

# Population-Based Disease Management Under Fee-For-Service Medicare

Pilot projects could act as a catalyst for improving the health of chronically ill beneficiaries cost-effectively over time.

by **Sandra M. Foote**

**ABSTRACT:** Medicare policymakers are considering testing population-based disease management (PDM) programs under fee-for-service (FFS) Medicare as a way to improve health and cost outcomes for selected subgroups of chronically ill beneficiaries. This paper provides a brief overview of how PDM programs are evolving in the private sector and describes how they differ from other approaches already being tested in Medicare disease management demonstrations. It also discusses some key opportunities and issues to be considered in adapting PDM programs for testing in the FFS Medicare context.

THE CONCEPT OF TESTING population-based disease management (PDM) programs in fee-for-service (FFS) Medicare is under study at the Centers for Medicare and Medicaid Services (CMS) and in Congress as part of the House Medicare prescription drug and modernization bill (H.R. 2473, Subtitle C, Section 721). Interest in the concept reflects growing recognition that managing chronic diseases cost-effectively requires not only new benefits (for example, prescription drugs), but also far-reaching efforts to help beneficiaries and providers increase their adherence to evidence-based treatment guidelines. To that end, many private-sector payers now sponsor voluntary PDM programs for selected subgroups of chronically ill beneficiaries and their providers. Preliminary findings suggest that some of these programs—carefully targeted and well executed—are producing positive results. However, few controlled studies have been done or are likely under private-sector plans.

Under FFS Medicare, a range of innovative program models could be developed and rigorously tested to identify cost-effective means of helping various subgroups of chronically ill beneficiaries and their providers improve health and cost outcomes. Structuring PDM programs would mean tying contractor payments to performance in achieving measurable, population-based goals for quality improvement, savings, and beneficiary and provider satisfaction. A major advantage

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of this performance-based contracting method, if successful, is that it would permit the federal government to make substantial new investments in improving chronic care nationally without increasing net Medicare costs. This paper describes how private-sector PDM programs are evolving and explains how they differ from ongoing Medicare disease management demonstrations. It also highlights some opportunities and issues to consider in program design and evaluation.

## Key Features Of PDM Programs

PDM programs are now common in the private sector, and their scope is evolving rapidly beyond a single disease focus. A new industry has emerged, consisting of firms that provide PDM programs as health plan subcontractors. Revenues of these firms have grown from \$85 million in 1997 to more than \$600 million in 2002.<sup>1</sup> In addition, many health maintenance organizations (HMOs) and commercial health insurers have developed their own programs in house.

Because PDM programs are diverse and evolving rapidly, there is considerable confusion about what the programs are—and are not. They are not an alternative to medical case management, a new type of managed care plan, or a substitute for quality improvement in medical care. Nor are they new covered benefits. They are a new form of customer service that payers are using to address serious deficiencies in quality of care among selected subgroups of chronically ill beneficiaries. Most PDM programs are designed to help participants improve their self-care and to provide better clinical information support for their physicians. The logic behind the programs is that facilitating adherence to evidence-based care guidelines by beneficiaries and providers should improve health and cost outcomes.

■ **Target populations.** Typically, private-sector payers (commercial insurers, HMOs, and self-insured purchasers) target subgroups of patients who account for a large fraction of plan expenditures and that have high, but modifiable, risks of adverse medical outcomes. Most payers implement PDM programs only if they seem likely to reduce claim costs at least enough to offset program costs within a year. Common target populations include beneficiaries with asthma, diabetes, congestive heart failure, and chronic obstructive pulmonary disease (COPD).

■ **New hybrid of beneficiary and provider support services.** Existing PDM programs differ widely, but they typically offer participating beneficiaries periodic phone calls from program staff (such as registered nurses); personalized goal-oriented feedback on self-care; access to twenty-four-hour nurse call centers; and educational materials by mail, Internet, or video.<sup>2</sup> Some high-risk participants receive home visits, biometric monitoring equipment, or daily calls to track vital statistics of concern. Participants' physicians receive alerts when patients need medical attention, reminders when preventive services are overdue, and periodic patient status reports. Many PDM programs have expert clinical information systems that integrate evidence-based clinical guidelines with participants' data from multiple sources (such as claims data and self-reports). Some programs have developed se-

cure Internet applications that give participants on-demand access to their data.

