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Medicare's Chronic Care Improvement Pilot Program: What Is Its Potential?

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OVERVIEW — *This paper describes the voluntary chronic care improvement program under traditional fee-for-service Medicare as authorized by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law 108-173; section 721). This brief analyzes the emerging issues raised by this new program, including which chronic conditions and regional areas will be targeted, the types of entities that may participate, the physician's role in care management, and the adoption and use of health information technology and evidence-based clinical guidelines.*

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INTRODUCTION

The new Medicare law puts into motion sweeping changes to the nearly 40-year-old program, from instituting a new prescription drug benefit to redesigning and renaming Medicare+Choice to become Medicare Advantage. Among its many far-reaching provisions, the law also aims to improve chronic care for Medicare beneficiaries by establishing several new programs and demonstration projects.

Chronic care improvement can be, and is, defined in many ways throughout the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law 108-173). For example, the law requires the Department of Health and Human Services (DHHS) to develop a research and demonstration plan focused on chronically ill beneficiaries.[1] Its "medication therapy management" provisions require prescription drug plans to ensure that Medicare beneficiaries with multiple chronic diseases are taking their prescribed drugs appropriately.[2] Other provisions establish pay-for-performance demonstration programs that will reward physicians for promoting continuity of care and managing chronic conditions according to evidence-based clinical guidelines.[3]

Perhaps most significantly, section 721 of the MMA adds a new section 1807 to the Social Security Act to establish a large-scale, chronic care improvement program. The new program promises to be far broader in nature than traditional demonstration projects. It is targeted at beneficiaries enrolled in fee-for-service (FFS) Medicare, which finances health care for nearly 90 percent of Medicare beneficiaries. The new program defines a new contracting entity that will be expected to achieve financial as well as clinical results. Moreover, the program will be rigorously tested with the use of randomized controlled trials to evaluate its effectiveness.

On April 23, 2004, the Centers for Medicare and Medicaid Services (CMS) published a request for proposals (RFP) outlining specifications for potential contractors.[4] Though the RFP provides many details about how CMS intends to run the program, several key policy issues still remain unanswered. For example, what kinds of entities can reasonably be considered a "chronic care improvement organization"? What is the physician's role in care management? How flexible is the program design? The initial phase of the program is required by statute to be up and running by December

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2004; applications from potential program contractors must be received by August 6, 2004. Thus, there is a sense of urgency for broader understanding and sharper clarification of some key details. This issue brief summarizes the major provisions of the program and the related RFP and considers key questions that have emerged.

PURPOSE

As reported by the Institute of Medicine (IOM), a huge chasm exists between best medical practices that follow evidence-based treatment guidelines and the care many patients—especially those with chronic conditions—actually receive.[5] A multispecialty expert physician study found that, during a three-year period, Medicare beneficiaries received certain recommended services less than two-thirds of the time for conditions with a high prevalence among the elderly population (such as heart disease, diabetes, breast cancer, and stroke).[6] More than half of all Medicare beneficiaries with chronic obstructive pulmonary disease (COPD) were hospitalized for what was considered an avoidable respiratory diagnosis. Vulnerable populations, such as African Americans and residents in areas of poverty with shortages of health care professionals, were even less likely to receive necessary care than their counterparts.

The implications for the care and cost of Medicare beneficiaries are staggering. Nearly 80 percent of Medicare beneficiaries have at least one of the following chronic conditions: stroke, diabetes, emphysema, heart disease, hypertension, arthritis, osteoporosis, Parkinson's disease, or urinary incontinence.[7] Several of these chronic conditions are associated with much higher spending in the Medicare program. The costliest 5 percent of Medicare beneficiaries account for about half of all Medicare spending each year. Among this top 5 percent, 47 percent had congestive heart failure (CHF) and 35 percent had diabetes.[8]

Beneficiaries with chronic conditions are more likely to experience problems with care coordination because they often receive care from a variety of physicians and specialists. They also typically require multiple prescriptions, which increases the likelihood of adverse drug interactions and errors, and they are more likely to be subjected to multiple tests or procedures.[9] These beneficiaries are at greater risk of being admitted to the hospital or of visiting emergency rooms for preventable conditions or complications.

Based on a belief that encouraging adherence to evidence-based treatment guidelines will reduce spending and achieve better health outcomes, lawmakers, led by Rep. Nancy Johnson (R-CT), devoted subtitle C of Title VII of the new Medicare law to chronic care improvement. Section 721 provides the most comprehensive, far-reaching approach toward reaching this goal.

