

Pharma: Making a Difference in Managing Chronic Disease in the new Era of Electronic Health Records

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Executive Summary

Chronic disease management is the new watchword in U.S. healthcare. Nearly all industry stakeholders recognize the value of care collaboration as a way to cut soaring costs, and improve care quality across all areas. Currently, pharmaceutical companies are on the periphery while other players, such as managed care organizations, healthcare providers, and health IT companies, are taking the lead in shaping the future of care collaboration as an electronic health record infrastructure emerges in the U.S. This white paper examines the issues involved in care collaboration, identifies the trends already taking shape, and outlines the value-add for pharmaceutical company participation in a collaborative care environment based on electronic health records. The pharmaceutical company that adopts and embraces the collaborative care model can become a critical contributor to improving the quality of life for individuals with chronic disease; significant improvements in market penetration, compliance and retention will also be realized.

Introduction

Managing chronic disease is a large and growing problem for the health care system in the United States. Almost one-half of the population has at least one chronic disease—a medical condition that is expected to last a year or longer—and fifty percent of these people are battling multiple chronic conditions. As the U.S. population continues to age overall, the number of people with a chronic disease will increase dramatically¹. These trends threaten to overwhelm the health care delivery system, which is designed to treat acute episodes of illness with a fragmented and uncoordinated web of suppliers and care providers.

Pharmaceutical companies (Pharma) —as major stakeholders in the management of chronic disease—are significantly and adversely impacted by this lack of coordinated care. Many who are either at risk for developing a chronic disease, or who already show symptoms of a chronic medical condition, remain unidentified and/or untreated. Preventive care and disease management programs where medication therapies are a major element of the care plan could help these individuals and be a source of new Pharma consumers. Direct-to-consumer (DTC) marketing may generate initial inquiries by individuals regarding their symptoms and possible benefits of a particular medication. However, pharmaceutical-initiated communications that are not a part of managed care and physician care management programs often cause confusion within the physician-patient relationship. The result is the minimal long-term impact of these programs on consumer compliance and retention. In fact, DTC messages may actually cause patient-initiated non-compliance². Because of the one-way nature of this communication medium, patient reasons for non-compliance often go unreported.

Pharmaceutical companies can instead play a major, more integrated role in more effective strategies in response to the chronic disease epidemic. The pharmaceutical industry shares three common goals in chronic disease management with managed care organizations and healthcare providers: (1) early problem detection, (2) patient compliance with self-care regimens (e.g. medications), and (3) improved health outcomes as measured by avoidance of expensive interventions and improvement in health status. Recognition of these shared interests is the first step in creating a coordinated approach to care management. The second step is to assess the readiness of the market for major change. Depending on the readiness of the market, pragmatic strategies for the active participation of Pharma in a new model of care collaboration may reap significant benefits.

Three major trends in the healthcare market indicate an industry poised for change through the leveraging of efforts from all three stakeholders to transform the chronic disease management paradigm. Right now, physicians and individuals do not have sufficient incentive to proactively manage chronic medical conditions, and an information technology infrastructure to make coordinated care management practical is lacking. These are the persistent barriers to coordinated chronic disease management. Slowly but surely, such barriers are coming down. More than ever, pay-for-performance reimbursement, consumer-directed health plans, and electronic medical records play increasing roles in the health care landscape. Health care providers and consumers have the financial reasons to invest in the active management of chronic medical conditions. Also, health care information technology is a significant enabler to realizing the rewards from these new incentives.

The first trend is the increasing popularity of pay-for-performance models, both public and private. The country's largest purchaser of health care has made a strategic commitment to re-designing its reimbursement model to reward those providers who demonstrate the active management of their chronic disease patients. The CMS Physician Group Practice Demonstration has ten physician groups participating in a three year project intended to reward those groups that achieve certain quality objectives through the management of chronic disease populations. A new wave of CMS demonstrations for performance-based reimbursement of chronic care management was launched with the passage of the Medicare Modernization Act of 2003.

Several states are following CMS' lead with Medicaid reform programs, which include pay-for-performance elements. Innovators in the private health insurance sector have implemented payment differentials for providers who achieve certain quality outcome targets. Providers who have embraced the programs are realizing increased payments³. This evidence suggests that pay-for-performance programs currently in place in the U.S., which currently number more than 100, are only the beginning⁴. Incentive-based programs for chronic disease populations, in particular, will continue to gain traction in the government and the private sector. As a result, providers are now investing in IT-based tools to assist in managing chronic care management protocols, and to help patients self-manage their disease.