■ **Evolution to “patient-centric” programs.** Program design has changed dramatically since first-generation disease management programs were introduced in the early 1990s. The early programs, created by pharmaceutical companies, were aimed primarily at increasing patients’ compliance with drug regimens. Current PDM programs are broader in scope and more holistic. Some are extending their reach beyond higher-risk beneficiaries to provide early interventions for lower-risk patients. Most are upgrading their clinical information systems and cross-training staff to be able to help beneficiaries manage their overall self-care, not just the disease that triggered their inclusion in a program (Exhibit 1).

This new “patient-centric” approach is better suited to FFS Medicare, since most Medicare beneficiaries have multiple chronic conditions. It is also more consumer-friendly and less administratively complex than the earlier single-disease focus. Although many payers still have several PDM programs targeting different subpopulations, usually beneficiaries who qualify for multiple programs are assigned to only one to avoid confusion and overlap.

■ **Disease management versus case management.** Under many health plans, PDM programs are distinct from medical case management programs. Case managers often work with patients who have complex problems to help them obtain needed medical and social services at the lowest level of care that is medically appropriate for them. Nurses in the two types of programs make referrals to one another based on individual beneficiaries’ needs. Under FFS Medicare, since there is no case management program, PDM contractors might need to handle some traditional case management functions to maximize program effectiveness.

■ **Complementary to quality improvement in medical care.** Most provider quality initiatives and payer PDM programs are complementary, but they are not well linked. In fact, they are sometimes portrayed as alternative approaches, one in-

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**EXHIBIT 1**

**Design Trends In Beneficiary-Focused Disease Management Programs**

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<b>From</b>	<b>To</b>
Disease-focused	Beneficiary-focused
High-risk people	At-risk populations
Case-based	Population-based
Cost management	Risk management
Opt-in recruitment	Opt-out option
Medical care coordination	Self-care management and care coordination
Patient education	Support for behavioral change
Fragmented patient information	Composite patient data
Written guidelines	Clinical decision support systems
Payment tied to services	Payment tied to population outcomes

**SOURCE:** Author’s analysis.

ternal to the delivery system and one external. PDM programs help beneficiaries manage their ongoing self-care outside the medical care context and cope with complexity and fragmentation in their care. For example, on average, Medicare beneficiaries see six different physicians and fill twenty prescriptions each year.<sup>3</sup> However, PDM programs also add to administrative complexity. Physicians may hear from multiple PDM programs for different patients and are not likely to interact with any particular PDM program frequently. Therefore, PDM programs are not well positioned to help physicians reengineer their clinical care practices. Conceivably, the creation of some geographically based PDM programs under FFS Medicare could stimulate a blending of the two approaches. FFS Medicare is so large that it might spark increased connectivity and some innovative new partnerships among regional providers and PDM program operators.

■ **Not managed care.** Typically, private-sector PDM programs do not apply any utilization management controls. Beneficiaries' participation is strictly voluntary. The programs do not restrict participants' access to care or interfere with physicians' control over clinical decision making. Payers tend to steer away from the term "disease management" in branding their programs to avoid any such misperceptions. In fact, one reason for the growing popularity of PDM programs is that they align payers with their beneficiaries and providers in support of health risk reduction, rather than placing them at odds over access to care.

PDM programs are also not new managed care plans. Although several Medicare demonstrations are designed to link PDM programs to new insurance products, this approach is atypical among private-sector payers. They generally overlay PDM programs on their existing plans and do not require PDM subcontractors to assume insurance risk for the target populations served.

■ **Customer service, not defined benefits.** Another common misperception is that PDM programs are new defined benefits. Instead, the programs are usually structured as administrative services, somewhat analogous to the new 1-800-MEDICARE call center and other decision-support services offered through Medicare's Center for Beneficiary Choices. Eligible beneficiaries can choose not to use the services, but they do not choose which PDM program is available to them.

By making the programs a component of plan management, payers retain more latitude to experiment with various types of programs and to refine or terminate programs that do not produce desired results. This same approach might be desirable under FFS Medicare. It avoids rigidifying the use of particular strategies when what is needed is an ongoing process of collaborative learning about ways to improve chronic care and increase the value of Medicare expenditures.

