CHAPTER 2

The Medicare Modernization Act and chronic care improvement

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In this chapter

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There are few incentives and little infrastructure to support the coordination of care for beneficiaries in fee-for-service payment systems. In recent legislation, the Congress established the Chronic Care Improvement Program to address these issues in the traditional Medicare fee-for-service program. The program targets beneficiaries with diabetes, congestive heart failure, and chronic obstructive pulmonary disease. It seeks to improve coordination of care across health care settings and among service providers, educate patients about how to care for themselves, and promote the use of evidence-based treatment guidelines. The program will test different models of care coordination and whether it reduces program spending. The Commission has expressed a strong interest in assuring physician involvement in the initiative and in promoting coordination of care for Medicare beneficiaries to improve quality.

Most beneficiaries have one or more chronic conditions, and too often their care is fragmented and poorly coordinated. Under fee-for-service (FFS) Medicare, they may see multiple physicians, frequently without any single provider responsible for managing their care. Moreover, a small proportion of beneficiaries accounts for a disproportionate share of program spending. These individuals often require repeated costly hospitalizations—some of which might be avoided if care were better coordinated.

Recognizing the need for better care coordination in FFS Medicare, the Congress established the Chronic Care Improvement Program (CCIP) in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The CCIP will begin by December 2004.[1] As distinct from the practice of medicine, the program is geared towards ensuring ongoing coordinated care across health care settings and among service providers, teaching patients how best to care for themselves, and promoting the use of evidence-based treatment guidelines. CMS will initially target two groups of FFS beneficiaries: those with congestive heart failure (CHF) and/or complex diabetes; and those with chronic obstructive pulmonary disease (COPD). Within each group, targeting will be limited to those with moderate to high risk-adjustment scores. Organizations will bid to manage care in specific regions with particular emphasis on areas that have a high prevalence of targeted conditions or poor Medicare quality rankings. Each program will operate under a randomized controlled trial design that requires at least 30,000 beneficiaries with the targeted condition to be split between treatment and control groups. This pilot program may be extended to cover more beneficiaries in a few years if policymakers conclude that care coordination has demonstrated that it can reduce growth in Medicare spending and improve quality.

The Commission strongly supports the goal of this program. Improving coordination of care for Medicare beneficiaries is central to MedPAC's quality agenda and has the potential to reduce program spending, especially since contractors will be at risk for meeting performance goals. However, implementation of the legislation will be challenging. The law requires contractors to assume risk for achieving savings and quality targets, coordinate care for a large identified population, manage all enrollees' chronic conditions, and, if needed, provide more intensive case management services to the highest-risk individuals.

The program will be evaluated on the basis of savings targets, quality indicators, and satisfaction measures. CMS requires contractors to guarantee at least 5 percent savings over three years. The agency does not indicate how quality and satisfaction factors will affect fees—bidders will propose adjustments to fees if they do not achieve performance targets, which are subject to negotiation with CMS. Improvements in quality will be an important factor in evaluating the success of the program.

In order for the CCIP to be successful, physician groups and disease management organizations will need to collaborate. It will be difficult for any single type of organization to meet all program goals. Beneficiaries, particularly those with multiple chronic conditions, rely on their physicians to guide and manage their care. However, it is unlikely that many physician groups will be able to participate in the program on their own. Physician groups generally do not accept performance risk and are unlikely to have the resources to coordinate care for populations of the size targeted by CMS. Disease management organizations have more experience educating large populations of patients about their conditions, often have more limited interactions with physicians, and generally depend upon external case managers for more complex patients. They also work primarily with people under age 65. Under the CCIP, contractors will have to coordinate care for a more medically complex group than is typically found among non-Medicare populations. For all of these reasons, we believe that CMS should encourage a partnership approach for the CCIP.

The Congress determined the overall design of the CCIP (see text box opposite), but left many of the details of individual programs to negotiations between CMS and participating organizations. Programs offered under the CCIP can be provided by disease management organizations, insurers, physician group practices, integrated delivery systems, or consortia of entities that meet CMS requirements. Contractors will bid to provide services to beneficiaries with the targeted conditions in a specific geographic area. Their fees, or a portion of them, will be withheld or returned if their programs do not meet contracted goals, but the organizations will not be responsible for the medical costs of beneficiaries. The Congress intended for the CCIP to be budget neutral over the long run, but provided for some initial start-up costs. For fiscal years 2004 through 2006, the MMA specifies that aggregate expenditures for payments to chronic care

improvement organizations net of program savings cannot exceed $100 million. Payments to organizations who win CCIP contracts could total more than this amount, but the Congress anticipated that either the program would reduce other types of Medicare spending or that CMS would recoup contractor fees. Some analysts argue that the conditions targeted in the CCIP lend themselves to even greater savings than CMS requires. However, given the complexity of the Medicare population, it remains to be seen the extent to which savings can be gained and quality improved within the program's three-year period.

The Medicare Modernization Act and chronic care improvement

Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) calls for voluntary chronic care improvement programs for fee-for-service (FFS) beneficiaries that focus on people with one or more chronic conditions as specified by CMS. The programs will be implemented in two phases. In the first phase, initial contracts will be awarded in areas where, in the aggregate, 10 percent of Medicare beneficiaries live. If independent evaluations find the first stage successful, additional contracts would cover other geographic regions or operate nationally. At least one contract must be awarded by December 2004; contracts may last up to three years.

According to the MMA, each program must:

- have a process to screen beneficiaries for comorbidities aside from the targeted condition;
- provide each program participant with a care management plan;
- carry out the care management plan and other chronic care improvement activities;
- guide participants in managing their health, including all comorbidities, relevant health care services, and pharmaceutical needs;
- use decision support tools such as evidence-based practice guidelines;
- develop a clinical information database to enable tracking and monitoring of each participant across practice settings and to evaluate each participant's outcomes; and
- report health care quality, cost, and outcomes for the program.

The care management plan, individualized for each enrollee, should include a point of contact for participants and providers and, if suitable, develop a program that includes nutritional information; teaches enrollees and their families how to manage their condition, using monitoring technologies as appropriate; provides information about treatment options including end-of-life care; and communicates relevant clinical information to the physicians who are treating program enrollees.

Overall, Medicare program spending for participants, including fees paid to contractors, cannot exceed what would have been spent in the absence of the program. For the short term, however, the Congress provided for initial start-up costs by authorizing $100 million in aggregate expenditures to contractors net of any program savings over the first three years. The initial stage of the CCIP will use a randomized controlled trial design, and independent contractors will evaluate programs on improvement to clinical quality of care, beneficiary and provider satisfaction, and achievement of target savings. However, the MMA does not specify the relative importance of each of these factors. Contracts will put administrative fees at risk if programs do not achieve their performance targets.

CMS will identify potential participants within a geographic region proposed by a contractor and will randomly assign beneficiaries to treatment or control groups. It will also notify targeted beneficiaries about the program and encourage them to participate. CMS's request for proposals states that 30,000 or more people will be split between treatment and control groups.

If contracts awarded during the initial phase meet standards for quality improvement, beneficiary satisfaction, and savings targets, the Secretary may expand programs to other geographic areas without

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further Congressional authorization. The broader expansion of the program could take place two to three years following the start of the initial phase.

The MMA includes additional provisions that touch on chronic care. These include a quality improvement program for beneficiaries enrolled in Medicare Advantage plans and a requirement for sponsors of Medicare Part D prescription drug plans to establish drug therapy management programs for beneficiaries with multiple chronic conditions requiring several medications. Another section of the MMA initiates a pay-for-performance demonstration program with physicians to improve care management for FFS beneficiaries with chronic conditions. Finally, the law requires the Secretary to develop a plan to improve quality of care and reduce costs for chronically ill beneficiaries. The Secretary must plan to integrate existing data sets, identify data needs, develop a capacity to store and process Medicare data quickly, and develop a research agenda using the data. ■

In this chapter, we summarize the provisions of the CCIP and discuss the issues that CMS and its contractors will need to address when implementing the program. Few could deny the need for greater care coordination and improvements in quality, but questions remain about how to attain these goals. The way in which the CCIP is implemented—particularly in its initial years—will determine its effectiveness and broader applicability. We begin by discussing the concept of care coordination and the approaches taken by organizations that provide such services today. We also identify outstanding issues that must be addressed as the CCIP is implemented, such as:

- Who will receive services?
- What is the role of contractors?
- What services will contractors provide?
- How will contractors be paid?
- How will contractors and CMS coordinate responsibilities?
- Can contractors meet the special needs of Medicare beneficiaries?
- How will CMS evaluate program effectiveness?

In addressing these issues, we highlight what we have learned from interviews with CMS officials, disease management organizations, insurers, physician groups, medical device manufacturers, academics, and other stakeholders. Finally, we include a case study of chronic kidney disease (CKD) to examine the potential for better care coordination to improve quality of care or to result in savings. We selected CKD because of the Commission's longstanding interest in improving the quality of renal care.

What types of services are envisioned in a chronic care improvement program?

Programs to improve care for individuals with chronic conditions can take a number of different forms. The goals of all programs are to improve health, coordinate care among providers, improve patients' compliance with their treatment regimens, and encourage provider adherence to evidence-based treatment guidelines. These programs attempt to contain or reduce health care spending for patients who incur higher costs, on average, than other patients.

The two most typical approaches to coordinating care for people with chronic conditions are disease management and intensive case management. These approaches tend to provide different services, summarized in Table 2-1. Typically, health plans combine the disease management approach with intensive case management as required for high-risk individuals who have multiple chronic conditions and more complex situations.

- Disease management services are generally provided on a broader scale than case management services. They teach patients to help manage their own

TABLE 2-1 **Differences between disease management and case management**

Program element	Disease management	Case management
Target population	People diagnosed with a specific disease	People at high risk for costly, adverse medical events and poor health outcomes
Reliance on evidence-based treatment guidelines	High	Low to medium
Reliance on protocols and standardized approaches	High	Low
Use of nonmedical social support services	Low	High

Source: Adapted from Chen et al. 2000 and Crippen 2002.

conditions and help to coordinate medical care (see text box). Programs typically use certain conditions to target individuals or populations for interventions. Currently, most disease management programs target individuals with specific conditions but then take responsibility for managing all the additional chronic conditions of the targeted individuals. Program interventions aim to ensure patient compliance with evidence-based treatment guidelines.

- Generally, case management services involve fewer people than disease management. These services are intensive and individualized, including coordination of medical care and social support services for a group of high-risk individuals. Support services provided to patients may include transportation, meals, homemaker or chore services, and recreational therapy. Case management focuses less upon patient adherence to medical guidelines.

What are disease management services?

Typically, the goal of services provided by disease management organizations is to educate patients in management of their own chronic diseases by making them more self-reliant and knowledgeable about their condition. Although companies use different models, they frequently use services such as those below.

- Nurses at call centers periodically contact enrollees and assess their health status, collect data about their care that may not be obtainable from claims data like laboratory test results, explain the meaning of these results, remind them to seek preventive services, and answer their questions. The nurses provide patients with information about their conditions and how best to manage them. Enrollees may also call in if they have questions.

- Call centers also encourage patients to share concerns that may be unrelated to their health conditions. For example, one interviewee reported that an enrollee's concern with the health of her spouse may prevent her from managing her own medical condition. By acting as an interested and informed listener, the nurse may help alleviate the patient's concern and allow her to comply with physician instructions about her own care. Many programs provide written information and reminder notices to patients about the need for physician visits or preventive services.

- Enrollees may use monitoring devices so that, for example, they can track their weight and blood pressure between doctor appointments.

- Programs supply information to help patients make decisions about their treatment options. The program might explain options open to patients and provide them with lists of questions to ask their physicians. In some cases, this includes providing information on end-of-life care. ■

Since it will focus on large populations, the CCIP emphasizes those services typically offered by disease management organizations. But because of the higher prevalence of multiple chronic conditions and other complications, more Medicare beneficiaries are likely to require case management services than beneficiaries in non-Medicare populations. As a result, any organization that operates as a contractor for the CCIP will need to provide access to both types of services.

What are the existing models for chronic care coordination?

The MMA provides the Secretary with broad authority to contract with different types of organizations—disease management companies, health insurers, integrated delivery systems, physician group practices, or consortia of these groups—for different approaches to chronic care management. All of these entities have already established programs designed to enhance care coordination and patient compliance with physician regimens using a variety of models.

In this section we look at the varied role of physicians in current care coordination models. We focus on two approaches at the opposite end of the spectrum: one in which programs are run by or for physicians, and another in which most or all communication between disease management organizations and physicians is mediated through the patient. In our interviews with providers and purchasers of these services, we found little agreement on the way these approaches affect program outcomes.

No matter what entity provides chronic care improvement services, the Commission believes that the role of the physician is critical. Most Medicare beneficiaries already have established and valued relationships with a regular provider. According to the 2002 Consumer Assessment of Health Plans Survey, nearly 90 percent of FFS beneficiaries have a regular doctor or nurse and almost 80 percent have seen their regular practitioner for two or more years. Sixty percent reported seeing their primary provider (usually a doctor) for over five years (MedPAC 2004).

Having a physician play a central role in coordinating a patient's entire plan of care is of particular importance to the Medicare population. Medicare beneficiaries are likely to have more complex medical conditions than the general population. A physician who knows the history of a patient and has an established relationship with him or her, will have the greatest capacity to tailor a care management plan to fit the needs of the individual. Because of this, some interviewees noted that beneficiaries were unlikely to participate in care coordination programs without encouragement from their physicians.

But some analysts contend that there is room for other models of care coordination (Foote 2003). They argue that the status quo—where Medicare beneficiaries see multiple providers who may or may not know about each other's actions—is inadequate. It can be difficult to identify a single provider who would be responsible for coordinating treatment regimens across providers and care settings. Disease management organizations say that while they do not practice medicine, they can help to keep providers informed about their patients' care. And by educating beneficiaries about how to help manage their conditions, care coordinators may encourage patients to comply with treatment plans more closely.

Physician-centered approaches

Physician-centered approaches to chronic care management often include fixed monthly payments for physicians charged with coordinating care for specific patients. In Medicaid, the approach may involve designation of a physician as the primary care case manager (PCCM) for a recipient. In North Carolina, for example, the Medicaid program links more than 75 percent of eligible participants with a primary care provider (Simms 2003). Although the program pays for medical services on an FFS basis, it also pays the PCCM $2.50 per recipient per month to coordinate care. Since 1998, the program has linked participating physicians in 13 local community networks with hospitals, health departments, and departments of social services. The state also gives these networks $2.50 per recipient per month and helps them determine how best to use the money to coordinate care, improve quality, or reduce unnecessary expenditures. Some networks use funds to hire case managers for patients requiring intensive services. Among other projects, the networks have implemented disease management programs for asthma and diabetes. Networks have also worked to reduce excessive emergency department use and inappropriate prescribing.