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MAJOR FEATURES

The new chronic care improvement pilot program has three major features:

■ **Population-based—**Modeled on extant disease management (DM) programs, CMS will identify, in advance, beneficiaries who might benefit from intervention. This population-based strategy is a departure from most current practices in Medicare. Eligible patients will be identified before program implementation rather than on the basis of referrals from physicians and other providers. Program contractors will be held accountable for the health outcomes and utilization of all members of the targeted group, not just those beneficiaries who choose to participate. Program contractors will be given historical claims data on their assigned targeted beneficiaries and be permitted to do proactive outreach.

■ **Large-scale—**The program is intended to be broad in scope and scale. Faced with multiple competing demands, CMS officials have indicated that the programs must be conducted on a large enough scale that they can be effectively managed at the federal level and that evaluation results will be statistically significant. As described in the RFP, CMS wants to test strategies that are "scalable, replicable, and adaptable nationally."[10]

The law requires that the program be offered in geographic areas in which at least 10 percent of the FFS Medicare population, in aggregate, resides. In the RFP, CMS indicates there will be approximately 10 pilot projects in different regions of the country, with each serving about 15,000 to 30,000 beneficiaries over a three-year period. The DHHS secretary will prospectively identify program participants as well as a comparable control group in each geographic area. These requirements indicate that the region will have to be geographically large or heavily populated.

■ **Demonstrated Effectiveness—**Throughout the legislative language, a strong emphasis is placed on evaluation and achievement of specified targets. DHHS is required to contract with an independent evaluator to monitor the chronic care improvement (CCI) programs, and the programs themselves are also required to provide CMS with progress reports. CMS will have to report regularly to Congress on the status of the pilots and of the whole program.

For evaluation purposes, the MMA requires that targeted beneficiaries be randomly assigned to an intervention or a control group. Because the program is voluntary, the intervention group will include beneficiaries who choose to participate in the program as well as those who refuse. The evaluation must assess the following factors:[11]

■ *Quality improvement measures, such as adherence to evidence-based guidelines and re-hospitalization rates.*

■ *Beneficiary and provider satisfaction.*

■ *Health outcomes.*

■ *Financial outcomes, including any cost savings to the program.*

The MMA requires that targeted beneficiaries be randomly assigned to an intervention or a control group.

KEY ELEMENTS

Targeted Beneficiaries

The legislation is designed to reach beneficiaries who have one or more "threshold" chronic conditions. The RFP specifies that the pilot program will focus on CHF, complex diabetes, and, in some cases, COPD.[12]

To be eligible to participate, beneficiaries must be entitled to benefits under Part A and enrolled in Part B, but *not* enrolled in a plan under Part C (Medicare Advantage). CMS has developed a method of identifying targeted beneficiaries who may benefit from participation in a CCI program.[13] CMS will initially contact the beneficiaries to let them know of their eligibility. The program is completely voluntary; beneficiaries who refuse to participate will not be contacted by CCI organizations offering services or for other reasons. Beneficiaries also may terminate participation at any time. Programs will be available at no charge to the beneficiary.

The program is completely voluntary.

Care Management Plans

CCI programs are required to develop an individualized, goal-oriented, care management plan in consultation with each targeted beneficiary. The plan must include the following (to the extent appropriate):[14]

- *A designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers under the plan.*
- *Self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members.*
- *Education for physicians and other providers as well as collaboration to enhance communication of relevant clinical information.*
- *The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.*
- *The provision of information about hospice care, pain and palliative care, and end-of-life care.*

CCI Program Responsibilities and Performance Risk Requirements

In addition to providing and carrying out care management plans for program participants, CCI programs must "use decision-support tools such as evidence-based practice guidelines...[and] develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes."[15]

In an effort to provide contractors financial incentives to achieve clinical and financial goals, the CCI program's fees will be at risk, based on performance.[16] CCI programs will be paid on a per-member–per-month basis for all beneficiaries who confirm participation. These fees will be separate from and in addition to basic Part A and Part B payments. CCI programs will not be responsible for beneficiary medical costs. Their fees will be considered a Medicare administrative fee.

The RFP specifies that contractors will be required to save the program a minimum of 5 percent of health care costs, net of the program's fees. Contractors will be at risk for all of their fees if the total Medicare claims payments in their targeted population are not at least 5 percent less than what CMS estimates would have been spent on the population had the services not been provided, compared with the control group. The target population's total expenditures will include those who refused to participate or dropped out. The contractors may also have to refund some or all of their fees if they do not meet agreed-on standards for improvements in the quality of care and patient satisfaction levels among enrollees.