### **The Meaning Of 'Population-Based'**

The term "population-based" is used in various ways, but it generally indicates that eligible beneficiaries are identified prior to program implementation through analysis of the payer's health plan data. Program operations are built around

reaching and serving the identified eligible beneficiaries. Historical claims data are used in assessing beneficiaries' support needs and risk levels.

For evaluation purposes, the target population serves as the denominator. Program performance is usually evaluated by tracking changes in clinical quality indicators, service utilization levels, costs, and satisfaction across the target population over time. Payers hold program operators accountable for improving population-based outcomes and often require PDM subcontractors to put their fees at risk, backing guarantees of quality improvements and savings in avoidable claims for the population that will more than offset program costs.

None of the current Medicare case management, care coordination, or disease management projects are population-based programs in this sense. The eligible beneficiaries in the target populations are not prospectively identified. Consequently, program operators cannot structure their operations or be held accountable or rewarded for serving assigned target populations.

### **Competition In The Disease Management Industry**

Many private-sector payers outsource at least some PDM functions, to tap subcontractors' expertise, avoid infrastructure development, and take advantage of competitive bidding and performance guarantees. To name a few such arrangements, Aetna contracts with AirLogix and Lifemasters Supported Self-Care Inc.; CIGNA contracts with American Healthways; and Humana contracts with CorSolutions.

For FFS Medicare, the U.S. Department of Health and Human Services (HHS) could choose to build or outsource PDM program operations. Medicare PDM contractors could be any of a wide range of sponsoring entities (such as commercial insurers or HMOs, disease management firms, provider-sponsored organizations, or consortia of partnering organizations). As noted, the contract structure—holding a single contractor accountable for serving a prospectively identified target population and requiring population-based performance guarantees—allows payers (including potentially Medicare) to foster and reward improvement in population health without increasing net costs.

### **Rationale For Testing PDM Programs In FFS Medicare**

The idea of testing PDM programs under FFS Medicare has appeal because many persistently costly beneficiaries have the same types of progressive chronic diseases that PDM programs are designed to address.<sup>4</sup> The landmark Institute of Medicine (IOM) report *Crossing the Quality Chasm* highlighted how poorly the existing medical care system supports chronically ill patients in managing their self-care and how inadequate information support systems are for their physicians.<sup>5</sup> Finding cost-effective ways to improve chronic disease management in FFS Medicare is critically important. The plan serves thirty-five million beneficiaries, costs more than \$200 billion annually, and may expand as baby boomers age.

In initiating PDM pilot tests, HHS would be developing and testing an innovative new quality improvement strategy that is beneficiary-centered and focused on reducing health risks for identified at-risk target populations. This strategy encompasses not only new evidence-based decision support services for participants and providers, but also a new business model (paying contractors based on population outcomes) and a new Medicare administrative model (setting goals, contracting with new program partners, and managing and analyzing plan data in new ways). These three strategic elements are all coordinated and aligned in PDM programs to improve population health cost-effectively. Designing and managing such PDM programs would be a major new HHS initiative because it involves organizing and operating a new set of ongoing plan management functions.

If some PDM pilot projects prove to be successful for selected beneficiary subgroups, the programs could be expanded through Medicare contracts for similar programs nationally, regionally, or locally, depending on the operational requirements of the particular programs. A wide range of population-based quality improvement initiatives can be envisioned in line with IOM recommendations for improving chronic care and Healthy People 2010 objectives for reducing health disparities. For example, HHS might solicit proposals for population-based quality initiatives for specific regions where the incidence of poor chronic care outcomes is particularly high, according to indices such as Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicators. Some PDM programs could prove to be particularly valuable in helping chronically ill beneficiaries who are less educated or non-English speaking overcome barriers to improving their care. Notably, for example, a recent study showed that people with no college education benefited much more from self-care support in the Diabetes Control Complications Trial than did people with more education.<sup>6</sup> Another recent study found that automated calls with nurse follow-up were associated with decreases in blood sugar levels among Spanish-speaking patients with diabetes.<sup>7</sup>