A number of large physician group practices have developed their own models for chronic care improvement. For example, the Geisinger Health System and the Marshfield Clinic, health care delivery systems based upon large multispecialty group practices, have created disease management programs for patients with chronic conditions. The programs give physicians more time to practice medicine by employing nurses to handle patient education and care coordination. Geisinger also has implemented an innovative electronic health record system. Geisinger staff believe that the future development of information technology could reduce the need for other types of disease management programs. Information recorded in the medical record could lead to prompts for office visits, prescription refills, and reminder phone calls. However, while information technology could incorporate some disease management functions, it would not fully address the need for case management of high-risk individuals.

Certain requirements of the MMA may discourage physician group practices—particularly smaller entities—from bidding to become contractors in the initial phase of the CCIP. For example, under the experimental design of the CCIP's first phase, bidders must assume that 20,000 beneficiaries will be in the intervention group and another 10,000 will serve as controls—both with the targeted condition. Smaller organizations have raised concerns that they will not be able to serve a big geographic area. Physician practices that wish to provide care coordination services only for their current patients would find it even harder to participate.

CMS is currently testing several other models of care coordination, albeit on a small scale, that focus more directly on physician groups. The MMA calls on CMS to establish a pay-for-performance demonstration program with physicians to serve FFS beneficiaries who have one or more chronic conditions identified by the Secretary. The demonstration aims to help stabilize medical conditions, limit acute exacerbations that can result in expensive hospitalizations, and reduce adverse outcomes such as drug interactions. The three-year demonstration program will operate in four sites throughout the country. Physicians who meet or exceed performance standards set by CMS will receive a fixed payment per member per month. The MMA specifies that the demonstration must be budget neutral.

Another vehicle for testing the physician-centered model for coordinating care is the physician group practice demonstration mandated in the Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000 (Table 2-2, p. 40). The demonstration is designed to encourage coordination of care and reward physicians for improving health outcomes. It tests a payment methodology for physician group practices that combines FFS payment and a bonus pool derived from savings achieved from improvements in managing care and services. CMS is working with 11 group practices that have been recommended for award. In contrast to the CCIP, this program is a demonstration project of limited size and duration.

Approaches used by disease management organizations

Programs run by disease management organizations differ from physician-centered approaches and have widely varying relationships with physicians. These programs do not practice medicine but seek to help enrollees better understand their conditions and comply with medical regimens. All programs rely on physicians to develop protocols for the management of patients with chronic conditions. Nearly all disease management organizations try to contact physicians when they enter a region to let them know that their patients may be targeted for a program, to answer questions, and to provide a contact point for any issues that may arise. They may also provide data on practice patterns to physicians and contact them if an emergency situation exists for a particular patient. Some programs seek physician aid in identifying patients who would benefit from program enrollment and in encouraging them to participate.

Typically, disease management programs establish physician advisory boards to foster communication between the program and the local medical community. Sometimes these advisory groups will contact physicians if they perceive problems in the medical care the physicians are providing. A number of programs have developed tools labeled "smart registries" to provide doctors with information on their patients and allow them to benchmark their care patterns with other physicians in their health plan. Some programs focus on providing patients with questions to ask their physicians about treatment options.

TABLE 2-2

Demonstrations of care coordination and disease management in Medicare prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Title and dates	Goals	Target population	Payment
Medicare coordinated care demo (BBA, 1997) 2/2001–6/2006	Test models of coordinated care to improve quality of services and manage Medicare expenditures.	Controlled trial design for 14,500 FFS beneficiaries with CHF, cardiac and other conditions at 15 sites.	All-inclusive monthly rate for coordinated care services.
Medicare disease management demo (BIPA, 2000) 11/2003–11/2006	Test disease management for beneficiaries with advanced-stage CHF, diabetes, or CAD.	Controlled trial design. Will enroll up to 30,000 beneficiaries in four states.	All-inclusive monthly rate for disease management services and prescription drug costs. DMOs must accept performance risk.
Capitated disease management demo Awards expected by summer 2004	Test capitated payments for case management of specific conditions. Contractors to provide all Medicare-covered services plus disease management services.	Enrollees must have a chronic disease such as stroke, CHF, or diabetes, or qualify as a dual eligible or frail elderly.	Full capitation with risk-sharing option. Payment greater of MA rate or 99 percent of risk-adjusted county FFS rate.
Physician group practice demo (BIPA, 2000) Not awarded yet, to run 3 years	Encourage coordination of care and investment in administrative structures among physician group practices.	CMS will assign 250,000 beneficiaries to physician group practices based on where they receive evaluation and management services.	Combines FFS payment with a bonus pool of savings from improved management of care.
Intensive case management 11/2001–11/2004	Test whether case management improves clinical outcomes, quality of life, and satisfaction.	Controlled trial design: 500 beneficiaries at one site. High-risk patients with CHF and diabetes.	All-inclusive monthly rate for coordinated care services.
ESRD managed care demo (OBRA, 1993) 2/1998–9/2001	Enroll ESRD patients in managed care settings. Health outcomes generally the same or better than in FFS Medicare. Provision of additional benefits such as prescription medicine found to be cost effective.	Demo enrolled 2,500 beneficiaries with ESRD at two sites.	Two M+C plans were paid 100 percent of risk-adjusted FFS spending.
ESRD disease management demo (OBRA, 1993) Not yet awarded, will run 4 years	Three models: FFS (expanded bundle), health plan, and PACE-like plan (interdisciplinary team).	Beneficiaries with ESRD.	FFS includes add-on for expanded bundle. Five percent of payment being withheld for quality incentive.
Social health maintenance organization demo (DEFRA, 1984) 1985–12/2004	Test S/HMO model. MedPAC reviewed performance of S/HMOs and recommended they be converted to M+C plans.	Enrolled 122,000 frail beneficiaries in four plans.	Risk-adjusted MA county payment rate.

Note: Demo (demonstration), BBA (Balanced Budget Act of 1997), CHF (congestive heart failure), FFS (fee-for-service), BIPA (Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000), CAD (coronary artery disease), DMO (disease management organization), MA (Medicare Advantage), ESRD (end-stage renal disease), OBRA (Omnibus Budget Reconciliation Act), M+C (Medicare+Choice), PACE (Program of All-Inclusive Care for the Elderly), DEFRA (Deficit Reduction Act), S/HMO (social health maintenance organization). Demonstrations not mandated by law are conducted by CMS under its general demonstration authority.

Source: Compiled by MedPAC from information on CMS's website, Federal Registers published from 1999 to 2003, and interviews with CMS staff.

In our interviews, officials from disease management organizations reported a range of physician reactions to their programs, from enthusiasm to active hostility. Some commercial programs have little direct involvement with physicians; they focus on educating patients to manage their own care. They emphasize the difficulty of identifying the primary physician for many patients outside health maintenance organizations. However, other programs do seek more active physician involvement. One interviewee remarked that primary care physicians tended to participate in the program largely because contact with disease management programs often led patients to use more primary care services and fewer specialist services.

Another representative of an insurer that uses disease management services reported that his organization focused on aligning physician incentives with improved care. One approach involves rewarding physicians for teaching patients techniques for managing their care and paying for improved performance on quality measures. In a second approach, the plan defines quality measures for specific chronic conditions and lets the physician determine how best to achieve the goals.

Who will receive chronic care improvement services?

If care coordination services were directed toward all Medicare enrollees with a chronic condition, the potential number of participants in the program would be very large. As estimated from Medicare claims data, about 78 percent of the Medicare population had at least one chronic condition in 1999, and 63 percent had two or more (Anderson 2002). Self-reported statistics put that number even higher, with over 70 percent reporting two or more conditions (CMS 2003).

In selecting who to identify for the CCIP, CMS must strike a balance between the cost of delivering services to a large population and the lost opportunities for savings and quality improvements that may occur with narrow targeting. Providing the same intervention to all beneficiaries with certain conditions would be costly. Interventions that cast too wide a net may be unable to provide the level of services necessary to improve outcomes or achieve savings. On the other hand, focusing solely on a sick, high-use population may mean that healthier beneficiaries who might benefit from better chronic care management to prevent future hospitalizations will not be helped.

CMS is using a population-based approach to target enrollees. Through claims data, it is prospectively identifying people who might benefit from care coordination based on the presence of one or more targeted conditions and past use of services. In its solicitation for proposals, CMS identified two groups of conditions that the CCIP will target: 1) CHF and/or complex diabetes; and 2) COPD. Eligible beneficiaries will also have high or moderate hierarchical condition category (HCC) risk-adjustment scores, which suggests that for the CCIP's first phase, CMS will enroll beneficiaries who are sicker than average and at higher risk for future Medicare spending.[2] Contractors who enroll beneficiaries in their programs must manage all of the participants' comorbidities, not just the targeted conditions. Beneficiaries with end-stage renal disease (ESRD), enrolled in hospice or a Medicare Advantage plan, or living in a region with an FFS chronic care demonstration project will not be eligible. Any program participant who develops ESRD or enrolls in hospice can no longer participate in the program.

Once CMS identifies potential participants, it will randomly assign them into treatment and control groups. Participation in care coordination programs is voluntary. CMS will send a letter to identified beneficiaries in the treatment group, explain the program, and encourage them to participate. Beneficiaries must opt out if they do not wish to be in the program. CMS will choose one contractor in each region and give it the names, Medicare claims data, and other information for all beneficiaries in the intervention group who did not decline to be contacted.

Each contractor will have six months to contact participants, confirm participation, and initiate services. After that period, CMS will only pay fees on behalf of beneficiaries that confirm participation in the program. Contractors will contact participants to screen them for additional chronic conditions, evaluate the level of complexity of their conditions, and determine the type of care management services to provide for each person. Among the group of participants, contractors may use their own predictive models to further target services toward individuals who they believe are most at risk for acute exacerbations of their conditions.

CMS will hire an independent organization to evaluate each contractor's program by comparing outcomes of the control group to the entire intervention group, including those beneficiaries who chose not to be contacted, those who dropped out of the program, and those whom the program could not contact.

Not all beneficiaries in the selected regions are eligible to participate in chronic care improvement programs. Specifically, people who do not have Medicare claims data indicating that they were diagnosed with a targeted condition would be excluded, as will those who have a condition but have lower risk-adjustment scores. In addition, a large group of people who reach the stage of being identified by CMS as potential participants will be randomly assigned to a control group that will not receive care coordination services. And among participants, contractors may choose to provide fewer services to those whom they believe are already managing their conditions well or those who cannot be managed.

The Commission supports the basic approach to the CCIP's first phase, which uses a randomized controlled trial design. By operating individual programs on a fairly large scale, CMS may have sufficient numbers of enrollees to test whether treatment and control groups have statistically significant differences in savings or clinical outcomes. That approach allows CMS to evaluate the effectiveness of the CCIP's approach before expanding it. Such an evaluation is an important step because past evaluations of disease management programs in non-Medicare populations suffered from methodological shortcomings that made it difficult to draw conclusions about quality improvements and savings, or to generalize from their results.

Nevertheless, one tradeoff in using a randomized controlled trial design is that it may initially limit the types of regions in which programs are offered—in particular, rural ones. While the approach does not preclude care coordination programs in rural areas, it means that programs would need to cover larger geographic regions than they would in more densely populated metropolitan centers to have a large enough sample. One provision of the MMA requires CMS to offer programs in areas where, in aggregate, at least 10 percent of all Medicare beneficiaries live. Given the short time frame for starting the CCIP, initial programs are apt to be centered in more densely populated regions.

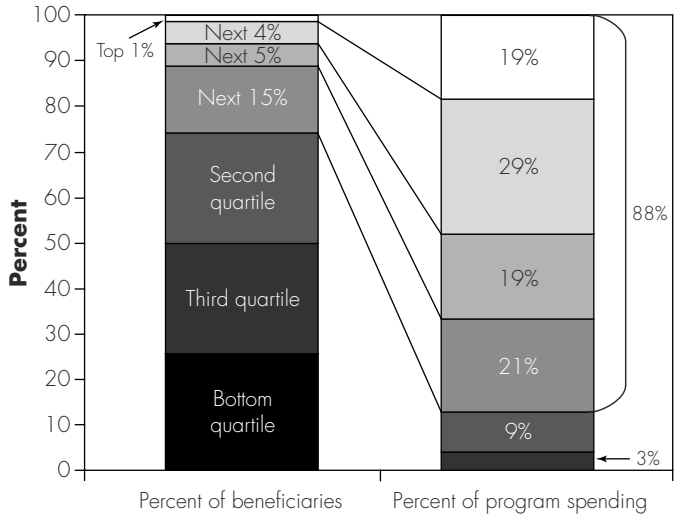
How will eligible participants be identified?

CMS can use risk scores to identify beneficiaries because Medicare program spending is highly concentrated. In 2002, for example, the top 5 percent of beneficiaries ranked by spending accounted for nearly half of total FFS program spending, and the top quartile (25 percent) accounted for nearly 90 percent of spending (Figure 2-1). Concentration in spending relates directly to the cost of providing inpatient care, and people who experience an inpatient stay usually consume more of all types of care during the year. If CMS could identify in advance people who will have very high costs, it could design a program that focuses on better managing their care, potentially improving the quality of their care and slowing growth in Medicare program spending.

But focusing solely on the highest-cost beneficiaries may not be an effective strategy for targeting care coordination services if people do not continue to have high costs over time. Data from Medicare claims show a substantial turnover among those beneficiaries who have the very highest program costs in any given year. Yet, beneficiaries who make up the top quartile of people ranked by program spending tend to remain high spenders over time.

FIGURE 2-1

FFS program spending is highly concentrated in a small group of beneficiaries, 2002



Note: FFS (fee-for-service).