A second trend is that health care consumers are assuming an ever-increasing share of their own expenses for health care. A major vehicle for this shift in liability is the emergence of consumer-directed health plans (CDHPs). The market share of CDHPs is projected to be 25% of all plans by 2010, compared to a negligible

market share in 2004⁵. As a result, health care consumers are more motivated than ever to avoid costly interventions due to complications from chronic disease. This dynamic is shifting care delivery models to include the individual with the chronic disease as a principal manager of his or her care. Thus, health care consumers, particularly those with chronic medical conditions, are becoming more knowledgeable of the benefits of adhering to prescribed self-care behaviors and are demanding credible information about their medical problems. Information provided by the care management team on medications is more readily accepted than other sources of the same information. These patients are also more likely to self-report medication compliance issues and adverse reactions to a medication, instead of making the unilateral decision to discontinue use of the medication.

The final trend concerns the rapid adoption of electronic medical record (EMR) systems by health care providers. Physicians are wary of being caught unprepared to maximize the opportunity of pay-for-performance programs designed to better treat an increasingly demanding chronic disease consumer population. Because the majority of providers still use paper-based medical records, with no means for electronic health information exchange, Pharma is correct to use separate communication channels to physicians and health care consumers for distributing information about a medication. However, a model based primarily on direct to provider and DTC marketing becomes anachronistic and inadequate in the new world of EMRs, particularly when targeting chronic disease.

By the end of 2007, more than 80% of hospitals with at least 200 beds⁶ (POCP) and more than half of all physician groups of three or more should have some level of EMR capabilities⁷. This significant and growing infrastructure is the conduit of the future for electronic exchange of medical information, including medication data among the suppliers, providers, and consumers of health care.

The stars are aligning for the adoption of fresh approaches by pharmaceutical companies to expand their role in the growing market of chronic disease management while at the same time reshaping public opinion. Key stakeholders have the incentives and shared goals to create a climate for innovation. Successful programs require a new paradigm that is based on leveraging the expanding infrastructure of health care information technology to connect health care consumers with chronic diseases, providers, managed care organizations, and pharmaceutical firms into a collaborative care environment. Adoption of this new paradigm by the innovative

pharmaceutical company provides a platform for Pharma to become a critical contributor in the improvement of the quality of life for individuals with chronic disease; significant improvements in market penetration, compliance and retention will also be realized.

The Collaborative Model of Chronic Care

As more Care Delivery Organizations (CDOs) implement EMRs, health information exchanges are emerging to enable the interconnectivity of different EMRs for the integration and presentation of a patient's record of care across the continuum, including self-reported health information. These "Electronic Health Record" (EHR) networks are new and potentially powerful channels for the exchange of information between pharmaceutical companies, managed care organizations, providers, and health care consumers.

Individuals in the community exhibiting risk factors and/or questionable treatment patterns where the onset of a chronic disease is indicated can be efficiently detected and enrolled into preventive or chronic care management programs. Electronic health records and self-reported risk assessments will play an increasing role in reporting these indicators. Interventions and self-care activities reported by the provider as well as the patient become the source for early detection of non-compliance, difficulties with adherence, and reasons for medication switching within the same therapeutic class. Finally, the EHR network becomes a credible channel for provider and consumer education on new developments in chronic disease management, updates on specific medication therapies, and new and off-label information.

Elements of a Health IT-Based Collaborative Care Model

A suite of data and application services enhances the EHR network to connect care managers, physicians and enrolled individuals into a network designed for health information sharing. Three major functional areas comprise the collaborative care IT model: (1) health risk assessment, (2) self-care management, and (3) a chronic care knowledge base. EMR and disease management systems of the participating providers and managed care organizations serve as foundational information sources for collaborative care applications. Self-care management and chronic care "knowledge bases" have the greatest near-term potential value for Pharma.

Self-care management tools help improve patient adherence with prescribed medication regimens. The chronic care patient is able to use web-enabled devices or SMS messaging (e.g. PDA and cell phones) to self-report changes in medication use. “Intelligent” medication usage analytics applications can mine the EHR for patient and clinician reported information, alerting clinicians to potential compliance issues. Patients are sent automated reminders of refills/renewals and alerts in the event missed doses are detected. Self-reporting of no symptoms or non-symptomatic conditions to the care team can trigger notices emphasizing the longer-term value of compliance. In addition to being tools for the proactive management of chronic care patients’ prescribed regimens, these self-care transactions, as well as others beyond the scope of this paper, are opportunities for the “transport” of pharma-generated therapy guidelines, label information, and disease-specific notices to the patient and other members of the collaborative care team.

However, these knowledge bases should not be confused with materials distributed to providers and consumers in Direct-to-Provider and DTC campaigns. The clinical content provided by Pharma as part of a chronic care management program is compiled in the context of a specific chronic care problem. When delivered to a consumer enrolled in the program who has given consent for the service, the content reflects the individual’s medical history, care plans (including medication regimens), and health status goals. The medication information made available to the patient and their physician is co-sponsored by the pharmaceutical company, care delivery organization, and managed care firm. This strategy establishes the credibility for an individual to view pharma-supplied information as medically sound and in the consumers’ best interest. Furthermore, the information received by the consumer is consistent with the clinical content consumed by the physician.