The jury is out, however, as to whether or not PDM programs can be adapted to serve FFS Medicare beneficiaries. Elderly and disabled people tend to have more comorbidities and more complex drug regimens and are more likely than commercially insured populations to be poor, frail, and cognitively impaired. Even though executives of some Medicare+Choice (M+C) plans indicate that their PDM programs are showing positive results, few randomized controlled trials or matched controlled studies have been done. Furthermore, disease management interventions that work under managed care might not translate well to the FFS Medicare context. It is not clear how such programs will affect health outcomes or costs. In testimony before the Senate Committee on Aging in 2002, Dan Crippen, then director of the Congressional Budget Office (CBO), cautioned that few rigorous studies have been done to evaluate performance of PDM programs for commercially insured populations, much less for elderly Medicare beneficiaries and those with severe disabilities.

The federal government is far better positioned than most private-sector payers to conduct controlled trials. Private-sector plans often have relatively few members and high turnover. The FFS Medicare population is large and extremely stable. Approximately 89 percent of Medicare beneficiaries and 90 percent of those eligible for both Medicare and Medicaid are in the FFS Medicare plan. Most beneficiaries remain covered under Medicare for more than a decade.

## Other Medicare Disease Management Demonstrations

Four FFS Medicare disease management demonstrations have been announced, but none is population-based. They include (1) fifteen projects under a coordinated care demonstration authorized by Congress in the Balanced Budget Act (BBA) of 1997 (Exhibit 2); (2) three large-scale disease management projects authorized under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000; (3) a capitated disease management demonstration

### EXHIBIT 2 Medicare Coordinated Care Demonstration

Program sponsor	Target no. of intervention subjects <sup>a</sup>	Targeted diseases	Average payment per member per month	Intervention
Avera McKennan Hospital	634	CHF, related cardiac disease, rheumatism	\$320	Case management; home devices; patient monitoring; use of guidelines; MD data sharing
Carle Foundation Hospital	1,518	CAD, CHF, MI, COPD, diabetes	\$147	Case management; patient monitoring; use of guidelines
CenVaNet Inc.	614	CVD, stroke, diabetes, lung disease	\$81	Case management; Rx benefit
CorSolutions Medical Inc. <sup>b</sup>	1,963	CHF	\$249	Case management; wraparound services; home devices; patient monitoring; Rx benefit
Erickson Retirement Communities	396	CHF, CAD, hypertension, diabetes	\$283	Case management
Georgetown University	1,025	CHF	\$410	Case management; wraparound services; home devices; patient monitoring; use of guidelines; MD data sharing, Rx benefit
Health Quality Partners	1,070	Asthma, diabetes, CHF, hyperlipidemia, hypertension, CAD	\$93	Case management
Jewish Home and Hospital	365	Diabetes, CHD, other heart diseases, cancer, asthma, Alzheimer's, mental disorders, liver complications	\$321	Case management; wraparound services; patient monitoring

**EXHIBIT 2**  
**Medicare Coordinated Care Demonstration (cont.)**

Program sponsor	Target no. of intervention subjects <sup>a</sup>	Targeted diseases	Average payment per member per month	Intervention
Hospice of the Valley <sup>c</sup>	1,092	CHF, other heart diseases, COPD, stroke, Alzheimer's, other dementia	\$225	Case management; wraparound services; patient monitoring; palliative care; physical/occupational therapy
Medical Care Development	1,218	CHF, MI	\$215	Case management; patient monitoring
Mercy Medical Care—North Iowa	607	CHF, renal failure, liver disease, COPD, stroke, CVD	\$279	Case management; telemedicine
QMed Inc. <sup>d</sup>	571	CAD	\$110	Home devices; use of guidelines; MD data sharing; Rx benefit
Quality Oncology Inc.	1,426	Cancer	\$117	Case management; use of guidelines
University of Maryland School of Medicine	339	CHF	\$375	Case management (no social service arrangement); home devices; patient monitoring; use of guidelines; MD data sharing
Washington University/StatusOne	5,422	Diabetes, asthma, COPD, CHF, other heart diseases, cancer, renal failure, chronic degenerative disease	\$165	Case management; wraparound services

**SOURCE:** Mathematica Policy Research, "Coordinated Care Programs in the Medicare Fee-for-Service Demonstration," 28 January 2003, [www.mathematica-mpr.com/3rdlevel/coorcareprograms.htm](http://www.mathematica-mpr.com/3rdlevel/coorcareprograms.htm) (12 June 2003).