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

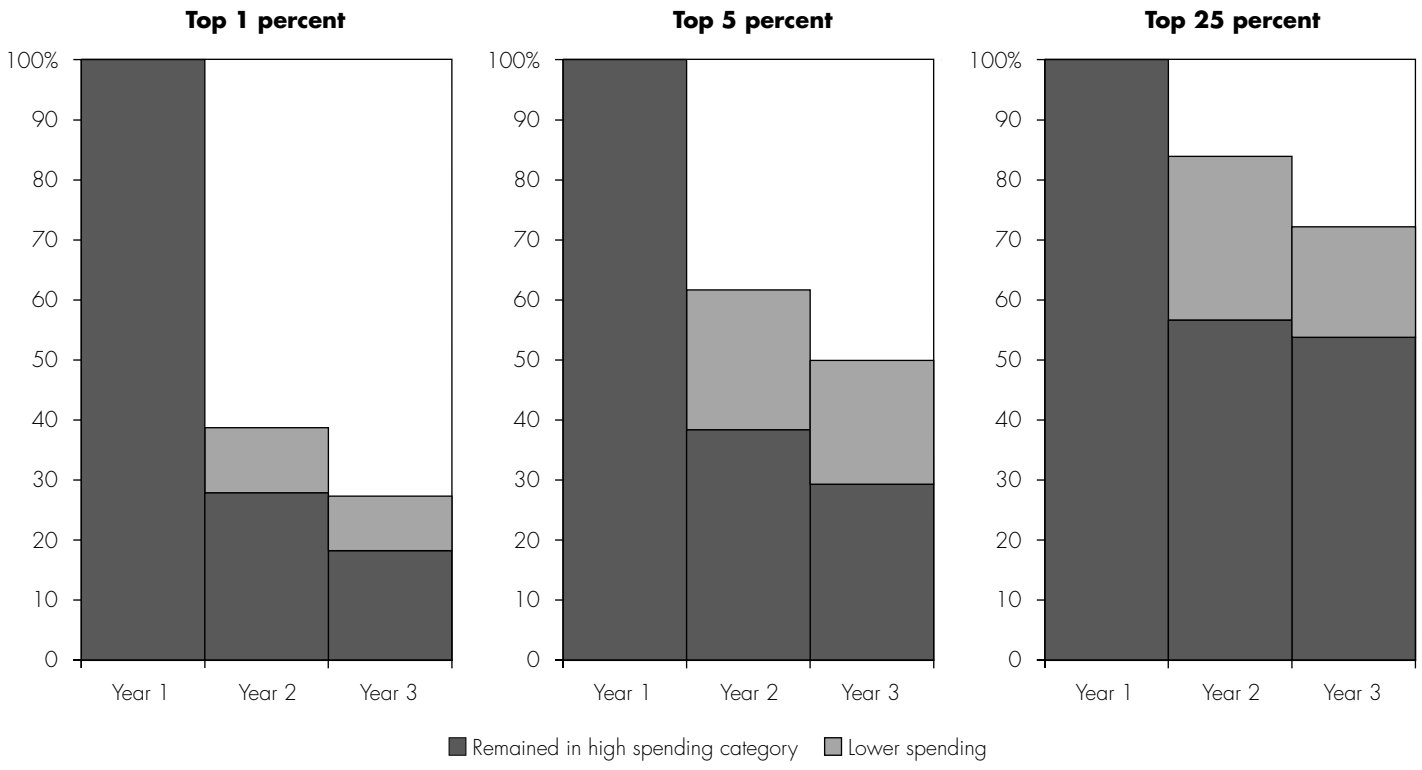
Most of the year-to-year change in the cohort of people who are among the costliest 1 percent of Medicare FFS beneficiaries can be attributed to their high rate of mortality. Figure 2-2 shows that in the base years 1996, 1997, and 1998, an average of 28 percent of the costliest 1 percent of beneficiaries remained in that highest ranking in the subsequent year, and 18 percent remained in that ranking the year after that. More than 60 percent of those beneficiaries died during the base year, and nearly 30 percent of those who survived died in the subsequent year.

Figure 2-2 also demonstrates some "regression toward the mean"—people who had high costs in one year had levels of spending that were lower (i.e., closer to the mean) in the following year. For example, only 38 percent of beneficiaries ranked among the top 5 percent by FFS program spending in the base year were also among the top 5 percent the next year. Even though some beneficiaries in the group died, a sizable portion of people in the top 5 percent during the base year subsequently had lower spending.

These data suggest that many beneficiaries move into and out of low- or high-risk status over time. Thus, focusing interventions on beneficiaries who have already had high program spending may not always be the most effective strategy for generating savings through preventing hospital admissions.

However, many beneficiaries remain in the top quartile of FFS program spending; enough to suggest some promise to targeting high-cost beneficiaries. For example, Figure 2-2 shows that among people in the top quartile during the base year, 57 percent remained among the top 25 percent in the subsequent year, and more than 50 percent fell into that category in the following year.

FIGURE 2-2 **Persistence of high spending and mortality in the FFS program, by year**



Note: FFS (fee-for-service). The total height of the bars shows the percentage of beneficiaries who survived into the subsequent year. The difference in height of bars between years primarily reflects the percent of beneficiaries who died. A small percent were lost from the sample between years either because they joined a Medicare+Choice plan or their claims data could not be matched. Base years are pooled from 1996–1998.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims linked over the 1996–2002 period.

In addition to Medicare claims, other types of data may help CMS and its contractors better target care coordination services. Today, disease management organizations often use predictive modeling to identify potential enrollees prospectively, using spending and information about diagnoses from claims data. Although claims data contain valuable information, they can suffer from inaccuracies in coding or inconsistencies in certain diagnoses from year to year, depending on whether or not the beneficiary sought care (see text box). For these reasons, diseases management organizations routinely use data—such as health assessments and prescriptions filled—in addition to medical claims.

Once Medicare's Part D benefit begins in 2006, CMS may have the benefit of prescription drug claims to use in its targeting for the CCIP. Knowing a patient's drug therapies may help CMS identify their conditions.[3] That information could also help the contractors to evaluate whether the patient's therapy follows evidence-based care guidelines. Part D is, however, a voluntary program, and it is not yet clear what share of the Medicare population will enroll.

It is also important for contractors to obtain physiological information from laboratory testing—such as the results from hemoglobin A1c for diabetes and lipid tests for cholesterol levels. Currently, however, Medicare does not obtain this information from the laboratories performing these tests. Medicare only collects physiological information for dialysis adequacy and hematocrit on the claims submitted by outpatient dialysis facilities. Several interviewees told us that laboratory results are important for planning and evaluating private disease management interventions, but that they have not been able to obtain

Methodology for MedPAC's analysis of fee-for-service spending

The database consists of a 0.1 percent sample of Medicare beneficiaries for the years 1996 through 2002, or about 38,000 persons per year. Statistics on total program spending for this sample are similar to other data published by CMS. To be included in a given year of data, the beneficiary had to have at least one month of Part A or Part B entitlement and no months of Medicare Advantage (MA) enrollment. This differs slightly from CMS's Chronic Care Improvement Program, in which beneficiaries must be enrolled in Part A and Part B but not enrolled in an MA plan. Payments were summed from Medicare fee-for-service claims for physicians, facilities, and durable medical equipment. Payments on facility claims include both pass-through amounts and capital amounts when those were reported separately.

For each person in the file, and for each year, program spending and enrollment data were combined to calculate a per member per month (PMPM) cost for that person. Each person's PMPM cost is that person's total program spending divided by months of A or B entitlement.

We identified individuals who had congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes, using definitions from the hierarchical condition category risk-adjustment model that CMS developed to pay MA plans. All diagnoses from all claims files were summarized by file and month. We required that a relevant diagnosis be reported twice—either in two different files, or in the same file in two different months. That requirement screens out a significant fraction of the population. By comparison, CMS will classify beneficiaries as having a targeted condition if they find two or more professional visits on separate dates or a hospitalization for CHF or COPD.

Several caveats apply whenever researchers use claims data to identify the prevalence of conditions. First, the list of diagnoses we used may vary from other definitions. Second, the actual prevalence of a disease is probably higher than that shown by a single year of diagnoses from claims data because diagnoses are not always reported persistently in claims data from year to year, even for conditions presumed permanent. Third, the population captured via diagnoses on claims will have higher costs than the true population that has the disease. In general, diagnoses are mostly reported when a beneficiary is actively being treated for that disease. This means that persons who have a condition (such as CHF) but whose condition is stable and does not require active intervention in a given year may not have diagnosis information appear in that year. ■

them. Similarly, it is not yet clear how CMS and contractors will collect such information for evaluating quality outcomes in the CCIP.

How prevalent and costly are the targeted conditions?

How prevalent are the conditions that CMS chose for the CCIP? Based on MedPAC's analysis of Medicare claims data, about 10 percent of FFS enrollees had CHF in 2002, 10 percent had COPD, and 17 percent had diabetes (see Table 2-3). But these figures are estimates: In general, claims data tend to understate prevalence (text box, opposite), and at least one condition, diabetes, sometimes goes undetected.

Medicare spends disproportionately on behalf of people who have these conditions. For example, beneficiaries with CHF accounted for 35 percent of total spending, with mean monthly spending of nearly $1,900 in 2002, or nearly four times that for the average FFS enrollee. Because of CHF's high prevalence within the Medicare population and its high average level of spending, patients with CHF made up 57 percent of those beneficiaries who ranked among the top 1 percent by program spending, and 38 percent of the top 10 percent.

CMS will identify beneficiaries in a very specific manner, using its own combinations of diagnosis codes to define the presence of a targeted condition.[4] In addition, beneficiaries must have moderate to high risk-adjustment scores to be eligible to participate. Using MedPAC's claims database and our own estimates of HCC scores, we estimate that nationwide nearly 6 percent of FFS enrollees would qualify under CMS's criteria for CHF or complex diabetes, and about 2 percent would qualify within CMS's criteria for COPD. By requiring that beneficiaries have moderate to high risk-adjustment scores, CMS significantly reduces the number of people who are eligible for the treatment and control groups. But eligible beneficiaries still account for a disproportionate share of Medicare program spending—18 percent and 8 percent, respectively.

TABLE 2-3

Prevalence of certain conditions and average monthly Medicare program spending among FFS enrollees, 2002

	Category as a percent of:					
Category	**FFS Medicare enrollees**	**Total program spending**	**Most costly 1% of beneficiaries**	**Most costly 10% of beneficiaries**	**Mean monthly spending**	**Ratio of spending to overall mean**
All persons	100%	100%	100%	100%	$502	1.0
MedPAC's definitions of conditions						
CHF	10	35	57	38	1,877	3.7
Diabetes	17	31	42	33	942	1.9
CHF or diabetes	21	51	72	53	1,102	2.5
COPD	10	28	42	31	1,483	3.0
CMS's definitions of conditions and moderate to high risk-adjustment scores						
CHF or diabetes	6	18	18	23	1,414	2.8
COPD	2	8	8	10	1,543	3.1

Note: FFS (fee-for-service), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Beneficiaries may have had more than one of the conditions shown above. Spending values are averages within each category and are adjusted for the number of months of FFS enrollment. Percent of total program spending and mean monthly spending include all Medicare FFS program spending, including that associated with comorbidities. CMS's definitions of threshold conditions are based on certain diagnoses codes for two or more professional visits on separate dates or (for CHF or COPD) a hospitalization for the condition in one year of claims data.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

Using MedPAC's definitions of conditions, 26 percent of FFS enrollees have CHF, diabetes, or COPD, 20 percent have one targeted condition, 5 percent have two, and the remainder have all three (Figure 2-3). Even though limiting the CCIP to CHF, diabetes, and COPD excludes most Medicare beneficiaries, people with one or more of those three conditions account for about 60 percent of FFS program spending.

Some providers of disease management services contend that certain chronic conditions require a shorter time period to show improvements in outcomes and spending than other conditions. Interviewees told us that their interventions focusing on CHF provide a greater return on investment in the short term than diabetes. This is likely to be the case if CHF patients have, on average, a greater number of hospitalizations during the year that are avoidable through better care coordination than patients with other conditions.

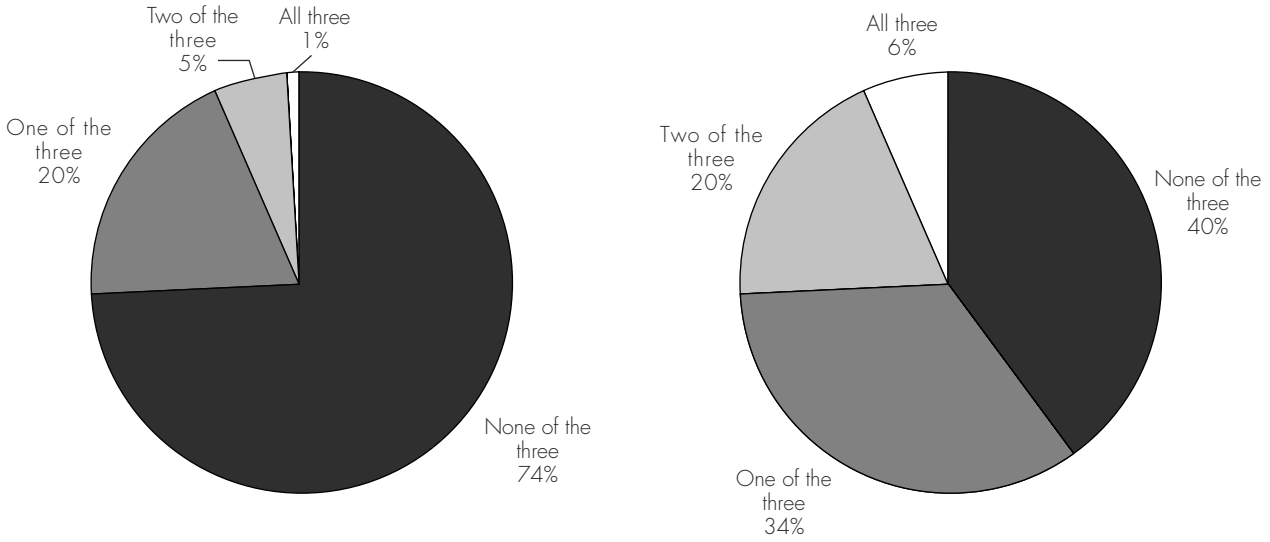
Using MedPAC's definitions of the presence of targeted conditions, claims data show that more CHF patients have hospitalizations than beneficiaries with other targeted conditions. On average, 62 percent of CHF patients had one or more hospitalizations during the year over the 1996–2002 period (Figure 2-4). By comparison, 35 percent of diabetes patients, 53 percent of beneficiaries with COPD, and 20 percent of all FFS beneficiaries had one or more hospitalizations. In addition, a larger share of CHF patients had repeated hospitalizations.

