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Disease Management to Population-Based Health: Steps in the Right Direction?

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OVERVIEW — *This issue brief reviews the evolution of the disease management model and the ways it relates to care coordination and case management approaches. It also looks at examples of population-based disease management programs operating in both the private and public sectors and reviews the evidence of their success. Finally, the paper considers the policy implications of adapting this model to a Medicare fee-for-service population.*

Disease Management to Population-Based Health: Steps in the Right Direction?

“Disease management,” raised as a potential beacon in an otherwise gloomy landscape, has become a catchphrase in health policy circles. Widely heralded as a means to both control cost and improve quality, disease management programs abound in the private sector. Now many people are calling on Medicare to follow the lead of some state Medicaid programs in incorporating disease management principles into broad public programs.

SHAPING THE CONCEPT

Disease management grew from attention to the truism that 20 percent of the patients in a given population will account for 80 percent of the costs. If this category of patients can be treated more appropriately and persuaded to comply more fully with the treatment regimen, the thinking runs, health outcomes will be improved and money saved. (It should be noted that the 20 percent is not a static population, as some people with chronic conditions develop complications and move into the high-cost category, while others stabilize or die.)

While “disease management” can refer to a wide range of services, the Disease Management Association of America (DMAA), the industry trade association, proffers this definition:

Disease management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management:

- supports the physician or practitioner/patient relationship with a plan of care,
- emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and
- evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.

Disease management focuses on chronic conditions, most commonly those affecting large numbers of beneficiaries, such as diabetes or congestive heart failure (CHF). Some programs also target rare but high-cost conditions, such as hemophilia and sickle-cell anemia. The philosophy in either case is to facilitate effective interventions as early as possible in the course of the disease.

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Chronic care accounts for an increasing share of Americans' health care needs. An estimated 125 million Americans have one or more chronic conditions; half of this group have multiple conditions.¹ Chronic conditions cut across all age groups, though they are especially prevalent among the elderly. Disease management is one effort to shift from health care's traditional acute-care orientation.

Well-designed disease management comports well with the chronic care model (CCM) proposed by leading researcher Edward Wagner, M.D., and widely accepted as a touchstone. The CCM integrates community and health plan resources to facilitate productive interactions between an informed, activated patient and a prepared, proactive practice team. Important elements are support for patient self-management, reliance on evidence-based guidelines or decision-support tools, delivery system redesign, and investment in clinical information systems.

Disease management sometimes is used interchangeably with "care coordination" or "case management." Distinctions among the labels are by no means clear-cut. A study by Mathematica Policy Research for the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services, or CMS) cast disease management and case management as the two subsets of care coordination. More recently, Barbara Cooper and Eliot Fishman, writing for the Partnership for Solutions, used "care management" as the summary category, suggesting that "Care-management services can range from a care manager simply reminding people to take their medicines to figuring out what care they need (assessment and care planning), helping them to get it (coordination), and making sure it is working (monitoring)."²

All of these concepts have in common the principle of getting a person clinically appropriate care in a timely manner without wasting resources. Care coordination seeks primarily to help a patient navigate the system, working across care settings and providers and frequently accessing other services, such as personal care or community programs, as well. Case management also incorporates the organization of benefits and services across multiple providers. It tends to be event-driven—a patient has an accident, is diagnosed with an additional comorbidity, or some similar trigger—and tailored to individual patients whose cases are expected to be high in cost or complexity. In fact, high-cost case management was a precursor to disease management, applied at the individual level.

Today's disease management is population-based; that is, its practitioners accept responsibility for the health outcomes and utilization of all members of a targeted group (such as health plan enrollees with a triggering diagnosis), not just those individuals who may seek treatment during a given period. Different interventions are targeted to different categories of patients, according to the severity of the condition and other risk factors. Population-based disease management (PDM)³ typically interfaces with one primary physician per patient and, relying on a clinical

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evidence base related to a particular condition or set of conditions, focuses on patient and physician education and adherence to a care plan.

Disease management vendors sometimes market case-management services separately from their disease-management services or call on case management services already in place in a health plan for complicated cases. One reason for separating the two is that case-management liability may be higher. PDM administrators stress that their programs are designed to augment and complement the care provided by a participant's physician, but not to provide (or advocate for) additional categories of service or to assume clinical responsibility apart from the physician.