**NOTES:** CHF is congestive heart failure. CAD is coronary artery disease. MI is myocardial infarction. COPD is chronic obstructive pulmonary disease. CVD is cardiovascular disease. Case management may include care coordination, social service arrangement, patient education and counseling, and self-care/self-management techniques. Wraparound services may include meal delivery, transportation, mental health, and family support.

<sup>a</sup> Over four-year life of the program; equal number in control group.

<sup>b</sup> Control group will receive disease management only; intervention group will receive disease management plus prescription drug (Rx) benefit.

<sup>c</sup> These patients will not be hospice patients (those with less than six months' life expectancy).

<sup>d</sup> Physician-centered; no case management component.

initiated by the Bush administration (proposals were due in May 2003); and (4) a recently initiated end-stage renal disease (ESRD) demonstration.

In all except the coordinated care demonstration, contractors must assume some risk for covered benefits and services. Under BIPA, Congress required that the contractors provide drug benefits and guarantee budget-neutrality. These features will affect program costs and could affect risk selection, cost-effectiveness, and beneficiaries' perceptions about the programs, since the contractors will be offering drug benefits as well as providing support services. The capitated disease management contractors will be paid risk-adjusted premiums for enrolling chron-

ically ill beneficiaries in new plans that combine disease management support services with FFS Medicare benefits. ESRD contractors will be paid either a risk-adjusted premium under a managed care model or a bundled payment for an expanded set of dialysis services including nearly all routine drugs and laboratory tests provided during dialysis.

### Design Of PDM Projects Under FFS Medicare

The first-order objective in testing PDM programs under FFS Medicare should be proof that they can produce major improvements in quality, cost-effectively, for at least some major subgroups of FFS Medicare beneficiaries. Additional objectives include evaluating whether or not such programs are sustainable over several years and are scalable, adaptable, and replicable regionally or nationally.

Many national experts are optimistic that there are some PDM opportunities worth pursuing under FFS Medicare, particularly for beneficiaries with congestive heart failure (CHF), but experts caution that program effectiveness depends heavily on how well the programs are targeted and executed. In addition, reported outcomes can be highly sensitive to the evaluation methods applied.

■ **Selection of target populations.** One of the most important design decisions for FFS Medicare demonstrations is to select target populations that seem highly likely to benefit from the types of interventions to be tested. Some possibilities to consider include beneficiaries with CHF or diabetes or both, and dually eligible beneficiaries with either of these conditions. All of these subgroups are major drivers of FFS Medicare costs nationally (Exhibit 3). Their health risks depend heavily

**EXHIBIT 3**  
**Medicare Outlays For Beneficiaries With Diabetes Or Congestive Heart Failure (CHF), Among Noninstitutionalized, Non-HMO Members Only, 1999**

	Beneficiaries (millions)	Percent of beneficiaries by subgroup	FFS Medicare outlays per year (millions)	Percent of FFS Medicare outlays by subgroup	Percent of total FFS Medicare outlays
Not Medicaid eligible					
CHF	3,113,151	13%	\$ 47,897	42%	34%
Diabetes	4,050,361	17	34,289	30	24
All non-Medicaid	23,732,291	100	112,810	100	80
Medicaid eligible					
CHF	749,265	19	13,010	47	9
Diabetes	1,028,770	25	10,812	39	8
All non-Medicaid	4,040,034	100	27,791	100	20
All FFS Medicare					
CHF	3,862,416	14	60,907		43
Diabetes	5,079,131	18	45,101		32
All	27,772,326	100	140,601		100

**SOURCE:** Medicare Current Beneficiary Survey Cost and Use files, 1999.

**NOTES:** Expenditures shown are for all Medicare outlays, not limited to CHF or diabetes treatment. Beneficiaries with any diagnosis of diabetes or CHF in a physician office visit were counted. Beneficiaries with CHF and diabetes appear in both categories. HMO is health maintenance organization. FFS is fee-for-service.

on their self-care and on whether or not they obtain appropriate medical treatment for all of their health problems. There are well-established clinical quality metrics for these conditions and common comorbidities. Although no randomized controlled trial results of PDM programs for older adults with these conditions have been published, some research findings suggest that quality improvement and savings may be achievable for at least some beneficiaries within these groups.

