be coordinated to facilitate better medication management and patient adherence over the next several years. Table 4 links six of the "mega-drivers" from the NEHI roadmap to examples of current programs and/or legislation that support medication adherence. These represent opportunities to better leverage the linkage between market-based adherence strategies and national health policy.

Supportive National Health Policy

The Patient Protection and Affordable Care Act of 2010 (PPACA), as well as related regulations and more recent legislation, have escalated the focus on care coordination and medication adherence. This focus has been advanced by strong industry support and participation in related activities and initiatives, such as the recently launched Partnership for Patients. Given that current legislation tends to more generally support coordination of care and medication management, it will take continued efforts from industry alliances and medical societies to help direct resources to realize the benefits of actual medication adherence programs.

The following sections of PPACA either directly support enhanced medication management services, or provides for increased support for intensified care oversight of high risk/multiple chronic condition patients.

⁶⁶ PharmMD. *Medication Homes Play Vital Role in the ACO*. PharmMD. N.p., 2011. Web. July 2011. <http://www.pharmmd.com/news/articles/2011/medication-homes-play-vital-role-in-the-aco/>.

Table 4 Roadmap mega-drivers linked to policy/legislation

Mega-driver	Policy Programs/Legislative Support
<p>Health care Information Technology—Encouraging deployment of electronic medical records, electronic-prescribing, and reminder technologies.</p>	<p>Medicare and Medicaid Electronic Health Record Incentive Programs—Meaningful Use requirements include maintenance of patient medication lists and e-prescribing. (HITECH Act). Almost all electronic prescribing systems offer built-in medication conflict alerts as well as automated reminder capabilities.</p>
<p>Care Coordination—Improving coordination between primary care practices, hospitals, pharmacies, and enhanced used of population management to identify high risk individuals.</p>	<p>Health care/medical home initiatives, including multi-state Medicaid and multi-payer medical home programs; Medicare Shared Savings Program for Accountable Care Organizations (PPACA Sec. 3022); New HHS Community-based Care Transitions Program (PPACA Sec. 3026); Community Transformation Grants from Centers for Disease Control and Prevention. (PPACA Sec. 4201).</p>
<p>Payment Innovation—Expansion of value-based purchasing, pay-for-performance, care coordination fees, risk-shared payments.</p>	<p>Medicare bundled payments demonstration (beginning in 2012), and pending Accountable Care Organization programs; New Medicare Annual Wellness visit which includes Health Risk Assessment PPACA Sec. 4103); CMS Value-based purchasing for hospitals (potential payment cuts for preventable 30 day readmissions); Reducing cost of medications for Medicare beneficiaries—phased reduction of cost sharing in the Medicare Part D “donut hole” (PPACA Sec. 1101); Most health plans require little or no co-pay for using generics. Many large pharmacies offer very low cost sharing for selected generics (e.g., \$4 for 30 day supply);</p>
<p>Quality improvement: standards and measures—Expansion of formal accreditation for high-performing practices (e.g. health homes) and performance measures for physician, hospital, and pharmacy practices, as well as patient safety measures.</p>	<p>CMS Physician Quality Reporting System; CMS performance “Compare” programs/public websites for hospitals, nursing homes, health home agencies; National Quality Forum set of 18 measures to improve medication safety and quality; Pharmacy Quality Alliance medication adherence measures; URAC Patient Centered Health Care Home program standards address medication reconciliation, management, and oversight; Joint Commission National Patient Safety Goals; PPACA HHS to develop health plan quality measures which include improving health outcomes...through medication and care compliance initiatives;</p>
<p>Patient Engagement—Patient incentives delivered through health benefit design Incentives; Increasing the level of shared decision-making and patient engagement in ensuring positive care outcomes, through greater public awareness and health literacy.</p>	<p>Health care/medical home standards and measures; URAC’s PCHCH Program has specific standards for shared patient-provider decision-making; National Consumer League “Script Your Future” campaign;</p>
<p>Research—Demonstration projects, data collection and analysis on best practices, comparative research.</p>	<p>Beacon Community demonstrations on chronic care coordination and use of advanced HIT;AHRQ comparative effectiveness research; CMS Center for Medicare and Medicaid Innovation (organizes care improvement demonstrations); PPACA Sec. 6301—Patient-centered outcomes research/establishment of Patient-Centered Outcomes Research Institute; URAC Quality Summit Best Practices; URAC International Health Promotion Awards</p>

Sec. 3503 supports the implementation of medication management services in the treatment of chronic disease. It provides for grants and contracts to allow licensed pharmacists to provide medication therapy management services using a collaborative multi-disciplinary approach, with the goal of improving quality and lowering cost through improving patient medication adherence.