Some health plans and employers use the disease management designation for what others might call a wellness program. Smoking cessation, weight loss, and stress management are behavior modifications that can reasonably be associated with better health outcomes and lower utilization of services. For example, Caterpillar has reported that its Healthy Balance program, focused on weight management, has produced lower health risk scores for employees and lower average claim costs to the company.⁴

THE GROWTH OF AN INDUSTRY

Pharmaceutical companies were among the first to experiment with disease management approaches. As Thomas Bodenheimer described in a 1999 *New England Journal of Medicine* article, the expansion of managed care in the 1990s meant that pharmaceutical manufacturers could no longer simply promote their products in visits to physicians' offices.⁵ In order for the manufacturer to make a sale, the physician had to prescribe a drug, the health maintenance organization (HMO) or pharmacy benefit manager (PBM) had to cover it, and the patient had to take it. Typically targeted to a health plan, disease management was a strategy to influence all these transactions and thus gain more control over demand. Some PBMs, with access to prescription data enabling them to identify patients with a wide range of conditions, developed their own disease management programs and marketed them to employers as part of a package of services.

These early versions of disease management had an arm's-length quality, consisting primarily of booklets and brochures designed to alert and educate patients about a targeted condition. Mailed to new enrollees or made available in physicians' offices, the written materials left any next steps to the patient.

A different approach was taken by Medicare's peer review organizations (PROs, known today as quality improvement organizations, or QIOs) when they were charged in the early 1990s with "helping providers to improve the mainstream of care."⁶ From 1992 forward, PROs worked with hospitals and physicians on quality-improvement projects

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focused on specified clinical conditions; among these have remained diabetes and heart failure.

The mid-1990s saw the emergence of disease management organizations (DMOs), typically organized around a particular disease state. As characterized by Robert E. Stone, executive vice president of DMO American Healthways and president of DMAA, a common strategy for health plans at this stage was to try to assemble a group of contractors on a disease-by-disease basis.⁷ Beneficiaries diagnosed with diabetes would be enrolled with Contractor A, those with asthma with Contractor B, and so on. What this approach failed to take into consideration was that persons with any chronic diagnosis very frequently have more than one. It was thus possible for a person to be enrolled in multiple disease management programs, with multiple care managers making multiple calls to (probably) exasperated physicians. The employer ultimately paying for these services would have found it very difficult to discern who was responsible for patient outcomes, good or bad.

Some health plans elected to develop their own in-house disease management capabilities. The most favorable development climate seemed to be the closed-panel HMO, in which the concept of accountability for delivering health care to a population was endemic. Kaiser Permanente, for example, developed a program featuring interdisciplinary care teams geared to address the clinical, behavioral, and social issues facing its CHF patients. Through its Care Management Institute, Kaiser has developed a network of physicians and other clinicians to help educate their peers and implement evidence-based medicine into everyday practice.⁸ Other insurers, especially those with more loosely structured network-based plans among their offerings, have opted to contract with one or more outside vendors for their disease management services.

Whether contracted or homegrown, disease management has proliferated rapidly. In survey data published in July 2002, Hewitt Associates found that 76 percent of large employers currently offered some type of disease management program, most commonly through their health plans. Some have found that designing their own programs better serves their needs. Lockheed Martin Aeronautics reported that a disease management program for diabetic patients run out of an onsite clinic realized savings of more than \$600,000 in reduced sick time usage in its first year of operation.⁹

Growth has been accompanied by further development. Within a few years, leading DMOs had refined their model, giving rise to what may already be described as second-generation disease management. Figure 1 illustrates some of the key transitions from disease management to population-based health care.

A priority for PDM managers has been developing a mechanism for identifying the members who will benefit most (and demonstrate the most financial return) from population-based care programs. The approaches

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FIGURE 1
Disease Management to Population-Based Health:
Some Key Transitions

From	→	To
Concentration on one particular disease state	→	Ability to provide services across multiple chronic conditions
Identification of potential participants through retrospective claims analysis, that is, those who have already been treated for the disease	→	Use of sophisticated computer models that permit the identification of those at varying levels of risk now and in the future
Recruitment via beneficiary “opt-in,” that is, beneficiary must take action to enroll	→	Automatic enrollment with opportunity for beneficiary to opt out

have evolved over the last few years from programs using only a diagnosis of a chronic illness, to those that added additional utilization criteria to the diagnosis, then to predictive modeling solutions.¹⁰ Predictive modeling is a new approach to identifying which patients are most in need of attention and which have the most potential for poor health outcomes and high costs over the following six months, one year, or longer. Predictive accuracy depends on the model’s sensitivity to the data fed into it and the variety and quality of that data, among which may be claims, pharmacy records, laboratory results and other diagnostic indicators, and information from the health assessments that may be conducted by a PDM program at the time of enrollment. Some models use artificial intelligence and “neural networks” to enable them, in effect, to learn from their own experience.