■ **Beneficiaries with CHF.** Only 14 percent of Medicare beneficiaries have CHF, but they account for 43 percent of Medicare expenditures, including the costs of treating comorbidities. Heart failure is the leading diagnosis-related group (DRG) for Medicare hospital admissions.<sup>8</sup> AHRQ estimates that 795,000 Medicare beneficiaries with CHF had avoidable hospital admissions in 1999—that is, admissions for treatment of CHF that could have been avoided through better outpatient management of their conditions. Medicare’s hospital costs associated with such admissions were \$4.6 billion, not including physician services billed separately.<sup>9</sup> Readmission rates for CHF tend to be high (30–50 percent) within the first six months after initial discharge.<sup>10</sup>

Research to date on self-care support for CHF patients relates mainly to those who have advanced CHF. A few recent randomized controlled trials indicate that hospital readmissions can be dramatically reduced through interventions to support recently discharged CHF patients in managing their self-care.<sup>11</sup> One study found that telephonic nurse guidance for CHF patients following initial hospital admission resulted in a 47.8 percent decrease in heart failure readmissions at six months ( $p = .01$ ). The authors reported medical care cost savings net of intervention costs.<sup>12</sup> In another study, readmissions for heart failure were reduced 56 percent in the first ninety days after discharge for high-risk CHF patients age seventy or older ( $p = .04$ ).<sup>13</sup> Some plan executives also report that they are seeing dramatic reductions in hospital admissions and substantial savings in total claims costs for beneficiaries with advanced CHF in PDM programs compared with similar beneficiaries under plans without PDM programs.

For patients who have advanced heart failure, one critically important aspect of care is weight monitoring and rapid intervention to avoid fluid buildup around the heart.<sup>14</sup> Helping affected people monitor their weight (for example, through automated calls with nurse follow-up) could be one component of patient-centric PDM pilot projects for FFS Medicare beneficiaries with advanced CHF. Some other ways for patients with CHF to reduce their health risks include diet and drug therapy, depression management, exercise, and smoking cessation.

■ **Beneficiaries with diabetes.** Diabetes is also common among Medicare beneficiaries and is laden with health risks. Diabetes can lead to cardiovascular disease, stroke, amputation, renal failure, and blindness. Canadian researchers found that 35 percent of the total medical cost burden for people with diabetes was attributable to treatment of cardiovascular disease (including peripheral vascular disease). They concluded, “The preventive management of diabetes should receive priority atten-

tion, and the prevention of cardiovascular disease in the patient with diabetes should become an imperative.”<sup>15</sup>

Some long-term randomized controlled trials have shown that intensive programs to support people with diabetes in adhering to their treatment regimens can be effective in avoiding or delaying the onset of complications.<sup>16</sup> Findings with respect to cost savings are not definitive, and most studies that evaluated costs have only been short-term.<sup>17</sup>

Despite limited research, virtually all private-sector plans now have diabetes disease management programs.<sup>18</sup> One example is the Diabetes Care Connection program implemented in 2000 by the Hawaii Medical Service Association (HMSA). The HMSA targeted all of its 40,000 beneficiaries with diabetes, including more than 6,000 Medicare beneficiaries.<sup>19</sup> All targeted beneficiaries were sent letters inviting their participation, and all were given the opportunity to decline by calling a phone number provided. Only 3 percent opted out.<sup>20</sup> Cap Gemini Ernst and Young found that a much higher percentage of beneficiaries had their blood glucose levels tested during the first year of the program than in the baseline year. Also, total per capita claims costs were lower for HMSA Medicare beneficiaries with diabetes in 2000 than in 1999, mainly because of reduced hospital costs.

Randomized controlled trials of patient-centric PDM programs for beneficiaries with diabetes would be highly informative. Given uncertainty about cost-effectiveness, the initial target population might be defined to be beneficiaries who have diabetes with other chronic conditions for which self-care support services are also likely to be clinically beneficial and cost-effective.