Sec. 10328 drives improvements in the Part D medication therapy management (MTM) programs. It requires Part D prescription drug plans to include a comprehensive review of medications and written summary of the review as part of their medication therapy management programs.

Sec. 3021 establishes the Center for Medicare and Medicaid Innovation (CMMI) within CMS. This Center is charged with researching, developing, testing, and expanding innovative payment and delivery arrangements to improve the quality and reduce the cost of care. This includes innovative care models incorporating medication therapy management services and establishing community-based health teams to support small-practice medical homes. CMMI has already used its demonstration authority to create two national health care/medical home demonstration programs.

Sec. 3022 relates to the Medicare shared savings program. It supports the creation of Accountable Care Organizations (ACOs) that take responsibility for the costs and quality of care received by their patient panel over time. CMS's proposed rule for this program (April 2011) requires ACOs to report on 65 quality measures, including one relating to performance of medication reconciliation for Medicare patients after an inpatient facility discharge. URAC has recommended to CMS that it expand its medication reconciliation quality measures, utilizing the much more detailed and comprehensive measures offered by the National Transitions of Care Coalition (NTOCC), of which URAC is a member, in its "Care Coordination Bundle".⁶⁷

Sec. 3502 allows for grants or contracts to establish community health teams to support the patient-centered medical home. It is intended to fund development of community health teams that support the development of medical homes. It includes a requirement to "provide access to pharmacist-delivered medication management services, including medication reconciliation".

Sec. 3026 establishes a community-based care transitions program (CCTP). It provides funding to hospitals and community-based organizations (CBOs) that drive evidence-based care transition services to Medicare beneficiaries at high risk for readmission. CMS in April 2011 issued a solicitation for organizations to participate, including a requirement for CBOs to "conduct comprehensive medication review and management, including, if appropriate, counseling and self-management support".

To assure a high level of impact for the CCTP, CMS in April 2011 launched the Partnership for Patients, a voluntary national public-private partnership aimed at (1) dramatically reducing harm and

hospital acquired conditions, including avoidance of adverse drug reactions and; (2) cutting avoidable hospital readmissions by 20 percent by assuring adherence to post-discharge medication orders. Over 300 have signed the Partnership pledge, including URAC. Programs that focus on discharge planning and other transitions of care are important to help minimize post-discharge complications and reduce readmissions. Medication management and adherence strategies are important drivers of reducing preventable hospital admissions and readmissions.

Sec. 2703 provides States the option of enrolling Medicaid beneficiaries with chronic conditions into a health home, comprised of a team of health professionals providing a comprehensive set of medical services, including "comprehensive care management, care coordination, health promotion, and comprehensive transitional care including appropriate follow-up".

In addition, there is pending federal legislation related to medication management – S.274 and H.R.891 – both of which place a strong emphasis on pharmacist-led medication therapy management, active engagement with patients, and coordination/consultation with other health professionals involved in the patient's care.

S.274 is the Medication Therapy Management Empowerment Act of 2011. It increases the number of diseases and conditions for which beneficiaries may be targeted for medication therapy management (MTM) services under Medicare Part D. It also provides pharmacies and other entities that furnish MTM services with additional incentive payments based on their performance in meeting quality measures which would be established under this Act. It will continue to be strategic to expand the number of chronic conditions that have been documented to drive overall health costs and utilize complex medication regimens.

H.R.891 is the Medication Therapy Management Benefits Act of 2011. This bill adds a requirement under the Medicare Part D drug program for the annual comprehensive medication review to include creation of a personal medication record and a recommended medication action plan in consultation with the individual and the prescriber. It specifies that medication therapy management (MTM) services must include targeted medication reviews furnished person-to-person by a licensed pharmacist

⁶⁷ National Transitions of Care Coalition. *Care Transition Bundle Seven Essential Intervention Categories*. NTOCC. N.p., n.d. Web. July 2011. <http://www.ntocc.org/Portals/0/PDF/Compendium/SevenEssentialElements.pdf>.

offered at least once every quarter to: (1) assess medication use since the last annual comprehensive medication review, (2) monitor unresolved issues, or (3) identify problems with either new drug therapies or transitional care support. It also increases the number of diseases and conditions for which beneficiaries may be targeted for medication therapy management (MTM) services. It requires the PDP sponsor to reimburse pharmacists and other entities furnishing MTM services based on the resources used and the time required to provide such services. Under this Act, the Secretary must (1) establish measures and standards for data collection by Part D Plan sponsors to evaluate performance of pharmacies and other entities furnishing MTM services; and (2) support the continued development and refinement of performance measures.