A health plan sponsor who undertakes to purchase a PDM component typically contracts to pay a per-member-per-month fee for a package of PDM services such as patient and provider education, support for patient self-management, and reminders and alerts. The PDM contractor agrees to specified performance guarantees, expressed in terms of cost savings and (sometimes) health outcome measures. Commonly, fees are at risk, that is, will be forfeit if performance guarantees are not met. This does not mean that the contractor is obliged to absorb any added patient treatment costs. In this, they differ from providers in a capitated system, who *are* at risk for excess treatment costs. PDM vendors express little interest in assuming such clinical risk and the insurance functions (and regulations) that go with it.

In addition to fees, plan sponsors may offer bonuses for performance beyond the guarantee. Some PDM programs have established a track record sufficient to win them risk-free contract renewals.

BETTER OUTCOMES AND LOWER COSTS: WHAT IS THE EVIDENCE?

A mantra that PDM programs share with other health care innovators is that better quality leads to lower cost. Their citations are instinctively appealing to most listeners: duplications are avoided, hospitalizations reduced, and expensive and drastic procedures such as amputations precluded by preventive regimens. In the chronic conditions most likely to be tapped for PDM (asthma, CHF, chronic obstructive pulmonary disease, coronary artery disease, and diabetes), analysis has shown ample room for improvement in both quality and cost.

Evaluation of PDM programs and of the model itself is thus a two-pronged proposition: *Does it produce better outcomes?* and *Does it generate savings?* There is some ambiguity on both sides.

PDM industry representatives have taken steps to promote measurement standards that will permit plan-to-plan comparisons of health outcomes. In February 2003, American Healthways and the Johns Hopkins Outcomes Verification Program published "Standard Outcome Metrics and Evaluation Methodology for Disease Management Programs."¹¹ These organizations hope to see the standards contained in this consensus report widely adopted, though some in the field have suggested that their product is at best a good start. Many PDM plans have sought accreditation/certification by the same accrediting bodies that assess health plan quality—the National Committee for Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, and the American Accreditation HealthCare Commission, more commonly known as URAC.

A body of peer-reviewed literature on PDM is accumulating, including a number of randomized controlled studies. Ronald Aubert and colleagues found significant decreases in fasting glucose levels among patients who were provided with the services of a nurse case manager who was also a certified diabetes educator. These patients also reported perceived improvement in their health status more than twice as often as their control-group counterparts. The study did not address cost.¹² Researchers at Geisinger Health Plan found that patients who chose to enroll in its diabetes management program had higher scores on diabetes-related HEDIS (Health Plan Employer Data and Information Set) performance measures and lower average monthly claims. Inpatient days per patient per year were lower, though there were more primary care visits.¹³

CHF programs have been most often studied, with varying results. For example, Michael Rich and colleagues found that a nurse-directed multidisciplinary intervention program reduced net cost of care an

average of \$153 per patient per month for the treatment group versus the control group. Readmissions in the control group were nearly double that of the treatment group, though survival for 90 days *without* readmission, the primary outcome measure, was not significantly different.¹⁴ An interactive home monitoring program studied by Nihir Shah and colleagues, on the other hand, produced a significant reduction in cardiovascular hospitalizations.¹⁵ In a systematic review of 11 CHF studies, Finlay McAlister and colleagues concluded that specialized follow-up by a multidisciplinary team led to a substantial reduction in the risk of hospitalization, whereas trials employing telephone contact with improved coordination of primary care services failed to find significant benefit.¹⁶

One theme that emerges from a literature review is that, even where PDM is shown to be effective, no one is altogether sure why. As McAlister observed, "our interpretation of these trials and the disease management programs that were used is hampered by the imprecise descriptions of the interventions and by the lack of data to determine the incremental benefits of each intervention."¹⁷ That is, in a bundle of educational, support, and monitoring services, what is the weight (or worth) of each separate component?

This question has cost as well as quality implications. As Rich wrote in the article referenced above,

Because of the multidisciplinary nature of the intervention, we are unable to say which elements were most important in reducing readmission rates and improving the quality of life. To do so is important from the perspective of cost, since the elimination of any unnecessary features could result in further cost savings.