■ **Special focus on dually eligible populations.** Pilot projects targeting dually eligible populations are another major opportunity to consider. The prevalence of chronic diseases is high in these populations. For example, approximately 23 percent of noninstitutionalized dually eligible beneficiaries have diabetes, compared with 16 percent of non-dually eligible people.<sup>21</sup> Most dually eligible beneficiaries have not joined managed care plans, so they receive very little ongoing guidance in self-care. They are costly for both Medicare (Exhibit 3) and Medicaid, accounting for 19 percent of Medicaid beneficiaries and 35 percent of Medicaid spending.<sup>22</sup>

Historically, management of Medicaid beneficiaries has been a state responsibility. For dually eligible beneficiaries, however, Medicare is the primary payer and stands to benefit more, financially, from reducing hospital admissions and emergency department visits. Conceivably, both the federal and state governments could contract with PDM program operators, requiring performance guarantees. Medicare and Medicaid claims files could be combined, including Medicaid drug claims and other services not covered by Medicare, for use in program operations and evaluation. Much planning and coordination of efforts would be required (for example, arranging monthly claims file exchanges and establishing communication between PDM nurses and Medicaid case managers), but the health gains for participants and the savings to public payers might be substantial.

■ **Beneficiary eligibility.** No single diagnostic label is sufficient to identify people who are likely to benefit greatly from PDM interventions. Therefore, the HHS secretary is likely to establish several inclusion and exclusion criteria (for example, risk adjustment scores or exclusion of hospice patients) in each program to identify eligible beneficiaries. Regardless of how the target populations are selected, PDM contractors will want to stratify eligible beneficiaries by risk levels (using claims data, nurse assessments, and predictive modeling techniques) and customize interventions to match individual beneficiaries' risks and needs. Contractors' algorithms for risk stratification are often proprietary, but results should be transparent. The federal government will need to know which types of interventions various subjects received and to have some measures of intensity (for example, calls per month) for subgroup analysis of program effectiveness.

■ **Outreach to eligible beneficiaries.** The federal government can expect to receive competitive bids and savings guarantees for Medicare PDM programs only if contractors will be given historical claims data on their assigned target populations and permitted to do proactive outreach to eligible beneficiaries (who do not decline to be contacted) and to their physicians. Such uses of plan data and outreach would be new in the FFS Medicare context. Two important issues to address are (1) assuring that communication to beneficiaries and providers is clear and accurate, and (2) protecting beneficiaries' privacy.

Clear communication is critical. In the failed Medicare case management demonstration projects in the early 1990s, evaluators reported that one obstacle to recruiting subjects was that some eligible beneficiaries thought that participating might jeopardize their future FFS Medicare coverage. To avoid a recurrence, HHS will need to communicate clearly to beneficiaries, physicians, and the public that participation is voluntary, is free of charge, and does not affect benefits.<sup>23</sup>

In addition, given public concerns about privacy, HHS will want to assure that beneficiaries understand that their information will not be released or used by Medicare or PDM contractors for purposes other than those permitted under federal privacy protection laws. HHS will also want to ensure that contractors have strong security protections built into their information systems, operating procedures, and contract terms.

Mailings and telephone outreach to identified eligible beneficiaries and physicians add greatly to program start-up costs. However, as Crippen pointed out in his Senate testimony, the advantage of this approach is that it is likely to engage a much larger fraction of the target population than would otherwise be served.<sup>24</sup>

■ **Information sharing and collaboration with physicians.** Private-sector experience indicates that physicians rarely object to a PDM program if they are informed of it in advance, are not asked to take on new uncompensated administrative tasks, and understand that guidance to patients will be based on physicians' treatment plans and evidence-based guidelines. One valuable service PDM programs can provide is to assure that alerts sent to physicians are clear and supported by relevant

patient information and evidence-based clinical guidelines, and that they can be acted upon. To foster more collaboration, HHS could consider giving priority to PDM programs that propose innovative modes of improving information sharing among health care providers and others (such as pharmacy benefit managers, supplemental insurance carriers, and clinical laboratories).