However, among CHF patients who had a hospitalization, CHF was not necessarily the main reason for their stay. About 17 percent had CHF as their principal diagnosis, 46 percent had it as a secondary diagnosis, and 37 percent were hospitalized but CHF was not reported as one of the diagnoses (Table 2-4).

The MMA specifically identifies CHF, COPD, and diabetes as targeted conditions, but allows CMS to include others as well. The question of whether to target additional conditions is not a simple one. On the one hand, most FFS enrollees could benefit in some manner from services that help to coordinate their care or educate them to help manage their own conditions. But such a strategy would not necessarily improve the quality of care for everyone:

FIGURE 2-3

About one quarter of FFS beneficiaries with CHF, COPD, or diabetes account for three-fifths of program spending, 1996–2002

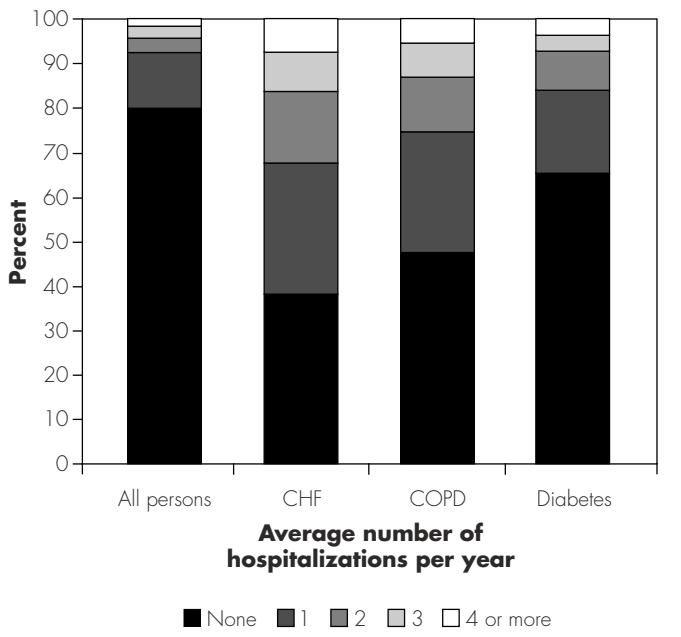


Note: FFS (fee-for-service), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Medicare FFS program spending includes that associated with comorbidities. Values are based on MedPAC's definitions of conditions.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

FIGURE 2-4

Beneficiaries with CHF, COPD, or diabetes are more likely to be hospitalized, 1996–2002



Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Values are based on definitions of conditions from the hierarchical condition category risk-adjustment model.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

TABLE 2-4

Acute inpatient discharges for beneficiaries with certain chronic conditions, 1996–2002

Presence of code for condition	CHF	COPD	Diabetes
Principal diagnosis	17%	11%	5%
Secondary diagnosis	46	56	71
Condition not listed on discharge	37	33	24
Total	100	100	100

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). The percentages above exclude all transfers, which are defined as a discharge and readmission of the beneficiary on the same day.

Source: Direct Research, LLC, based on a 0.1percent sample of Medicare fee-for-service enrollees and their claims.

Some people's conditions are already well-managed, and the complexity of others' circumstances may make it extremely difficult to keep their health stable. On the other hand, CMS has limited resources, and it is not clear that organizations can provide these services to a broader share of the Medicare population in a cost-effective manner.

Although one could suggest several candidates for other conditions to target, MedPAC chose CKD as a case study for analyzing the potential for care coordination. (The case study is the last section of this chapter.) Treating beneficiaries whose kidneys deteriorate to the point of ESRD is extremely expensive—in 2002, program spending for ESRD beneficiaries was nearly $3,900 per month. Although only 1 percent of FFS enrollees have ESRD, these patients account for 6 percent of total program spending. Delaying the progression of kidney disease could both improve quality of care and help to use Medicare's resources more efficiently.

What is the role of contractors?

This section describes the role of contractors within the care coordination program: What services they will provide, how they will be paid, and how they will coordinate activities with other programs.

What services will contractors provide?

The MMA establishes general service requirements but allows contractors maximum flexibility in designing and targeting specific interventions. Among the services outlined in its solicitation, CMS will evaluate applicants' plans for outreach to and assessment of participants; the proposed frequency and type of interventions, including how they will provide support for participants with more intensive needs; descriptions of proposed services and educational materials; mechanisms for encouraging physician participation; plans for coordinating with state and local agencies; and plans for data collection and analysis.

Most current disease management contractors base their intervention on evidence-based guidelines that are developed by unbiased organizations and accepted by the majority of providers. However, most guidelines are developed for a single chronic disease and may be of

limited help for a patient with many comorbidities because key clinical protocols and performance measures can differ when managing patients with multiple chronic conditions.[5] For example, a physician might use a lower target level of low-density lipoprotein for a patient with diabetes and coronary artery disease than if that person did not have diabetes. Contractors will need to ensure that the guidelines they use are current and appropriate for patients with multiple chronic conditions. Chronic care programs managed by physicians who already have detailed knowledge of a patient's medical history may have clear advantages in this regard.

The MMA requires contractors to provide any services in their care management plan that are generally not covered by Medicare, such as at-home monitoring technologies. Contractors can also furnish other services not explicitly mentioned in the MMA and not covered under FFS Medicare that will help them meet quality and financial goals.

Among all types of noncovered services, case management is likely to be particularly important to certain Medicare beneficiaries with complex medical conditions or who are near the end of life. Currently, most commercial disease management programs refer patients to case management services provided by the sponsoring health plan and do not have internal capacity to provide these services. Other organizations specialize in these types of activities but may not be well equipped for handling population-based approaches to care coordination. Organizations that provide distinct sets of services may need to partner or contract with one another in order to address the CCIP's population-based approach and the case management needs of the Medicare population.

How will the contractors be paid?

The MMA requires that contractors be paid on a per member per month basis, but the law is not specific as to how the payment will be set. CMS plans to pay varied fees to contractors because it aims to test a variety of models that include different services and thus have different cost structures. Applicants will propose a fee in their bid, subject to negotiation with CMS. In addition, fees will be adjusted based on whether contractors achieve targets for program savings, clinical outcomes, and satisfaction. Fees paid to contractors are distinct from the medical claims for program participants, which CMS will continue to pay in the usual manner as part of the FFS program.

In principle, the CCIP's approach of requiring contractors to take performance risk for their fees is consistent with the Commission's goal of holding providers accountable and linking payment to quality. As we learn from the CCIP's initial phase, CMS may want to consider approaches that make even greater use of contractor incentives to achieve savings and quality improvements.

CMS's proposed relationship between payment and quality is not yet clear. The request for proposals states that bidders must be willing to guarantee that total Medicare claims for the treatment group and chronic care improvement fees will be no more than 95 percent of total Medicare claims payments for the control group over a three-year period. In other words, if a contractor does not reach a 5 percent savings target, CMS will reduce its fees by the amount needed to ensure those savings with up to 100 percent of fees at risk. After 2006, Medicare drug expenditures will be included in the calculations of Medicare program spending for treatment and control groups.

The solicitation is less clear about the relationship between payment and outcome measures and satisfaction targets. Although it provides measures of clinical outcomes, CMS did not specify performance targets for those measures. The agency plans to negotiate targets based on bidders' proposals.

Applicants will use data made available by CMS to set their bids; they will propose the geographic area where the program will operate, performance targets and how their fees will be adjusted if they do not meet the goals. CMS's solicitation requests applicants to assume that they will serve 20,000 beneficiaries in the treatment group, even though the ultimate number may differ. This will allow CMS to evaluate bids that are more comparable to one another. If the prevalence of disease or use of services by beneficiaries differs in the proposed region from that in nationally representative data, bidders may propose adjustment factors to reflect those differences.

CMS's solicitation permits applicants to propose up to two alternative payment structures if bidders want to serve a larger population or if they believe they can achieve more than 5 percent net savings. For example, an organization

with experience coordinating care for CHF patients might argue that it could lower program spending by, say, 15 percent. In return, it might propose higher fees such that net program savings would reach 10 percent rather than 5 percent.

Contractors will be paid the same amount per enrolled beneficiary, but they can choose where to place their resources in order to see the greatest returns in quality, satisfaction, and savings. That approach corresponds to current practices by many disease management organizations. Interviewees told us that they believe it is most effective to target broadly, but to stratify people who have the same condition by their level of complexity and provide a different level of service to each risk segment. For those with controlled diabetes, for example, some organizations contact patients once or twice a year to make sure they have received the appropriate preventive services. By contrast, organizations may contact patients with uncontrolled diabetes more frequently, maintain closer contact with the patients' physicians, and use case management services.

Contractors may require a higher monthly fee for participating in the CCIP than they customarily receive from private clients. In general, the Medicare population is more medically complex than other populations, and CMS plans to target sicker than average beneficiaries. In addition, programs will have to offer a broader array of services, likely including case management, than is provided by many current programs. However, the risk provisions of the program should limit the amount of the bids. Contractors must achieve program savings in order to avoid returning some or all of their fees to Medicare because they could not meet financial performance goals.

How will contractors and CMS coordinate responsibilities?

Implementing the CCIP will require contractors and CMS to interact with each other, with FFS providers, with state Medicaid programs, and with other programs implemented by Medicare.

Furnishing data in a timely fashion to contractors

Contractors will need claims data from CMS for:

- developing predictive models to determine appropriate levels of intervention for the targeted population,
- reevaluating the risk levels of participants, and
- assessing the effectiveness of intervention strategies.[6]

Interviewees indicated that they usually supplement claims data with health assessment information obtained from patients. In the future, drug claims data should also be useful for these purposes.

It is not clear how frequently CMS will provide contractors with this information, but some interviewees suggest they would need data at least quarterly, and ideally, monthly. These data could come directly from CMS or the agency's contractors. A strong commitment from CMS will be absolutely critical for these data to be available in a timely manner.

Contractors must coordinate with fee-for-service providers

The MMA requires contractors to collaborate with physicians and other providers to improve communication of relevant clinical information. In current disease management programs, the ability to provide effective feedback to physicians relies heavily on the underlying relationship between the physician and the health plan or disease management organization. This relationship is important as a source of referrals to the disease management program. Physicians also may be enlisted to help design care coordination strategies.

Contractors will need to create new relationships in geographic areas where they do not currently furnish disease management and care coordination services, and build upon their existing networks in areas where they furnish services. In addition to physicians, contractors will also need to communicate with other providers, particularly providers of end-of-life care. The law explicitly requires that care management plans include information about hospice care, pain and palliative care, and end-of-life care where appropriate.

Coordinating efforts with state Medicaid programs

The MMA is silent on whether and how Medicare's CCIP should coordinate with state Medicaid programs for beneficiaries who are eligible for both programs. Almost half of all states have implemented or are in the process of implementing disease management programs (Center on an Aging Society 2004). The number of state programs

will probably increase at the same time that Medicare's CCIP is launched. CMS recently announced that Medicare will match the Medicaid costs states incur in furnishing disease management programs aimed at improving health outcomes while lowering the medical costs associated with chronic illnesses (CMS 2004).

Beneficiaries who are dually eligible for Medicare and Medicaid are likely to account for a disproportionate share of participants in the CCIP because the prevalence of targeted conditions is much higher in this population than among all other FFS enrollees. CHF and COPD are about twice as prevalent, and 26 percent of Medicaid dual eligibles have diabetes.[7] In MedPAC's claims database, dual eligibles made up 17 percent of all FFS beneficiaries in 2002, and accounted for about 26 percent of FFS program spending. Similarly, in 1999 they represented 19 percent of all Medicaid beneficiaries and accounted for 35 percent of Medicaid expenditures, or $63 billion.

Few mechanisms exist for coordinating care for these beneficiaries across both payers. Medicare is the primary payer for this group and may benefit more if growth in spending for acute-care services slows. By contrast, Medicaid will benefit more if spending for long-term care services is contained. At issue is whether federal and state governments can or even should coordinate efforts—by contracting with the same organization and using the same performance standards for example. Doing so might prevent dual eligibles from receiving redundant care.

CMS and contractors may also need to coordinate with Medicaid to obtain claims data for both targeting and monitoring care. CMS might be able to better target populations if Medicaid claims data could augment Medicare data. Similarly, contractors might be able to develop a more effective care plan and monitor the care beneficiaries receive if Medicaid claims data were made available to them. For example, verifying when dually eligible beneficiaries fill their prescriptions might help contractors to monitor compliance with their drug therapies. Medicaid claims data would most likely improve the ability of CMS and contractors to set the per member per month payment rate (see Chapter 3).

Coordinating efforts with other Medicare contractors

In at least two instances, Medicare contractors other than those selected for the CCIP may also be providing care coordination services to beneficiaries. The MMA requires sponsors of Medicare Part D prescription drug plans in 2006 to establish drug therapy management programs for beneficiaries with multiple chronic conditions requiring multiple medications. The program is designed to promote the appropriate use of medication by beneficiaries, improve adherence to medication regimens, and detect adverse drug events and patterns of underuse and overuse of drugs. The Secretary is required to issue guidelines for coordinating this program for beneficiaries enrolled in the CCIP.

In addition, CMS has proposed extending efforts by the quality improvement organizations (QIOs) to address the care of patients with multiple comorbidities under their next scope of work (a three-year period beginning August 2005). Under this scope of work, QIOs would:

- assist physician offices in providing chronic care for diseases such as coronary artery disease, congestive heart failure, hypertension, and depression, and also preventive services, such as colorectal cancer screenings; and
- reduce misuse of prescription drugs by helping physicians to adopt electronic prescribing.

Regardless of whether CMS decides to include these new responsibilities in the next scope of work for the QIOs, the QIOs are already working with some physicians to improve management of chronic conditions such as CHF and diabetes. In order to reduce duplication of effort and improve efficiency, it would be useful for CMS to define guidelines for how CCIP contractors should interact with drug plans and QIOs.

How will contractors meet the special needs of Medicare beneficiaries?

Contractors will need to consider the special needs and characteristics that are common among older patients when they implement their interventions in fee-for-service Medicare. For example, contractors must address the needs of:

- older patients who suffer from comorbidities such as dementia and frailty, who often see several physicians or receive care in multiple settings; and

- special populations such as beneficiaries needing end-of-life care.

The Medicare population's high prevalence of multiple chronic conditions should make it particularly well suited for care coordination. Contractors are required to manage all comorbidities, relevant health care services, and pharmaceutical needs. But other characteristics—such as higher prevalence of frailty and dementia, and greater need for end-of-life care—mean that organizations that have typically created disease management programs for healthier, younger populations must now use different strategies.