The contractual details of performance guarantees and results achieved are considered proprietary, so it is difficult to establish prevailing savings levels. Demonstrating savings is an ongoing challenge for PDM managers themselves, as witness session titles at virtually every disease management conference convened. Measurement issues include the following:

- *Group composition.* New enrollments in a health plan, disenrollments, and deaths all change the population being studied over the course of the measurement period. Accurate identification and stratification of those with a condition or conditions or at risk in the future remains challenging.
- *Disease progression.* Some chronic diseases, by their nature, worsen over time, bringing deteriorating health and higher costs in spite of DM intervention.
- *Regression to the mean.* This statistical property, whereby a person measured at an extreme (such as high utilization cost) will tend to move closer to the population average at next measurement, is clearly illustrated in DM populations.
- *External variables.* Events unrelated to the PDM program, such as availability of a new clinical therapy, passage of a legislative coverage

Demonstrating savings is an ongoing challenge for PDM managers.

mandate, a recession, or problems in the patient's family, may have a substantial impact on its performance.

Even more problematic than a before-and-after cost comparison are attempts to establish what expected cost trends would have been in the absence of DM intervention. However, the observer must infer that methodologies adequate to satisfy plan sponsors are devised, as PDM contracts continue to be signed.

PARTICIPANT PERSPECTIVES

Consumers

An effective PDM program requires that potential members be screened with respect to the target disease(s). A starting point is an individual health assessment instrument. Some PDM programs offer incentives both to employers (such as a reduction in the cost trend calculation when a participation threshold is achieved) and to employees (such as a small financial reward) to encourage completion of health assessments. Rewards may also be offered for agreeing to participate in the PDM program; for example, one insurer waives some prescription drug copayments for PDM participants.

A major component in the PDM strategy is patient education and self-management. A PDM program participant may receive written materials, have access to a nurse call line, receive regular telephone calls from a nurse, or be placed in an electronic communication loop. An interesting example of the latter is the talking scale issued to CHF patients by several health plans. When the patient weighs in each day, the scale asks several questions about symptoms and compliance with diet and exercise guidelines; responses are electronically transmitted to plan records. One plan sponsor, pointing to better health outcomes by patients with scales, observed that the improvement might well consist in patients' complying because "Big Brother is watching." It is difficult to know what element(s) of self-care interventions—the extra attention, the reminders, the training, the Big Brother effect, or something else—have the most impact.

Even with training and monitoring, PDM managers have found, adherence to a care regimen on the part of patients is still a concern. LifeMasters Supported Self-Care chief executive Christobel Selecky has proposed that insurers grant a premium rebate to participants who abide by their care plans for a specified period. Patients with dementia or other cognitive disability obviously represent a particular challenge in this area.

Evidence on consumer response to PDM tends to be anecdotal or assumptive (that is, of course people like attention and better health and knowing they have somewhere to turn for help). While health plans may conduct their own consumer satisfaction surveys, PDM as an industry has yet to develop a standard satisfaction instrument, analogous to CAHPS

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(the widely used Consumer Assessment of Health Plans Survey), that would permit cross-program comparisons.

Physicians

The decision to establish a PDM program is usually made by a health plan or an employer. Identification and notification of participants' physicians comes later in the process. Most PDM programs require the enrollee to identify a primary physician contact. The health plan may already have a relationship with that provider as an employee of a staff-model HMO or a member in a preferred provider network, though outreach still may be required. For example, PDM contractor Health Management Corporation sends a short questionnaire to a new enrollee's physician, seeking to capture the basics of his or her care plan for that patient. Response rate varies by location, but in no case approaches 100 percent. The preponderance of contact originates with case managers, who may fax reminders of tests due to be performed or alerts of worsening or indeed alarming symptoms the patient is experiencing. In the Shah study cited above, researchers noted that 52 physician notifications were generated by the monitoring service for 65 reported problems; physicians intervened in 19 cases.¹⁸

PDM managers like to characterize their role as "physician extenders," selling themselves as a source of help to the busy practitioner. Anecdotal evidence for the success of this approach is equivocal; the physician response to PDM seems to range from gratitude to repugnance. For the individual physician, response may depend on the degree to which he or she has been involved in the development and use of the PDM approach or the chronic care model. If dealing with a case manager as well as a patient is an obligation imposed on the physician by a health plan, the first impression well may be negative. As one physician noted, "It's another layer, more second-guessing." Another used the verb "pestering." The pestered feeling may be exacerbated if among a physician's patients are enrollees in a number of different PDM programs.