This “bidirectional” exchange of information among the members of the collaborative care team, including the patient and the pharmaceutical company, delivers benefits that cannot be realized with less integrated methods of communication. First, the capturing of self-reported usage information provides a higher-quality and more complete profile of patient medication behavior than alternative methods. For example, patterns of patient non-compliance can be discerned that are not evident in a retroactive review of claims-generated data. Consumption of samples is also captured. Second, applications supporting the collection of self-reported data are structured to enable targeted responses and precise analysis of the patient’s self-care behavior compared to

plan. A significant by-product of this self-reporting method is better data supporting an evidence-based case for formulary inclusion.

In addition to the direct benefits of the collaborative care elements discussed above, pharmaceutical company participation in a collaborative care network yields two additional sources of value from the information captured during the chronic care management process. These “downstream” capabilities include a ready-made infrastructure for managing clinical trials and a clinical data repository for “near time” outcomes analysis. The discussion now turns to the value of connectivity to EHRs via a collaborative care network in Pharma’s strategically important clinical trials and outcomes analysis programs.

Clinical Trials Supported by Collaborative Care

The prevailing methods of recruiting participants and physicians for clinical trials are inefficient, and take place outside of the normal flow of health information among caregivers and patients. The network of physicians and their patients with chronic medical conditions are intrinsic to the collaborative care model.

This network can be leveraged into a highly efficient “clearinghouse” for the promotion of clinical trials, aggregation of prospective volunteers, selection of research participants, and identification of physicians. Participant criteria for registered trials can be applied against patients identified in the electronic health record and notices about the trial sent to patients who appear to meet the requirements. Physicians treating patients with conditions commensurate with registered clinical trials are also easily identified in an electronic health record system.

Management of the clinical trial operation itself is also streamlined by leveraging the patient and physician profiles found in an EHR. Much of the information required for clinical trials is captured real-time in the care delivery process and with patient self-care management tools. Any additional data not available in the EHR that must be collected becomes an adjunct application, which can be incorporated into the workflow of the many commercial EMR and disease management systems on the market today using widely used standards (e.g. XML, HL7).

Structured Clinical Data Repository for “Near Time” Outcomes Analysis

Participation in a collaborative care network by the pharmaceutical firm opens up the potential for access to a rich repository of structured and actionable information on physicians and consumers. Medication usage patterns, adherence factors, adverse reactions, and new indications are reported soon after capture at the point of care (i.e. “near-time” reporting). Analytics software is used to mine the repository for subtle and hidden changes in health status where there appears to be a causal link to the medication regimen. Rapid turnaround of these types of discoveries to the clinicians and patients enhances the value of the collaborative care partnership with the pharmaceutical company. This type of near-time outcomes analysis is not possible with traditional sources of patient health information, including claims and the unstructured text captured as a by product of direct-to-health-care provider (DTHCP) and DTC programs. Finally, the clinical data repository provides a continuous stream of new evidence to improve the quality of the knowledge bases, to support the collaborative care process.

Conclusion

The chronic disease epidemic requires a major response from all industry stakeholders, to avoid what could be a systemic crisis with serious economic and social implications. Pharmaceutical companies have a major stake in the outcome. Clearly, market forces are creating a potentially fertile environment for a model of collaborative care based upon the emerging health care information technology infrastructure. This model presents an opportunity for pharmaceutical companies, managed care organizations, and health care providers to evolve away from silos of information that propagate inefficient chronic disease management and obscure health events that could be managed with targeted therapies, particularly medications.

Achieving a collaborative system of care is, however, beset with major challenges. EMR implementation and the emergence of EHRs is a difficult and expensive proposition. Privacy and data standards are inconsistent and in various stages of maturity from region to region, and from industry sector to sector. Complex data ownership issues need to be resolved before elements of the collaborative care model can be implemented. Perhaps most importantly, pharmaceutical companies need to embrace a “coopetition” culture, collaborating

with their competitors to provide universal services that will be accepted by the consumers of the information (e.g. physicians and patients).

The time is ripe for Pharma to be a major agent of change in the use of information technology to support chronic care management. Pharma can take a leadership role in helping advance the industry's understanding of the role of Health IT by sponsoring the development of use cases and case studies incorporating concepts and elements discussed in this paper. Active participation in national standards development organizations and commissions to develop standards in support of chronic disease is essential to ensure that the industry's requirements are addressed. Finally, pharmaceutical companies should partner with health care IT firms and their customers. These partnerships would enable participation in targeted chronic care initiatives, to measure the effectiveness of Health IT applications in A) improving medication adherence and B) the reporting of adverse drug events.

Electronic medical record implementations by care delivery organizations and physicians are well underway. EHRs are emerging. While the health care industry is admittedly in the early stages of having robust EHR networks that can support the majority of individuals with chronic disease, this is the time when innovations are occurring and stakeholders are establishing their market positions. Will the pharmaceutical companies have a role as a key contributor of collaborator care—commensurate with the magnitude of their resources and the market opportunity at stake? Stay tuned.

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