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Phased-In Implementation

The legislation calls for two distinct phases of implementation. Under Phase I, CMS and CCI programs will enter into agreements lasting for a three-year period. During this period, CMS is required to test and evaluate the CCI programs using randomized controlled trials. If independent evaluations find that a program has met certain conditions, including improving the clinical quality of care, improving beneficiary satisfaction, and achieving targets for savings, then that program or components of that program can be expanded to Phase II without further congressional authorization. Phase II cannot begin earlier than two years after the implementation of the initial program or later than six months after the completion of the program. Under Phase II, the secretary must expand the implementation of the program to other geographic areas, which may include expansion on a national basis.

KEY QUESTIONS

The CCI program offers an important opportunity to improve the care of chronically ill beneficiaries enrolled in FFS Medicare. Moreover, if the programs are rigorously tested, they can provide evidence about the cost-effectiveness of certain interventions.

As CMS prepares to launch this program, stakeholders have raised a number of key questions ranging from the practical to the rhetorical. Some have been answered by the RFP, such as which conditions will be targeted and how regions will be selected. Other questions, relating to how well these strategies work for the elderly, the role of physicians, and how CCI programs will be integrated with prescription drug benefits, will have to be tested in the field.

Which Conditions Will Be Targeted?

The legislation requires that one or more "threshold" conditions be present for beneficiaries to be eligible. Lawmakers decided not to limit eligibility to only those with multiple conditions. The legislation does require each program to have a process with which to screen each targeted beneficiary "for conditions other than threshold conditions, such as impaired cognitive ability and co-morbidities."[17]

The question of which conditions to target was carefully considered by CMS. The legislation suggests targeting diabetes, CHF, or COPD but does not mandate it. Mindful of the three-year evaluation period, CMS seems to have been persuaded by arguments that they should target conditions most likely to achieve short-term results. The RFP specifies that the initial programs should be designed for beneficiaries with CHF and/or diabetes with significant co-morbidities (that is, complex diabetes). In one or two regions, a program may address COPD.

CHF and diabetes are among the five most common chronic diseases in the Medicare population. In a *Health Affairs* article, Sandra Foote argues that "[o]ne of the most important design decisions for FFS Medicare demonstrations is to select target populations that seem likely to benefit from the types of interventions to be tested."[18] Beneficiaries with CHF, for example, represent only 14 percent of Medicare beneficiaries, but they account for 43 percent of Medicare expenditures (Table 1).[19] The potential for savings to the Medicare program is enormous. According to the Agency for Healthcare Research and Quality (AHRQ), nearly 800,000 Medicare beneficiaries with CHF had hospital admissions in 1999 that could have been avoided through better outpatient management of their conditions.[20]

In the RFP, CMS says it chose CHF and/or complex diabetes or COPD, "because they are major population subgroups within Medicare with significant health risks and disproportionately high health care costs that are not being consistently managed."[21] Moreover, CMS has explicitly decided to target those beneficiaries at greatest risk. To assess risk, CMS will focus on beneficiaries who have moderate to high Hierarchical Coexisting Condition (HCC) risk adjustment scores "in order to achieve our clinical and financial objectives within the 3-year program window."[22]

This emphasis on short-term return on investment (ROI) may have precluded CMS from selecting as thresholds those conditions with a longer projected ROI, such as arthritis or depression. CMS maintains that they chose to focus on two or three conditions to simplify the evaluation and to allow comparisons between the sites. Nonetheless, agency officials recognize that other conditions are amenable to chronic care improvement interventions. Moreover, CMS will expect CCI organizations to manage all of a beneficiary's conditions, according to officials.

CMS seems to have been persuaded that they should target conditions most likely to achieve short-term results.

Will Disease Management Work for Medicare Beneficiaries?

The structure of the program suggests a strong bias toward disease management (DM) models currently in operation today. DM programs have proliferated in the private sector since the early 1990s. Pharmaceutical companies created the early programs, which were aimed at increasing patients' compliance with drug regimens.[23] Today's programs typically target individuals with specific diseases (for example, asthma, diabetes, CHF) who are covered by commercial insurance, Medicaid, or Medicare Advantage. DM programs generally provide physicians with evidence-based practice guidelines and promote patient self-management through education. More recently, DM programs have reportedly evolved to manage multiple chronic conditions. Nearly half of all states have implemented or are in the process of implementing Medicaid disease management programs.[24] However, Medicaid beneficiaries who are concurrently eligible for Medicare (so-called "dual eligibles") are almost always excluded.[25]

Beneficiary advocates and some physician groups have raised concerns about whether or not these programs can be modified to effectively treat the Medicare population. Elderly and disabled people tend to have multiple chronic conditions. Nearly 80 percent of Medicare beneficiaries have at least one chronic condition, while more than 60 percent have two or