On the positive side, some physicians see PDM as a means of delivering to their chronically ill patients self-care support that they themselves are not positioned to supply. Aware of the tensions, DMOs report that they are exploring innovative ways of working with physicians, streamlining communications, and offering incentives such as a management fee. The Geisinger Health Plan places its own nurse-employees in primary care physicians' offices, where among their responsibilities is PDM patient education and monitoring.

PDM IN MEDICAID AND SAFETY NET PROGRAMS

The Kaiser Commission on Medicaid and the Uninsured reported that 20 states had disease management/case management programs in 2002, with

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an additional 6 signaling an intention to adopt new programs during the fiscal year.¹⁹ As in the private sector, state programs are a mixture of vendor contracts and in-house projects. States have found that PDM is particularly compatible with primary care case management (PCCM) systems already in place, as both PDM and PCCM are designed to foster care coordination, preventive services, and beneficiary support.

Florida's pioneer PDM program might be viewed as a mirror of the industry's growing pains. Directed by the state legislature in 1997 to develop a PDM program, initially for beneficiaries diagnosed with diabetes, hemophilia, asthma, and HIV/AIDS, the state's Agency for Health Care Administration (ACHA) awarded contracts to separate DMOs for each disease. While the agency seemed to feel that this would allow the testing of several models simultaneously, the design as well as subsequent performance came in for considerable criticism. In May 2001, the Florida legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) issued a report charging that

- PDM services were not available for some diseases in all areas of the state.
- The agency was unable to prove the program had generated savings, and had failed to include in DMO contracts an explicit methodology for doing so.
- Provider support and participation were limited.
- Disease-specific contracts did not adequately address the holistic health care needs of chronically ill beneficiaries.²⁰

The legislature went on to adopt a preferred drug list and to direct ACHA to negotiate supplemental rebates with pharmaceutical companies that wished to place products on the list. Permitted in lieu of cash rebates were additional services, such as disease management programs. ACHA eventually entered into agreements with two manufacturers for disease management programs with savings guarantees. (OPPAGA has been, if possible, even more critical of this arrangement and recently called for the programs' repeal.)

Other states have also chosen pharmaceutical management as their PDM focus, acknowledging the role that rising drug costs have played in Medicaid budget hikes. Such programs are readily available from manufacturers and PBMs, and they are easy to administer and low-cost or even free to taxpayers. Critics continue to hold that drug manufacturers use PDM simply as a carrot to boost sales of their products.

A number of states have entered into multiple-disease arrangements with DMOs. For example, Washington contracts with McKesson for asthma, CHF, and diabetes management. Fees are at risk, 80 percent based on the cost savings guarantee and 20 percent based on improvements in clinical indicators. In some cases, health plans have taken the lead in developing disease management programs for a Medicaid population. Neighborhood

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Health Plan in Boston achieved a dramatic reduction in HIV/AIDS costs, accompanied by improved health status, by sending nurses and outreach workers into the community to provide training and support to Medicaid beneficiaries with the disease.

State-developed programs have had a mixture of outcomes. The Virginia Health Outcomes Partnership, another pioneering effort, aimed to help physicians in a PCCM program manage asthma for Medicaid beneficiaries. Evaluators calculated that, net of increased asthma drug costs, the state saved \$659 per physician trained.²¹ However, the state eventually opted instead for an outsourced PDM model focused on pharmaceutical management that was simpler and cheaper to administer.²² North Carolina also began with an asthma add-on to its PCCM program, later adding diabetes as well. State officials report success in terms of both clinical indicators and cost. Administration builds on existing PCCM mechanisms; primary care doctors, already paid a per member per month fee for PCCM, receive an additional increment for disease management.

While establishing an expenditure baseline on which to calculate savings remains a challenge, the fact that savings guarantees and cost data are in the public domain makes evaluation of Medicaid PDM programs somewhat less arcane than evaluation of commercial programs. The state of Washington's savings guarantee requirements have been detailed in presentations by Medical Assistance Administration officials.²³ Christobel Selecky has testified that LifeMasters' CHF program in northern Florida produced \$3 million in savings to the state in its first year of operation.²⁴

The U.S. Department of Health and Human Services' (DHHS') Bureau of Primary Care has implemented disease management programs in its network of community health centers (CHCs). As part of its Health Disparities Initiative, the bureau has collaborated with the Institute for Healthcare Improvement to train coordinators from five geographic clusters in chronic illness care. In 2002, 371 CHCs had chronic care projects in diabetes, cardiovascular disease, asthma, or depression.²⁵

PDM IN MEDICARE

Beneficiaries with certain chronic diseases account for a disproportionate share of Medicare expenditures. Lawmakers are recognizing the need to coordinate the often fragmented care Medicare beneficiaries receive for both quality and cost reasons.