In the remainder of this section we focus on two types of older persons: Patients with cognitive impairments and patients requiring end-of-life care.

Cognitive impairments

Cognitive impairments such as dementia are comorbidities that contractors will need to consider when designing their programs. MedPAC's Medicare claims data show that about 5 percent of FFS enrollees suffered from dementia in 2002, and people with dementia accounted for about 15 percent of FFS spending in that year which includes care for their comorbidities. That rate of prevalence is probably understated because it is based on Medicare claims: Some beneficiaries may be reluctant to seek treatment at the early stages of mental impairment, or providers may simply attribute it to the aging process.

How might dementia complicate care coordination? Approaches to disease management that are used widely today rely extensively on educating the beneficiary to help manage their own care. For example, patients with CHF are taught to monitor their weight closely and take their medications regularly to avoid acute flare-ups that could lead to hospitalizations. That strategy may not work well for beneficiaries with dementia if they have difficulty understanding or remembering their physician's recommended therapy.

Advocates contend that disease management services can still improve outcomes for beneficiaries with dementia. For people with mild cognitive impairment, such services might promote earlier screening or help to identify reversible factors. For those whose condition is more advanced, contractors might focus their efforts on educating a primary caregiver on how to care for the patient or manage any comorbidities, and suggest techniques for coping with memory loss during the patient's day-to-day activities.

End-of-life care

Patients at the end of life incur high costs. MedPAC's analysis shows that in calendar year 2002, Medicare spending for the 5 percent of beneficiaries who died constituted 18 percent of total Medicare program payments.[8]

One of the biggest challenges for chronic care improvement programs will be identifying beneficiaries at the end of life. It is particularly difficult to predict timing of death with administrative data even for some of the sickest beneficiaries (Buntin et al. 2004). However, guidelines do exist for determining prognosis in some noncancer diseases including the need for hospice or palliative care (Lynn 2001). Even with these additional tools, prognosis is very difficult for diseases like CHF and dementia. Physicians could help contractors identify patients who could benefit from end-of-life services.

Consensus has grown among experts about the components of quality end-of-life care. To the extent that they can be identified prospectively, these beneficiaries can benefit from coordination of services across multiple settings, advance care planning, family and caregiver support, pain management, physical symptom relief, and counseling (Lynn 2001). These services are provided to Medicare beneficiaries through the hospice benefit, but many recipients of hospice care do not receive benefits soon enough to obtain significant advantage from them (see Chapter 6). In addition, many beneficiaries who could benefit from palliative services may not have a clear prognosis or be ready to give up on curative care.

Current care coordination programs do not usually target beneficiaries near the end of life, so they may not be accustomed to providing the services that these beneficiaries need. Ongoing communication with the patient's physician and other caregivers will be critical. Educational materials may need to be less focused on preventive care for a specific condition and more focused on advance planning, family and caregiver support, and pain management. Many of our interviewees agreed upon the need for care coordination for this population but added that most programs were not yet effective in providing services for them. The MMA requires that contractors' care plans include information about hospice care, pain and palliative care, and end-of-life care, but it is not clear how contractors would identify patients who

need this information. Targeting beneficiaries near the end of life and providing appropriate services for them will require collaborative efforts among physicians, care coordinators, and case managers.

Evaluating the effectiveness of chronic care improvement programs

The MMA calls for CMS to evaluate the clinical and financial outcomes of each intervention. In this section, we first discuss the randomized controlled trial design. We then raise key measurement and evaluation issues that the MMA does not explicitly address but that are becoming clearer as CMS begins to implement the CCIP. Specifically, should CMS use a standard set of clinical and financial measures to evaluate effectiveness?

Using a randomized controlled trial design

In recent years, employers and private insurers have been using disease management programs to try to improve quality and control costs during a time of strong upward pressure on health spending (Short et al. 2003). Typically, those programs target beneficiaries with certain conditions and higher-than-average costs, but only if the cost of providing disease management services seems to be offset by reductions in claim costs (Foote 2003). Nevertheless, there is still only limited evidence of the effects of these programs on outcomes and health spending. Studies that attempt to demonstrate improved outcomes or savings have often suffered from serious methodological shortcomings (Fetterolf et al. 2004, Crippen 2002).

Evaluating existing disease management programs has been hampered because:

- few programs have used a rigorous study design to assess the clinical and financial effectiveness of their interventions;
- most programs use a combination of strategies and are not able to measure the relative contribution of each strategy to program outcomes; and
- providers have not reached consensus about which outcomes should be used to assess effectiveness.

If carried out carefully, a randomized controlled trial design and independent evaluations of effectiveness should provide important information to all stakeholders—Medicare, private payers, employers, contractors, physicians and other providers—about the potential of the CCIP to improve beneficiaries' clinical outcomes and reduce health care spending.

Prior attempts to measure the impact of disease management programs have been complicated by the lack of a control group with which to compare outcomes, and the difficulty in defining a time frame in which to expect measurable results. Most often, existing programs compare outcomes and medical costs after a program has been implemented with benchmark data for the same population from some pre-treatment period. But general improvements in treatment regimens for all patients with a given medical condition can confound the results. In addition, some evaluations have counted savings caused by regression to the mean among beneficiaries who had high costs in the benchmark period. Many of our interviewees recognized these issues and spoke of developing new evaluation methods to address them. For example, one health plan described an evaluation based on comparing medical costs for a client that purchased a disease management program with medical costs for another client that did not.

How many beneficiaries will participate in each program?

The number of beneficiaries who will initially participate in each program is largely driven by the Congress's intent to use the first phase of the CCIP to evaluate whether this approach is more broadly applicable in Medicare. The law calls for large numbers of people who have targeted conditions to serve as controls in each program, and requires that an independent organization evaluate each program.

The number of beneficiaries in a treatment group may differ among contractors. Key factors that affect the size of treatment groups include the prevalence of targeted conditions within each geographic region and the amount of variation in the outcome variables of interest—such as program spending and clinical characteristics. If the number of participants varies from area to area, the statistical power to detect clinical and financial outcomes may vary. The ability to detect a statistical difference will be greater for larger treatment groups, all else constant.

CMS will enroll beneficiaries who have both a targeted condition and are at high risk for future FFS program spending. This approach reduces the number of participants needed to detect a statistical difference because there is less variation in their spending.

Depending upon how CMS chooses to evaluate programs, mortality rates of people with targeted conditions may become an important factor (see text box, p. 54). CMS's solicitation for bids notes that at the end of each three-year award for the CCIP's initial phase, each contractor will undergo a financial settlement process to ensure that the program achieved 5 percent net savings. If medical claims plus contractor fees for the treatment group are more than 95 percent of medical claims for the controls, the awardee must refund the difference up to 100 percent of its fees. If the treatment group is more expensive than the control, Medicare will still cover the extra medical costs. Under this approach, evaluators will compare total program spending for both groups at the end of three years—no matter how many participants died or survived. But CMS also states that it may require awardees to refund fees based on interim reconciliations and performance monitoring. If CMS uses the approach of comparing average spending in each year, mortality rates would be important for ensuring that one could compare values for sufficiently large numbers of survivors several years after the program's start.

Some organizations contend that CMS should refresh the treatment and control groups periodically during the three-year study period. In other words, CMS would randomly assign new people with the same targeted conditions and similar risk-adjustment scores to replace decedents in both groups, thereby keeping sample sizes sufficiently large over time. However, even with this approach, CMS would likely need to evaluate cost savings separately for the original cohort and for newer entrants. For example, if new participants in a chronic care improvement program were more likely to suffer from acute flare-ups of their condition than beneficiaries who already received one or two years of services, savings from the intervention might appear higher than they would be otherwise.

Using a standard approach and measures to evaluate programs

Evaluation requires standard measures and definitions of savings and quality. CMS has set out some of these:

- Contractors must achieve at least a 5 percent savings target, although they can propose additional savings.
- Contractors must use a core set of measures defined by CMS to assess the quality of diabetes, CHF, and COPD care, the use of preventive services, and the rates of hospital admission and emergency service use. Contractors can propose additional measures of quality, particularly for measuring the quality of care for comorbidities.

The Commission supports CMS's approach of using core quality measures. If contractors do not use a core set of clinical outcome measures and a standardized tool to assess beneficiary and provider satisfaction, it will be difficult to determine whether certain programs are more effective than others.

By requiring use of a core set of measures, CMS will help promote a set of standardized measures for evaluating outcomes of disease management programs, something now lacking. Currently, many different categories of measures are being used, including medical cost savings, return on investment, quality of care, and worker productivity. The industry has recently attempted to define valid indicators to compare programs. In February 2003, one firm and the Johns Hopkins Outcomes Verification Program published a report outlining standard outcome metrics and evaluation methodology for disease management programs (American Healthways and Johns Hopkins Consensus Conference 2003). However, in the same year, the disease management industry was not able to agree on a uniform outcomes methodology (Disease Management News 2004).

CMS's solicitation leaves several open issues concerning how quality and satisfaction will be measured and collected. First, CMS needs to determine how quality performance will be evaluated. Options are improving the care contractors furnish above the enrollees' baseline level, exceeding national averages, improving indicators to levels higher than those for the control group, or some combination. CMS's new ESRD disease management demonstration uses a mixed strategy when linking

How many participants are needed in each treatment group?

The number of beneficiaries that CMS will need to enroll in each program depends on its strategy for evaluating savings. Table 2-5 shows that CMS would need about 4,000 beneficiaries in each Chronic Care Improvemnt Program (CCIP) treatment group to detect a 5 percent difference in the average value of beneficiaries' three-year sum of program spending. It would also need an equal number of people in the control group. Those are much lower than figures described in CMS's request for proposals because the numbers needed to detect a statistically significant difference between treatment and control groups depends on the amount of variation in spending: the three-year sum of each person's spending varies less, relative to the mean, than does annual spending. This calculation assumes that CMS would compare three-year spending without regard to the number of people who survived to the third year.

If CMS conducts annual reconciliations with contractors to evaluate whether they are achieving savings targets, it may decide to use a different approach. Table 2-6 shows the number of enrollees needed each year to measure a significant difference between average program spending. For example, among beneficiaries who have congestive heart failure (CHF) or complex diabetes, CMS would need to enroll a sample of 14,250 persons during the base year for the treatment group if it wanted to detect a statistically significant 5 percent difference in mean spending three years after the start of the program. It would need an equal number in the control group as well. Since about 15 percent of fee-for-service enrollees within that CHF or complex diabetes cohort die in a given year, only about 10,210 of the 14,250 participants would be alive at the end of the third year after the program began.

The second set of calculations factor in attrition of each condition group over time, mainly due to deaths in these populations. As the intervention progresses, the number of persons remaining falls. This means that the later the CCIP is to be evaluated, the more people must be chosen to assure adequate sample size in the evaluation period for any given level of statistical precision.

The high mortality rates of these groups raise important issues for evaluating savings under the CCIP. If the program affects the annual mortality rate, it may be difficult to evaluate savings from the program because the treatment and control groups would no longer be equivalent. By the second year, the treatment group would have more people—presumably more acutely ill people—than the control group. Even though the avoidance of deaths in the treatment group would likely reduce first-year costs, it is not clear what effect reduced mortality would have on per capita costs in subsequent years. There may be several ways to evaluate program savings or costs over the CCIP's initial phase, but it seems prudent to also compare the mortality rates of treatment and control groups.

TABLE 2-5

How many beneficiaries would CMS need to detect a 5 percent difference in the average three-year sum of spending with 95 percent confidence?

	Average three-year program spending	Number of beneficiaries needed in the first year
CHF or complex diabetes	$35,840	4,100
COPD	34,950	3,830

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). The values shown above describe mean spending and the number of people that CMS would need to enroll in order to make statistical inferences about a difference between spending in treatment and control groups. All values are based on CMS's definitions of conditions and the presence of a moderate to high risk-adjustment score. CMS identifies beneficiaries based on certain diagnoses codes for two or more professional visits on separate dates or (for CHF or COPD) a hospitalization for the condition in one year of claims data. These calculations are for a two-tailed significance test with treatment and control groups of equal size.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims, linked over the 1996–2002 period.

How many participants are needed in each treatment group? *(continued)*

TABLE 2-6

How many beneficiaries would CMS need to detect a difference in average annual program spending with 95 percent confidence?

	Number of beneficiaries in original group			Surviving number of beneficiaries		
	Year after start			Year after start		
	First	Second	Third	First	Second	Third
To detect a 5 percent difference						
CHF or complex diabetes	9,940	12,760	14,250	9,800	10,780	10, 210
COPD	8,500	10,330	14,030	8,420	8,480	9,530
To detect a 7.5 percent difference						
CHF or complex diabetes	4,420	5,670	6,330	4,350	4,790	4,540
COPD	3,780	4,590	6,240	3,740	3,770	4,240
To detect a 10 percent difference						
CHF or complex diabetes	2,480	3,190	3,560	2,450	2,700	2,550
COPD	2,130	2,580	3,510	2,110	2,120	2,380

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). The values shown above describe the number of people that CMS would need to enroll in order to make statistical inferences about a difference between spending in treatment and control groups. The surviving number of beneficiaries shows the number who are alive one, two, and three years after the program's start. All values are based on CMS's definitions of conditions and the presence of a moderate to high risk-adjustment score. CMS identifies beneficiaries based on certain diagnoses codes for two or more professional visits on separate dates or (for CHF or COPD) a hospitalization for the condition in one year of claims data. These calculations are for a two-tailed significance test with treatment and control groups of equal size. The required numbers of beneficiaries would be much smaller in the base year than in subsequent years because the variance of spending would exclude that for any decedents or any persons who had no claims data. Numbers in Table 2-6 are larger than those in Table 2-5 because the variance in the sum of spending over three years is smaller relative to its mean than that for annual average spending.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims, linked over the 1996–2002 period.

Estimates shown in Tables 2-5 and 2-6 reflect an assumption that CMS would need to detect a 5 percent difference in program spending between treatment and control groups. However, the agency will likely need to detect an even greater difference, since programs need to achieve 5 percent net savings after accounting for contractor fees. The magnitude of fees could substantially affect the number of required enrollees, since generally it takes fewer people to detect a larger difference. For example, if CMS allowed a contractor to aim for a 2.5 percent fee, the contractor would need to achieve 7.5 percent gross savings in average program spending. Under that scenario, CMS would need 6,330 people in the treatment group rather than 14,250 to detect the larger difference at the end of the program's third year. Likewise, if a contractor needed to achieve 10 percent gross savings because it wanted to aim for a 5 percent fee, CMS would need just 3,560 people in the treatment group at the end of the third year. ■

payments to quality. For each of the five measures used, the agency awards one-half of one percent of payments for improving quality and one-half of one percent for exceeding national targets. Using a mixed strategy minimizes the negative aspects of each method. Measuring quality based only on improvements could reward contractors who achieve significant improvement but remain at a relatively low level of quality. By contrast, setting goals too high might discourage contractors at the low end from trying to improve.