■ **Contractor payment.** For cash-flow purposes, PDM program operators are usually paid per member per month fees. These fees are linked to criteria for including and excluding beneficiaries, which need to be tightly defined. The fees are also typically linked to contractual language specifying the program delivery model and minimum operational requirements. HHS can work with private-sector experts and prospective bidders to determine appropriate operational requirements for the pilot tests and to assess the adequacy and appropriateness of proposed fees. Total annual payments to contractors are typically subject to contractually defined performance guarantees. These guarantees and the reconciliation processes to determine if performance standards were met also need to be tightly defined to minimize disagreements. Here, too, private-sector experience can be instructive to HHS in avoiding operational and methodological pitfalls.

■ **Study design.** Randomized controlled trials are highly desirable to control for selection biases (such as regression to the mean in beneficiary costs following hospital stays) and confounding variables (such as new medical technology). Randomization of beneficiaries might not be appropriate in all circumstances, however. An exception would be if the planned interventions have a strong physician-support focus and are likely to change physicians' behavior with control-group patients as well as with experimental-group patients. In such instances, other types of controlled studies could be done.

Either randomized or matched controlled studies are highly preferable to the pre-post observational analyses that many private-sector payers have been using for lack of control groups. Some payers have found that selection biases and lack of comparability in measurements between the baseline and program years have produced dramatic effects on reported results from pre-post analyses.

In controlled trials, HHS would have the advantage of being able to tie performance measures to comparisons between the intervention and control groups rather than just to baseline measures for similarly defined populations. The results of controlled trials would contribute greatly to the state of knowledge in the field and would be extremely valuable in setting benchmarks for future performance expectations if pilot projects prove to be successful.

■ **Lack of prescription drug benefits and claims data.** The variability in beneficiaries' prescription drug coverage and the lack of prescription claims data are two serious handicaps that HHS and PDM program operators could face in the FFS Medicare context. PDM contractors could nonetheless be expected to help participants understand and comply with their drug regimens. PDM program contractors can be expected to use participants' self-reports about their prescription drug use as

the basis for coaching, regardless of how participants are financing their drugs. It would be useful to learn whether or not drug coverage plays a major role in PDM program effectiveness. Program contractors could be required to gather drug coverage information from participants. Sample surveys would be required to obtain comparable information for the control groups.

**F**OR HHS TO LAUNCH MAJOR NEW INITIATIVES in FFS Medicare has sometimes proved to be difficult, given political pressures and CMS resource constraints. However, political support seems to be growing for federal leadership in addressing widespread failings in chronic care. The recent IOM report *Leadership by Example* urges the federal government to take a more active role in setting performance standards and in acting as a value-oriented purchaser of health care.<sup>25</sup> One advantage of PDM pilot projects is that HHS could launch such programs in partnership with private-sector entities without creating a large new government operation.

The advent of PDM programs offers federal policymakers an opportunity to test an innovative new strategy to promote quality improvement for at-risk populations in FFS Medicare. Pilot tests would not require expanding the scope of Medicare benefits or increasing net Medicare costs, but they would be a major new initiative for HHS in proactive management and formative evaluation of the quality initiatives to be tested.

PDM programs are clearly not a single-source solution for many current failings in the traditional health care delivery system or for Medicare's limited benefit plan, but they might yield incremental improvements of great value in a program the size of Medicare. Ultimately, the greatest impact of PDM pilot projects could be in serving as a catalyst to more federal experimentation and collaboration with the private sector to improve the health of chronically ill FFS Medicare beneficiaries cost-effectively over time.

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*This paper draws on insights gained from discussions with many national experts on disease management and on fee-for-service Medicare, including, in particular, those who participated in a series of small-group meetings that the Health Insurance Reform Project held on the topic during 2002 and 2003. Descriptions of those meetings and participant lists appear online at [www.gwu.edu/~Ehirp/intros/meetings.htm](http://www.gwu.edu/~Ehirp/intros/meetings.htm). The author thanks Elyse Pegler for research support and Christopher Hogan and Bernard Friedman for assistance with data analysis. The author is solely responsible for the views expressed. The Robert Wood Johnson Foundation provided support for the meetings and the paper through a grant to the Health Insurance Reform Project at the George Washington University.*

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