Many Medicare+Choice contractors already have PDM programs in place. For example, Anthem Blue Cross Blue Shield developed PDM programs in CHF and coronary artery disease in 1999, as well as adapting existing case management programs in diabetes and asthma. On the fee-for-service side, QIOs continue to work with providers on quality-improvement projects around various chronic diseases. In an assessment of such projects in all 50 states, Stephen F. Jencks and colleagues documented that the

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median state's performance improved on 20 of 22 performance indicators between the 1998–1999 baseline and a 2000–2001 follow-up.²⁶ In addition, CMS has undertaken a number of demonstration projects to look at various facets of care management.

The Omnibus Budget Reconciliation Act of 1990 mandated demonstrations to provide case management services to Medicare beneficiaries with selected catastrophic illnesses, particularly those associated with high costs. Three demonstrations ensued, carried out by an insurer, a Peer Review Organization, and a tertiary-care teaching hospital. Evaluators found that none had much impact on either health behaviors (such as self-management and symptom control) or Medicare costs.²⁷ The primary reason they identified for the ineffectuality was that case managers received little or no cooperation from the clients' physicians.

Currently underway is a coordinated care demonstration called for in the Balanced Budget Act of 1997. Sixteen organizations have undertaken projects to provide case management and disease management services to Medicare fee-for-service beneficiaries with chronic conditions. CMS has said in testimony that the demonstration is designed to test "whether coordinated care programs can improve medical treatment plans, reduce avoidable hospital admissions, and promote other desirable outcomes."²⁸ Projects that offer such improvements and prove cost-effective as well may be allowed to continue beyond the initial demonstration period.

A second demonstration (this one required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000) is designed to show whether providing disease management services to Medicare beneficiaries with diabetes, CHF, or coronary heart disease can produce better health outcomes without increasing program costs. A unique feature of this demonstration is that Medicare will reimburse DMOs for their enrolled patients' prescription drugs.

Aimed at physician groups, a third demonstration seeks "to encourage coordination of Part A and Part B services, reward physicians for improving beneficiary health outcomes, and promote efficiency through administrative structure and process."²⁹ Participating physicians will be paid on a fee-for-service basis but be eligible for bonus payments based on patient outcomes. Notice of still another demonstration was published in the *Federal Register* on February 28; this one will test disease management under capitated payment.

Still in the works is a more broadly based demonstration of disease management in fee-for-service Medicare. While the Medicare population is aptly suited for PDM, some Medicare policies are not so accommodating. For example, Medicare is not currently authorized to pay providers a quality-based differential or to pay an add-on fee to physicians willing to undertake PDM. The methodological challenges of documenting savings remain. The budget neutrality requirements normally imposed by authorizing legislation may be a sticking point if measured in the short term.

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Would PDM be considered a covered benefit or should it be regarded as a method of delivering benefits already covered?

A question that nags some policymakers is how disease management can operate successfully in the absence of a drug benefit. PDM advocates respond that this is not a disease management issue; in effect, the entire practice of medicine operates in the absence of a drug benefit under current law. As DMOs would not be the only health care providers to welcome Medicare coverage of prescription drugs, so they are not the only providers to continue to encourage prescription compliance while drugs are financed by the patient or a Medigap plan.

Drugs are only part of a larger coverage issue. Many items and services routinely covered by commercial health plans are not paid for by Medicare. How can a PDM program be expected to increase beneficiaries' compliance with regimens that include items or services not covered by insurance?

A number of design and definition challenges face proponents of PDM in Medicare. For example, which conditions will be targeted? What will constitute core services? On what criteria will a program be evaluated?

It may be that many of these challenges can be met in the demonstration process. It may be that the incorporation of PDM should be considered in concert with broader Medicare reform proposals. It may be that more research and more transparency are needed to determine whether PDM can be moved from the "promising" category to the "proved." Given the growing burden of chronic care, however, it seems appropriate that Medicare be part of the quest for definitive answers.

CONCLUSION

Research on PDM generally concurs that such programs can improve the quality of care that people receive. Evidence that PDM can save money is most often presented in the form of reduced costs associated with hospitalization; there has been little public attention to total savings net of PDM intervention costs. Campaigns and demonstrations are underway to bolster the clinical and budgetary case for PDM. If successful, PDM's accomplishment raises questions of another order: does the societal will exist to pay for improvements in clinical quality, health, and quality of life on a broad scale? And is DHHS willing to take the lead?

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