Second, CMS needs to address whether quality will be assessed measure by measure or aggregated across measures. Its solicitation for bids permits contractors to propose methods to aggregate the quality measures. If the

measures are to be aggregated, CMS will need to ensure that contractors use an appropriate weighting methodology. Otherwise, important deficiencies in quality may be obscured.

Third, CMS needs to determine the standard for improving clinical quality. Unlike the savings target, the request for proposal does not call for contractors to achieve a minimum percentage change in quality. Rather, it calls on each bidder to set its projections for quality improvement on a year-to-year basis. CMS could require all contractors to meet at least a minimum quality standard. This would address a concern raised by some policymakers that contractors might compromise quality to meet or exceed savings targets.

Fourth, quality measures need to be measured and collected in a manner to ensure comparability across contractors. CMS or its evaluation contractors will need to audit data to ensure its accuracy and consistency across sites.

Finally, an important task remaining for CMS is to develop instruments to measure beneficiary and provider satisfaction. The agency needs to set a minimal standard for all contractors to achieve in improving satisfaction.

Two additional issues to consider related to the evaluation of the CCIP are the implementation of Medicare's Part D prescription benefit and the generalizability of the results obtained from the evaluations.

During the three-year course of the initial phase, CMS will implement Medicare's Part D prescription drug benefit. CMS plans to include Part D spending in the evaluation of target savings. Will introducing that new benefit confound the CCIP's results? The answer might be no, so long as beneficiaries from the treatment and control groups enroll in Part D at the same rates. Under that scenario, the new benefit would affect spending for both groups equally, and any differences in outcomes could be attributed to the treatment. However, if one group is more likely to enroll than the other, the calculation of target spending may be biased. Contractors may have an incentive to encourage the treatment group to enroll at greater rates than the control group, in order to improve compliance with their drug regimens. CMS and its evaluators should assess the rate of participation in Part D between the study and control groups.

The effectiveness of care coordination interventions at reducing spending and improving quality cannot necessarily be generalized to the entire FFS Medicare population. The initial phase of the CCIP tests care coordination for only three conditions—complex diabetes, CHF, and COPD. Participants will be sicker, on average, than Medicare beneficiaries with these conditions who are not participating in the program. Policymakers should not assume that the savings targets and quality and satisfaction goals achieved in the initial phase can be realized in the second phase if different populations are targeted.

The budget neutrality constraint

The Congress required that the CCIP be budget neutral. The aggregate sum of Medicare program payments for beneficiaries participating in the program and funds paid to contractors should not exceed estimated program payments that would have been made for targeted beneficiaries in the absence of the program. In other words, CMS's payments to contractors need to be offset by other program savings, such as lower inpatient spending. However, for the CCIP's initial phase, the MMA did allow for certain startup costs by authorizing up to $100 million in net aggregate payments—amounts paid to contractors less any program savings attributable to the chronic care programs—for fiscal years 2004 through 2006.

Will the CCIP maintain budget neutrality? It seems reasonable to expect that contractors should reduce other types of Medicare program spending—particularly for hospitalizations—since one of their major goals is to reduce acute exacerbations of beneficiaries' chronic conditions. Some analysts suggest that contractors could achieve even greater savings than the 5 percent required in CMS's solicitation, particularly since the initial phase targets beneficiaries with CHF—considered the "low hanging fruit" among chronic conditions. Also, the MMA provides a strong incentive for contractors to accomplish program savings targets by requiring them to put administrative fees at risk.

However, savings cannot be guaranteed. Employers and other groups that have used disease management programs have never operated on the scale needed for the Medicare program, nor on populations with the unique medical and social characteristics of the elderly and disabled. Establishing programs for this population may involve significant startup costs for contractors. Case management services are more expensive to provide than the services

typically offered by disease management organizations today. And once CMS begins making monthly payments for CCIP programs, recouping payments from contractors that do not meet performance standards could prove difficult. The Congressional Budget Office estimated that the CCIP would not maintain budget neutrality—it estimated that the program would cost $500 million over the 2004–2013 period.

Chronic kidney disease and chronic care improvement programs: A case study

This case study focuses on the potential benefits of improved care coordination for renal patients because of MedPAC's long-standing interest in the quality of renal care. Most recently, we recommended linking payments to physicians and facilities caring for ESRD patients to the quality of care furnished to patients (MedPAC 2004). In the future, MedPAC may examine the potential of care coordination programs to improve quality for other populations with chronic conditions.

CKD includes conditions that affect the kidney, with the potential to cause either progressive loss of kidney function or complications resulting from decreased kidney function. Persons with CKD range from those with decreased kidney function to those with permanent kidney failure—ESRD—who require either maintenance dialysis or a kidney transplant to survive. In most instances, ESRD develops as the consequence of progressive damage to the kidney over a decade or more. The National Institutes of Health (NIH) and the Centers for Disease Control have recognized CKD as a major public health problem because of the increased numbers of those with the disease, their high costs, and the substantial morbidity and mortality experienced by affected patients.

Although CKD is not a threshold condition under the MMA, CKD patients will most likely be among the participants of the program because they suffer from conditions targeted by the law—diabetes, CHF, and COPD. Diabetes is the leading cause of renal failure; about 45 percent of dialysis patients have diabetes, 30 percent have CHF, and 8 percent have COPD. Patients with ESRD will not be among the participants because CMS has excluded them from the CCIP.

Based on our review of the scientific literature, our discussions with providers of care coordination services, and our analysis of Medicare claims data, we find that:

- The ESRD population is growing and is costly.
- Slowing or preventing permanent renal failure may be possible.
- Earlier referral to a renal team may improve patients' outcomes.
- Coordinated care programs may improve some aspects of care for renal patients, although the impact of such programs on Medicare spending is unclear.

The end-stage renal disease population is growing and is costly

The impetus behind coordinating the care of CKD patients is to delay or prevent new cases of ESRD. The number of new cases of ESRD continues to grow, particularly among diabetics, African Americans, and the elderly. Patients with ESRD, particularly patients on dialysis, are one of the costliest populations for Medicare and have significant morbidity and mortality. Permanent renal failure lowers most patients' quality of life. Healthy People 2010, a set of health objectives for the first decade of the new century developed by the Department of Health and Human Services, calls for the rate of new cases of ESRD to be reduced by one-third (Office of Disease Prevention and Health Promotion 2004).

The ESRD population comprises about 293,000 patients requiring dialysis and 114,000 patients who have undergone a kidney transplant and have a functioning kidney graft. Dialysis is the process by which wastes and excess fluids are removed from a patient's body.[9, 10] Kidney transplantation is preferred over dialysis because it improves both survival and quality of life while reducing long-term costs of care. Dialysis patients, however, outnumber transplant patients, not because of a lack of demand for transplants, but because of the well-documented shortage of kidneys available for transplantation. In 2001, only 15,331 kidney transplants were performed. By contrast, 57,336 patients were awaiting a transplant (United Network for Organ Sharing 2004).[11]

Left unchecked, the number of ESRD patients is estimated to be more than 650,000 patients by 2010. Incidence rates have increased during the past decade from 223 per

1,000,000 people in 1991 to 334 per 1,000,000 people in 2001. Diabetes accounts for most new cases of ESRD, and diabetics and the elderly are the fastest growing segments of the ESRD population. About half of the nearly 100,000 new cases in 2001 were patients 65 years or older. Other conditions that contribute significantly include high blood pressure and other cardiovascular conditions, and obesity.

ESRD patients are costly to Medicare. Although representing less than 1 percent of beneficiaries, they account for about 6 percent of all Medicare spending. According to the U.S. Renal Data System, average spending per ESRD patient was $45,000 in 2001. Dialysis patients, with average annual spending of $52,000 in 2001, were 2.8 times more costly than kidney transplant patients. The high spending of dialysis patients is partly driven by the costs for outpatient dialysis, which account for about 42 percent of total spending.[12] However, because many dialysis patients suffer from and are frequently hospitalized for other chronic comorbidities, spending for inpatient hospital services accounts for about 36 percent of total spending.

Rates of hospitalization and mortality for dialysis patients have remained high and relatively unchanged during the past 10 years. Between 1993 and 2001, hospitalization rates per 1,000 patient years ranged from 2,019 to 2,062. Adjusted annual mortality rates have remained relatively constant during this time, ranging from 236 to 253 per 1,000 patient years at risk (USRDS 2003).

Finally, ESRD patients experience a decline in their quality of life, although transplant patients have higher quality-of-life scores than those treated with dialysis. Women and older ESRD patients have lower scores than do men and younger patients.

Slowing or preventing new cases of end-stage renal disease may be possible

Earlier intervention and better management of CKD patients may, for certain cases, delay or even prevent permanent kidney failure. The NIH, Healthy People 2010, and the renal clinical guidelines developed by the National Kidney Foundation (NKF)—the Kidney Disease Outcome Quality Initiative (K/DOQI)—all conclude that early referral to a renal team is important to reduce the substantial morbidity and mortality associated with ESRD (NIH 2004, NKF 2004).

The first step in slowing or preventing the progression to ESRD is identifying patients with CKD. The K/DOQI recently published a clinical guideline in which CKD is defined according to the presence and absence of kidney damage and the level of kidney function—glomerular filtration rate (GFR)—with higher stages representing more severe kidney damage (Table 2-7). This guideline defines CKD as either having structural or functional abnormalities of the kidney or having a GFR of less than 60 mL/min—stages 3 and 4—for three months or more. K/DOQI recommends that stage 3 patients be evaluated and treated for complications of CKD and that stage 4 patients be prepared for renal replacement therapy.

Populations at risk for CKD include patients with one of the conditions targeted by the CCIP—diabetes. Other at-risk groups include: older persons, persons with hypertension, and minorities. How large is the at-risk population? Using data from the National Health and Nutrition Examination Survey III, Coresh and colleagues (2003) estimated that 14.2 percent (about 2.6 million) of all diabetics have stage 3 and 0.92 percent (about 167,000) have stage 4 CKD. Among persons age 70 and older, 24.6 percent (about 6.3 million persons) have stage 3 and 1.3 percent (about 332,000 persons) have stage 4 CKD.[13]

Screening at-risk populations may be necessary because kidney disease in its early stages is often asymptomatic; thus, many people who would benefit from early intervention are not identified. In addition, some evidence

TABLE 2-7 **Stages of chronic kidney disease**

CKD stage	Description
1	Kidney damage with normal or elevated GFR (≥90)
2	Kidney damage with mildly decreased GFR (60–89)
3	Moderately lower GFR (30–59)
4	Severely lower GFR (15–29)
5	Kidney failure GFR (<15)

Note: CKD (chronic kidney disease), GFR (glomerular filtration rate). GFR is a measure of kidney function and measures the rate at which the kidneys filter the blood of toxins. Normal GFR values in adults are between 100 and 150 milliliters per minute.

Source: Adapted from the National Kidney Foundation's clinical guideline for chronic kidney disease, 2004.

suggests that CKD is underdiagnosed even when clinical measures are available to identify the disease (Coresh et al. 2003, Kausz et al. 2001, McClellan et al. 1997).

Once CKD is identified, it may be possible to slow or halt the progression of kidney disease to ESRD by improving the care of cardiovascular disease and diabetes. The American Diabetes Association recommends diabetic patients receive hemoglobin A1c testing at least two to four times per year and lipid testing at least annually. Care for some CKD patients did not meet these targets:

- About half of CKD patients with diabetes did not receive two to four hemoglobin A1c tests in 2001.
- 37 percent of CKD patients with diabetes did not receive at least one lipid test in 2001 (USRDS 2003).

Reducing the complications of CKD—such as anemia, bone disease, and malnutrition—may also slow the progression to ESRD and improve quality of care. Opportunities exist to improve the care of CKD complications:

- About 75 percent of patients initiating dialysis did not receive erythropoietin in the pre-ESRD period (USRDS 1999). K/DOQI calls for erythropoietin therapy for CKD patients with anemia.
- A substantial number of CKD patients do not receive appropriate dietary instruction (Pennell 2001). Fifty percent of hemodialysis and 43 percent of peritoneal dialysis patients reported that they had not seen a dietician before starting dialysis.

Prescription of angiotensin-converting enzyme (ACE) or angiotensin-receptor blocker (ARB) therapy in persons with microalbuminuria—the presence of protein in the urine, indicating that the kidneys are not working properly—has been demonstrated to decrease both the progression of kidney disease toward ESRD as well as the incidence of cardiovascular events and death. CMS's request for proposals includes two quality indicators for monitoring the frequency with which contractors test persons with diabetes for microalbuminuria and prescribe either ACE or ARB therapy.

Finally, better management of patients with CKD may lower their risk of mortality due to cardiovascular disease. Cardiovascular mortality is three times greater in patients with CKD than in the general population. CKD patients are 5 to10 times more likely to die due to cardiovascular disease than to develop ESRD (USRDS 2003). Healthy People 2010 calls for reducing the mortality rate due to cardiovascular disease.

Improving the quality of care for patients progressing to end-stage renal disease

Earlier intervention and better management of CKD patients may reduce the substantial morbidity, mortality, and costs associated with ESRD. More integrated care among primary care physicians and providers with expertise in nephrology—physicians, nurses, dieticians, and social workers—may improve the care furnished to CKD patients. Healthy People 2010 calls for increasing the proportion of CKD patients under the care of informed health care providers 12 months before the start of renal replacement therapy.

Referring patients with chronic kidney disease to a renal team

Many CKD patients are not seen by providers with expertise in nephrology until they are very close to beginning dialysis. Kinchen and colleagues (2002) reported that 30 percent of patients were seen by a nephrologist less than 4 months before dialysis initiation, 22 percent were seen 4 to 12 months before, and 48 percent were seen more than one year before. Potential reasons for late referral include asymptomatic CKD, noncompliance with referrals, and the attitudes of primary care physicians about referring CKD patients to specialists. These researchers also found that referral patterns varied based on patients' demographic characteristics.