Industry Collaboration

There is widespread support and consensus in the health care industry for the value and benefits of effective, patient-centered medication management and adherence outreach and support. The involvement of industry has allowed for national health policy to evolve and become more specific for medication adherence education and intervention strategies. Examples include medication adherence-related standards, measures, policies and programs from a variety of organizations including the National Quality Forum, Academy of Managed Care Pharmacy, National Transitions of Care Coalition, Care Continuum Alliance, Pharmacy Quality Alliance, URAC, American Pharmacists Association, National Association of Chain Drug Stores, Case Management Society of America, and the Partnership to Fight Chronic Disease. Also included is the Patient Centered Primary Care Collaborative, which promotes the Joint Principles of the Patient Centered Medical Home⁶⁸ issued by four major national medical societies (and which has been incorporated into URAC's PCHC program). The national roadmap for medication adherence is led by NEHI, which is a national health policy institute, and has over 80 members from industry, health providers, medical societies, insurers, advocacy organizations, employers and other stakeholders. Likewise, NCL's campaign has the involvement of over 100 partners from every sector within the health care arena.

Summary

There is now a convergence of health care stakeholder initiatives and national health policy that focuses on the systemic issues of care coordination and poor medication adherence to improve health outcomes, avoid the overuse of medical resources, and reduce overall health-related costs. Medication adherence is one of the rare areas of health care policy considered to be a "win-win" for patients, providers, and payers alike. In an era of fiscal austerity and soaring health care costs, medication adherence represents a tremendous opportunity for a return on investment; for example, the PCPCC has reported for every dollar spent on medication management services, the return on investment ranges from 3:1 to as high as 12:1.^{69,70}

One goal of this paper is to highlight the enormous opportunity and the myriad of stakeholder strategies that have been created to improve medication adherence, while recognizing that the patient remains at the center of the medication adherence process and therefore must be an integral part of every solution. A successful approach to medication adherence will be one that is patient-centered, leverages the unique skill-sets of the pharmacist, and is ideally coordinated by a dedicated high-performance care-team approach with timely sharing of pharmacy data. There is an opportunity to better support busy physicians by expanding the care team with highly-trained pharmacists and non-physician staff that enhance communication with the patient and leverage new technology to drive effective adherence strategies. The deployment of multi-disciplinary and multi-component strategies for medication adherence optimization is rapidly proliferating and reporting successful outcomes and cost-savings.

The other goal of this paper is to sound a "Call to Action" to ensure coordination, quality, and outcomes measurement in the field of medication management and adherence programs. The NEHI "Patient Medication Adherence Roadmap" has highlighted the multiple and complex nature of solutions that are available and being used in multi-pronged strategies to optimize medication adherence. The role of accreditation and quality improvement is crucial as these programs continue to proliferate. The need for industry standards and harmonized measures to be established, implemented, periodically reviewed and improved over time is

⁶⁸ American Academy of Family Physicians, et al. *Joint Principles of the Patient Centered Medical Home*. Patient Centered Primary Care Collaborative. N.p., Feb. 2007. Web. July 2011. <http://www.pcpcc.net/joint-principles>.

⁶⁹ Patient Centered Primary Care Collaborative. "The Patient-Centered Medical Home" (2010), *ibid*.

⁷⁰ PQA Quality Forum Lecture Series. "The intersection of the medical home, medication management and quality improvement". December 3, 2010. Retrieved at <http://www.pqaalliance.org/files/PQADecemberWebinarOnPCMH.pdf>.

important to driving quality, protecting patients, and ensuring that there are effective medication adherence processes. Delivery models that focus on the coordination of care are positioned for success in implementing effective medication adherence strategies and establishing a quality improvement cycle. URAC is pleased to have established its new suite of tools, standards and measures for the Patient-Centered Health Care Home, which has the potential to drive industry best practice in care coordination and medication management. Demonstration projects need to be funded that can show the effectiveness of multi-stakeholder approaches within coordinated care programs. Outcomes research to assess the effectiveness of medication adherence programs should specifically be targeted for the medical home, health care home, and medication home environments.

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