Earlier referral to a renal team may lead to better ESRD outcomes. The risk of death was significantly greater among ESRD patients referred to a renal team late (less than 4 months before the start of dialysis) compared to patients referred early (more than 12 months before the start of dialysis) (Kinchen et al. 2002).[14] Other researchers have also found that late referral to a renal team is associated with: (1) a higher risk for unplanned first dialysis, (2) more complications, (3) higher hospital costs

and longer duration of hospitalization in the first three months of dialysis, and (4) greater use of temporary vascular access.

Some care coordination programs promote earlier referral to a nephrology team for patients with CKD as one way to improve quality. MedPAC contracted with Direct Research, LLC, to examine the potential impact of early referrals to nephrology care on the use of services, outcomes, and Medicare spending for CKD patients before and after they started dialysis. This analysis uses Part A and B claims data from 1996 to 2002 for a 5 percent representative sample of FFS beneficiaries.

First, we identified a cohort of incident dialysis patients. The study population is comprised of patients who received at least six dialysis sessions during their initial month of dialysis and whose initial dialysis date from the outpatient dialysis claim matched the start of dialysis date from the Renal Beneficiary Utilization System/Program Management and Medical Information System (REBUS/PMMIS) to within two weeks. So that we could examine the use of services for up to two years before dialysis, we excluded patients starting dialysis in 1996 and 1997. We also excluded patients whose Medicare entitlement was due to ESRD so that we would have at least two years of data before the start of dialysis.[15]

Because of this latter exclusion, the study population is older, on average, than all new dialysis patients. In the study population, 16 percent of patients are under age 65, 40 percent are between 65 and 74 years, and 45 percent are 75 years and older.[16] By contrast, among all new dialysis patients in 2001, 50 percent of patients were under age 65, 25 percent were between 65 and 74 years, and 25 percent were 75 years and older. Thus, the results derived from this analysis are not representative of all new dialysis patients.

Next, we classified patients based on when they first saw a provider with expertise in nephrology and when they started dialysis:

- late (on or after the start of dialysis),
- intermediate (within 4 months before starting dialysis or between 4–12 months before starting dialysis), or
- early (more than 12 months before starting dialysis).

Providers with expertise in nephrology are defined as physicians who reported the specialty code of nephrology on at least one Part B claim. Ideally, we would have preferred measuring access to any physician with expertise in nephrology but this information is not available in Medicare claims data. Thus, our results will be affected to the extent that physicians are either under reporting or over reporting nephrology as their specialty.

We examined the use of services during the pre-ESRD period that are recommended in renal clinical guidelines: (1) prescription of Medicare-covered injectable medications, such as erythropoietin, for complications of CKD and (2) outpatient placement of an arteriovenous (AV) fistula.[17] We measured the use of peritoneal dialysis—the most common home dialysis method—as the initial dialysis method because of interest by the Congress and others in promoting home dialysis. We examined outcomes that better care coordination during the pre-ESRD period might improve: (1) hematocrit at dialysis onset, (2) hospitalization in the month prior to starting outpatient dialysis, and (3) mortality in the first and second years following dialysis.

We were not able to examine the rate of kidney transplantation among the study population because this analysis would have led to small, unstable estimates. As noted earlier, the study population is older, on average, than all new dialysis patients and the rate of kidney transplantation among persons 65 years and older is low. About 8 percent of all transplants were received by patients 65 years and older in 2001. MedPAC may, in the future, examine the factors associated with receiving a kidney transplant among all CKD patients. As compared to dialysis, renal transplantation improves survival and quality of life while reducing long-term costs of care.

We also were not able to examine the use of medical nutrition therapy services because Medicare coverage did not begin until January 1, 2002. Included in the Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000, this benefit provides nutritional counseling to patients with diabetes or CKD. MedPAC may, in the future, examine use of this service among all CKD patients.

The results presented below are not adjusted for potential differences in the demographic and clinical characteristics of patients in each group. For example, we were not able to adjust for differences in the level of renal function at which dialysis was initiated.[18] Other researchers have shown some differences in their results after they adjusted for potential confounders (Kinchen et al. 2002).

The majority of the study population first saw a nephrologist less than one year before dialysis. About 28 percent of patients did not see a nephrologist until they started dialysis, 17 percent saw one less than 4 months before starting dialysis, 15 percent saw a nephrologist 4 to 12 months before, and 40 percent saw a nephrologist more than one year before. Ten percent of the study population had no record of a claim submitted by a nephrologist either before or after dialysis. Because this analysis uses claims data, we do not know whether these patients were never treated by a nephrologist or whether they were treated by a nephrologist who reported a physician specialty code other than nephrology.

Patients may not be seeing a nephrologist before starting dialysis because CKD has yet to be diagnosed. We determined, however, that 51 percent of the study population had a Part A or B claim indicating chronic renal failure more than one year before starting dialysis, 46 percent in the year before starting dialysis, and only 3 percent on or after starting dialysis.

Our results about the association between earlier referral and use of services and outcomes are generally consistent with those reported by other researchers (Table 2-8). A greater proportion of patients with early referrals were prescribed at least one medication for complications of CKD and had an AV fistula placed compared with late referral patients. The average initial hematocrit of early referral patients was greater than that of late referral patients (31 percent versus 27 percent, respectively); K/DOQI recommends a target hematocrit ranging from 33 percent to 36 percent.

Early referral may have a small, positive effect on peritoneal dialysis use: 2.3 percent of late referral patients chose this modality compared with 5.8 percent of early referral patients. Overall, the use of peritoneal dialysis among all new dialysis patients in the U.S. is 7.8 percent. Our results are lower because the study population is older than all new dialysis patients and use of peritoneal dialysis is inversely related to age (USRDS 2003).

TABLE 2-8

Some differences in the use of services based on the timing of nephrology care

	Time between first visit to nephrologist and start of dialysis			
	Same time or after	Less than 4 months	4–12 months	More than 12 months
Received at least one medication for complications of CKD	4.7%	9.8%	15.2%	17.9%
Average initial hematocrit	27.3%	28.1%	28.1%	31.0%
Use of arteriovenous fistulas:				
5–12 months before dialysis	2.2	0.4	8.1	10.8
1 month before dialysis	9.5	16.1	30.8	29.8
Hospitalized in the month before starting dialysis	83.2	71.2	66.5	64.8
Peritoneal dialysis is initial dialysis modality	2.3	6.2	5.3	5.8
Mortality in the first year after dialysis	29.9	31.3	27.4	24.8
Mortality in the first two years after dialysis	51.6	49.4	49.4	47.9

Note: CKD (chronic kidney disease). To permit for sufficient data, patients starting dialysis in 2002 are excluded from the first year mortality rates; patients starting dialysis in 2001 and 2002 are excluded from the mortality rates for the first two years after dialysis.

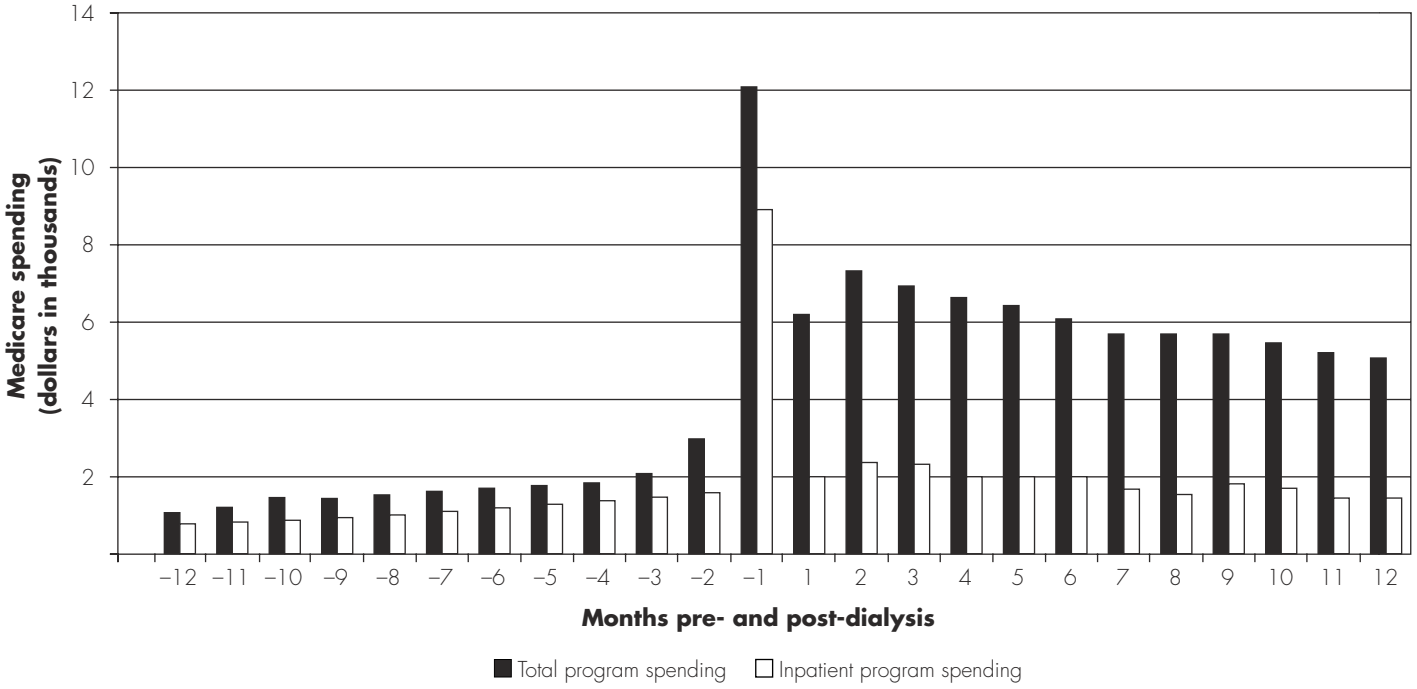
Source: Direct Research, LLC, based on a 5 percent sample of Medicare beneficiaries, their claims, and information from REBUS/PMMIS.

Although hospitalization rates are high in the month before dialysis begins, the rate is lower for patients who saw a nephrologist more than 12 months before starting dialysis. Mortality rates among the study population are also high. Two years after dialysis, 48 percent of patients who were referred early had died compared with 52 percent of patients who were referred late.

CKD patients are costly: average Medicare spending was $29,804 in the 12 months preceding dialysis and $61,434 in the 12 months after dialysis begins. Not surprisingly, total Medicare spending increases once patients start dialysis (Figure 2-5, p. 62). However, spending is also high in the month before starting dialysis because a substantial proportion of patients are hospitalized.

FIGURE 2-5

Inpatient spending spikes in the month before dialysis begins



Note: Month 1 is the start of dialysis.

Source: Direct Research, LLC, based on a 5 percent sample of Medicare beneficiaries, their claims, and information from REBUS/PMMIS.

Providers of renal care coordination services told us that they aim to decrease rates of hospitalization by better preparing patients for dialysis.

Inpatient hospital spending modestly differs by when patients first saw a nephrologist (Figure 2-6). Inpatient spending in the year before dialysis averaged $20,137 for late referral patients compared to $14,878 for early referral patients; in the year after dialysis began, the difference in average inpatient spending narrowed to $20,941 for late referral patients compared to $18,229 for early referral patients. The difference in inpatient spending between early and late referral patients after starting dialysis may be associated with care at the end of life. Nearly all ESRD patients (92 percent) are hospitalized in the last year of life, and 60 percent of ESRD patients die in the hospital (MedPAC 2000).

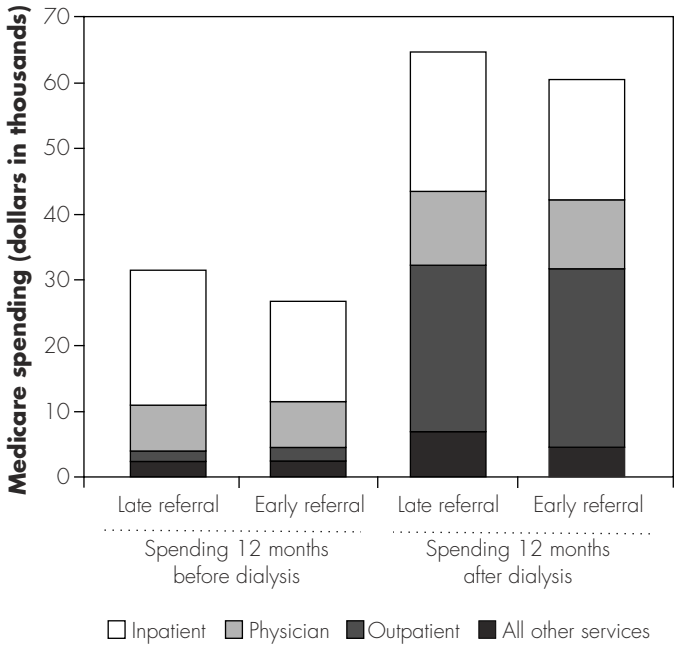
One of the important reasons to look at patterns of care among CKD patients is to consider chronic care management. While there appear to be opportunities to improve quality and reduce spending, it is not clear how care coordination programs would affect Medicare spending once the fees associated with such programs are considered in a spending analysis. Total program spending for early referral patients was 16 percent lower in the year before dialysis and 6 percent lower in the year after dialysis compared to late referral patients. What is unknown is the level and intensity of care coordination services that CKD patients would require and the fees associated with these programs. Some patients would most likely require case management services, which are more expensive to provide than the services typically offered by disease management organizations.

Preparing chronic kidney disease patients for renal replacement therapy

As noted in the prior section, earlier intervention may lead to improved care of complications from CKD and comorbidities, particularly diabetes, lipid abnormalities,

FIGURE 2-6

Inpatient spending is somewhat lower for early referral patients



Note: Late referral patients are those whose first visit to a nephrologist was on or after the start of dialysis. Early referral patients are those whose first visit was more than 12 months before dialysis. The increase in outpatient spending in the one year after dialysis is primarily associated with outpatient dialysis services.

Source: Direct Research, LLC, based on a 5 percent sample of Medicare beneficiaries, their claims, and information from REBUS/PMMIS.

and high blood pressure, and may reduce morbidity and mortality once patients progress to ESRD. Two interventions that may benefit patients are:

- educating CKD patients about the different renal treatment options, and
- surgically placing a permanent vascular access device instead of a temporary access device.

Educating CKD patients about renal treatment options Better education in the pre-ESRD period gives patients an opportunity to learn about the different ESRD treatment options. Only 25 percent of CKD patients who were ultimately treated with hemodialysis reported that one type of peritoneal dialysis—continuous ambulatory peritoneal dialysis—was discussed with them as a treatment option (USRDS 1997). By contrast, 82 percent of patients who received information about continuous ambulatory peritoneal dialysis during the pre-ESRD period chose home dialysis. The lack of appropriate education during the pre-ESRD period may have contributed to the decline in the use of peritoneal dialysis from 13 percent of all new dialysis patients in 1991 to 8 percent in 2001 (USRDS 2003).[19]

Many CKD patients are not educated about kidney transplantation. For example, among patients under age 60 years, only 60 percent of peritoneal dialysis and 45 percent of hemodialysis patients recalled being informed about kidney transplantation. The lack of knowledge about transplantation is just one of the many factors that affect access to this treatment option. As noted earlier, a limited supply of donor organs is available. Access differs based on race and ethnicity: African Americans are less likely than Whites to be identified as potential candidates, be referred for transplant evaluation, and receive a transplant (Alexander and Sehgal 1998).

Using arteriovenous fistulas Vascular access services are needed by the 90 percent of all dialysis patients who undergo hemodialysis. AV fistulas are considered the best long-term vascular access because they provide adequate blood flow for dialysis, last a long time, and have a complication rate lower than the other access types—AV grafts and venous catheters. However, AV fistulas need more time to mature than grafts and catheters. K/DOQI recommends that a fistula should be allowed to mature for at least one month, and preferably for three to four months. Data from 2001 show that only 29 percent of new dialysis patients had an AV fistula (CMS 2002). Healthy People 2010 targets increasing the proportion of new hemodialysis patients who use AV fistulas.

Care coordination programs may improve the outcomes of renal patients

Care coordination programs offer the potential of improving the quality of care for CKD patients. Some health care organizations and providers have begun to implement programs focusing on the care of CKD patients (Schorr 2003, Yeoh et al. 2003). These programs emphasize:

- Early identification of at-risk patients. Laboratories calculate patients' GFR when physicians order a lab test that measures serum creatinine;[20]

- Managing CKD and comorbidities to delay or avoid renal replacement therapy;
- Educating patients and families about the role of nutrition, weight management, compliance with prescribed drug regimens, types of renal replacement therapy, and types of vascular access;
- Referring patients to nephrologists and multidisciplinary teams. (One program, for example, refers stage 3 patients with structural damage or with risk factors for developing ESRD and those in stage 4 to renal multidisciplinary teams); and
- Measuring outcomes.

Evidence is lacking on the effectiveness of these programs. MedPAC was unable to locate studies examining the effectiveness of programs targeting patients with CKD in the scientific literature.

Care coordination programs also offer the potential for broadening providers' focus of care from ESRD to all comorbidities and, in doing so, better coordinating care. ESRD patients, particularly dialysis patients, fit the profile of a population that could benefit from coordinated care programs because they suffer from multiple comorbidities, are hospitalized frequently, are prescribed many medications, and incur high costs.

Several private payers, including Aetna, PacifiCare, Empire Blue Cross and Blue Shield, Blue Cross and Blue Shield of Minnesota, and Elderplan have arranged for disease management organizations to provide services for their ESRD members. These programs often offer a range of services including outreach to the primary care physician and nephrologist, initial assessment and ongoing monitoring of patients, and patient education. Providers of ESRD disease management services told us that they too vary the level and intensity of the services by the severity of the illness. Some state Medicaid programs are also contracting with outside vendors to provide ESRD disease management services. Two of the four national for-profit dialysis chains have affiliate organizations offering renal disease management services.

Like programs for other populations, the effectiveness of care coordination programs for ESRD patients has yet to be conclusively demonstrated. One study evaluating a disease management program showed that hemodialysis patients enrolled in a health plan with a disease management program had 19 to 35 percent significantly better survival rates and 45 to 54 percent fewer hospitalization rates compared with all hemodialysis patients enrolled in FFS Medicare (Nissenson et al. 2001).

Conclusion

Renal patients experience substantial morbidity and mortality and are among the costliest populations for Medicare. Evidence from the literature suggests that earlier intervention and better management of patients with CKD may, in some cases, delay or prevent permanent kidney failure. In addition, MedPAC's analysis of claims data suggests that earlier referral of CKD patients to a nephrologist may reduce some of the morbidity associated with ESRD.

The CCIP will provide opportunities to promote earlier intervention and improve management of CKD. Patients with CKD will undoubtedly be among the program's participants because of the high prevalence of diabetes and CHF in this population. In the initial phase of the CCIP, policymakers should consider including in the evaluation how well each contractor met the special needs of patients with CKD.

As more information becomes available, MedPAC may examine the potential of different approaches to coordinate the care for patients with CKD. Such an effort would include interviewing providers of programs focusing on improving the quality of CKD care and reviewing studies examining the effectiveness of different approaches. It is not yet clear that population-based disease management is the optimal approach because CKD is asymptomatic for many persons. Programs that coordinate the care of CKD patients may need laboratory data for targeting patients.

CMS has excluded patients with ESRD from participating in the CCIP, but not patients with other costly conditions, such as rheumatoid arthritis and multiple sclerosis. Care coordination programs as configured under the MMA might have provided opportunities to improve renal care. Although CMS will be initiating a disease management demonstration for ESRD patients in the near future, not all ESRD patients will be able to participate in this program. ■

Endnotes

1 CMS published a request for proposals on April 23, 2004, and applications are due to CMS by August 6, 2004.

2 Hierarchical condition category scores are used by CMS as part of its formula for risk adjusting payments to Medicare Advantage plans.

3 Since many drugs are prescribed for multiple conditions, prescription data will not always be useful to determine diagnoses.

4 In addition, CMS only recognizes outpatient diagnoses from professional (physician) office and emergency room visits and consultations, not from other providers or from other physician services. For example, physician services for procedures, test, and imaging are not counted when flagging the target populations for the intervention.

5 The National Kidney Foundation is in the process of developing diabetes- and cardiovascular-related guidelines for patients with chronic kidney disease.

6 Interviewees informed us that they periodically reevaluate the risk level of each patient participating in their disease management and care coordination programs. Some patients who are at a higher risk level may shift to a lower risk level. On the other hand, the condition of some patients may worsen during the course of the year. Having claims data may enable contractors to monitor changes in a patient's condition.

7 Here we use the term "dual eligible" to refer to people for whom a state has paid their Medicare Part B (or A) premium. This includes those eligible for a state's full package of Medicaid benefits, as well as Qualified Medicare Beneficiaries and Specified Low-Income Beneficiaries.

8 Note that the 18 percent share is lower than other figures from studies on care provided at the end of life. Those analyses tend to examine the amount of program spending on beneficiaries during the last 12 months of their lives, rather than for a calendar year (Hogan et al. 2000).

9 About 90 percent of all dialysis patients undergo hemodialysis, in which blood from the patient's body is circulated through an external machine and returned to the patient's blood stream. About 10 percent of all patients undergo peritoneal dialysis, a procedure that introduces dialysate into the abdominal cavity to absorb and remove waste products through the peritoneum.

10 The estimate of kidney transplant patients includes patients undergoing transplantation in 2001 and patients with a functioning kidney transplant.

11 To help address this problem, the Department of Health and Human Services awarded grants totaling $4.3 million in 2003 to support social, behavioral, and clinical intervention programs to increase organ and tissue donation.

12 Outpatient dialysis services include composite rate services, injectable drugs administered during dialysis, physician monthly capitation services, vascular access services, and peritoneal access services.

13 Estimates obtained from the American Diabetes Association and the U.S. Bureau of the Census were used to estimate the number of diabetics and persons 70 years or older who have CKD, respectively.

14 The median follow-up period for the population was 2.2 years.

15 The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who were fully or currently insured or eligible for Social Security, their spouses, and their dependent children. About one-third of ESRD patients are entitled to Medicare on the basis of ESRD alone.

16 Sum does not total to 100 because of rounding.

17 Vascular access refers to the site on the patient's body where blood is removed and returned during hemodialysis. The AV fistula is the type of vascular access recommended by renal clinical guidelines because it is associated with fewer complications and lasts longer than the other types of vascular access.

18 Clinicians are still debating the level of renal function at which dialysis should be initiated. Some clinicians suggest that early dialysis leads to reduced mortality among dialysis patients. Others recommend a strategy of careful management until dialysis becomes inevitable (Kausz et al. 2000).

19 Other factors related to the decline in peritoneal dialysis include the medical conditions, preferences, and social circumstances of patients and the preferences of medical personnel. In addition, MedPAC has noted that the rapid growth in the number of dialysis facilities throughout the 1990s has created an incentive to direct patients to in-center treatment so that facilities operate at capacity. Finally, the profitability of separately billable drugs may also provide an incentive for in-center care.

20 Creatinine is a waste product from muscles and protein in the diet removed from the body by the kidneys. As kidney disease progresses, the level of creatinine in the blood increases.

References

Alexander, G. C., and A. R. Sehgal. 1998. Barriers to cadaveric renal transplantation among blacks, women, and the poor. *Journal of the American Medical Association* 280, no. 13 (October 7): 1148–1152.

American Healthways and Johns Hopkins Consensus Conference. 2003. Consensus report: Standard outcome metrics and evaluation methodology for disease management programs. *Disease Management* 6, no. 3: (Fall) 121–138.

Anderson, G. 2002. Written testimony before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives. 107th Cong., 2nd sess. April 16.

Buntin, M. E., A. M. Garber, M. McClellan, et al. 2004. The costs of decedents in the Medicare program: Implications for payments to Medicare+Choice plans. *Health Services Research* 69, no. 1 (February): 111–130.

Center on an Aging Society. 2004. *Disease management programs: Improving health while reducing costs.* Washington, DC: Georgetown University.

Centers for Medicare and Medicaid Services. 2004. CMS urges states to adopt disease management programs, agency will match state costs. CMS press release (February 26).

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2003. *The characteristics and perceptions of the Medicare population: Data from the 2000 Medicare Current Beneficiary Survey.* Baltimore: CMS. www.cms.hhs.gov/MCBS/CMS.src/2000/sec2.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2002. *2002 annual report ESRD clinical performance measures project*. Baltimore: CMS.

Chen, A., R. Brown, N. Archibald et al. 2000. *Best practices in coordinated care*. Princeton, NJ: Mathematica Policy Research.

Coresh, J., G. L. Wei, G. McQuillan, et al. 2003. Prevalence of high blood pressure and elevated serum creatinine level in the United States: Findings from the third National Health and Nutrition Examination Survey (1988–1994). *Archives of Internal Medicine* 161, no. 9 (May 14): 1207–1216.

Crippen, D. L., Congressional Budget Office. 2002. Disease management in Medicare: Data analysis and benefit design issues. Written testimony before the Special Committee on Aging, U.S. Senate. 108th Cong., 1st sess. September 19.

Disease Management News. 2004. DM industry faces "year of reckoning" in 2004. *Disease Management News* 9, no. 7 (February 10).

Fetterolf, D., D. Wennberg, and A. DeVries. 2004. Estimating the return on investment in disease management programs using a pre-post analysis. *Disease Management* 7, no. 1 (Spring): 5–24.

Foote, S. M. 2003. Population-based disease management under fee-for-service Medicare. *Health Affairs Web Exclusive* (July 30): w3-342–w3-356.

Hogan, C., J. Lynn, J. Gabel, et al. 2000. *Medicare beneficiaries' costs and use of care in the last year of life.* Washington, DC: MedPAC.

Kausz, A. T., S. S. Khan, R. Abichandani, et al. 2001. Management of patients with chronic renal insufficiency in the northeastern United States. *Journal of the American Society of Nephrology* 7, no. 12 (July): 1501–1507.

Kausz, A. T., T. Gregorio, P. A. Obrador, et al. 2000. Late initiation of dialysis among women and ethnic minorities in the United States. *Journal of the American Society of Nephrology* 11: 2351–2357.

Kinchen, K. S., J. Sadler, N. Fink, et al. 2002. The timing of specialist evaluation in chronic kidney disease and mortality. *Annals of Internal Medicine* 137, no. 6 (September 17): 479–486.

Lynn, J. 2001. Serving patients who may die soon and their families: The role of hospice and other services. *Journal of the American Medical Association* 285, no. 7 (February 21): 925–932.

McClellan, W. M., D. F. Knight, H. Karp, et al. 1997. Early detection and treatment of renal disease in hospitalized diabetic and hypertensive patients: Important differences between practice and published guidelines. *American Journal of Kidney Disease* 29, no. 3 (March): 368–375.

Medicare Payment Advisory Commission. 2004. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2000. *Medicare beneficiaries' costs and use of care in the last year of life.* Washington, DC: MedPAC.

National Institutes of Health. 2004. *Morbidity and mortality of dialysis.* http://consensus.nih.gov/.

National Kidney Foundation. 2004. *K/DOQI Clinical Practice Guidelines*. http://www.kidney.org/.

Nissenson, A. R., A. J. Collins, J. Dickmeyer, et al. 2001. Evaluation of disease-state management of dialysis patients. *American Journal of Kidney Diseases* 37, no. 5 (May): 938–944.

Office of Disease Prevention and Health Promotion. Department of Health and Human Services. 2004. *Healthy People 2010.* http://www.healthypeople.gov/.

Pennell, J. P. 2001. Optimizing medical management of patients with pre-end-stage renal disease. *The American Journal of Medicine* 111 (November): 559–568.

Schorr, W. 2003. Western New York kidney disease project shows how disease management can work. *Nephrology News & Issues* (August): 31–32.

Short, A., G. Mays, and J. Mittler. 2003. *Disease management: A leap of faith to lower-cost, higher-quality health care.* Issue brief no. 19. Washington, DC: Center for Studying Health System Change.

Simms, G. 2003. Statement presented at the Medicare Payment Advisory Commission meeting. Transcript, October 9. http://www.medpac.gov/public_meetings/transcripts/100903_disease_ NR_transc.pdf.

United Network for Organ Sharing. 2004. *U.S. transplantation data.* http://www.unos.org/.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2003. *USRDS 2003 annual data report.* Bethesda, MD: NIDDK.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 1999. *USRDS 1999 annual data report.* Bethesda, MD: NIDDK.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 1997. *USRDS 1997 annual data report.* Bethesda, MD: NIDDK.

Yeoh, H. H., S. Rasgon, M. Rutkowski, et al. 2003. Management of patients with chronic kidney disease at Kaiser Permanente. *Nephrology News & Issues* (August): 25–28.