TABLE 1
Medicare Outlays for Beneficiaries with Diabetes or Congestive Heart Failure, among Noninstitutionalized, Non-HMO Members Only, 1999

	No. of Beneficiaries	Percent of Beneficiaries by Subgroup	FFS Medicare Outlays per Year (in billions)	Percent of FFS Medicare Outlays by Subgroup	Percent of Total FFS Medicare Outlays
Not Medicaid-Eligible					
Congestive Heart Failure	3,113,151	13%	$47.9	42%	34%
Diabetes	4,050,361	17	$34.3	30	24
All Non-Medicaid	23,732,291	100	$112.8	100	80
Medicaid-Eligible					
Congestive Heart Failure	749,265	19	$13.0	47	9
Diabetes	1,028,770	25	$10.8	39	8
All Non-Medicaid	4,040,034	100	$27.8	100	20
All FFS Medicare					
Congestive Heart Failure	3,862,416	14	$60.9		43
Diabetes	5,079,131	18	$45.1		32
All	27,772,326	100	$140.6		100

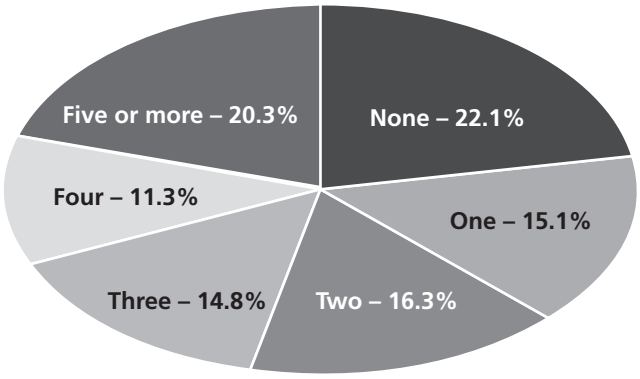
Source: Sandra M. Foote, "Population-Based Disease Management under Fee-For-Service Medicare, Health Affairs, *22, no. 4 (July/August 2003); based on Medicare Current Beneficiary Survey Cost and Use files, 1999.*
Notes: Expenditures shown are for all Medicare outlays, not limited to congestive heart failure (CHF) or diabetes treatment. Beneficiaries with any diagnosis of diabetes or CHF in a physician office visit were counted. Beneficiaries with CHF and diabetes appear in both categories. HMO = health maintenance organization. FFS = fee-for-service.

more. Of this group with two more conditions, almost one-third (20 percent of the total Medicare population) has five or more chronic conditions or co-morbidities (Figure 1).[26] Fewer clinical guidelines exist for treatment of beneficiaries with multiple chronic conditions, making the identification of the "evidence-based" care more difficult.

Patient self-management is a key component of most commercial DM programs.[27] Medicare beneficiaries are more likely to be poor, frail, and cognitively impaired than enrollees of commercial plans. Geriatricians have argued that self-management and patient education techniques simply do not work for persons with Alzheimer's disease or a related dementia.[28] On the other hand, at the press conference announcing the RFP, Rep. Nancy Johnson argued passionately that caregivers of individuals with dementia could find these CCI programs tremendously helpful.

Robert Berenson and Jane Horvath have cautioned that the DM approach "is likely to be of limited benefit to a significant portion of beneficiaries who have complex chronic care needs."[29] These patients often are treated by multiple physicians and have complicated drug regimens. Care coordination or intensive case management may be more appropriate. Care coordination services can include multidisciplinary care conferences and coordination of clinical care across multiple providers.[30] Case management typically focuses on the individual health care needs of high-risk patients with multiple or complex medical conditions, who may be at increased risk for hospitalizations.[31]

FIGURE 1
Percentage of Medicare Beneficiaries with Varying Numbers of Chronic Conditions, 1999



Source: Gerard Anderson, Johns Hopkins University, testimony before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, April 16, 2003.

Noting these concerns, the RFP does require applicants to "describe strategies for supporting participants with more intensive needs,"[32] as a consideration in the selection process. Nothing prevents CCI programs from including care coordination and intensive case management in their array of services. Moreover, CMS notes that DM programs have not been rigorously tested with large populations of people aged 65 or older or with severely disabling conditions in a fee-for-service context. The pilot program provides an opportunity to do so.

What Types of Organizations Can Implement CCI Programs?

The legislation specifies that CCI programs may be implemented through a "disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program."[33] The RFP repeats this list of

eligible organizations. CMS officials insist they will wait to see what the market brings, rather than define the organizations in advance. The RFP purposefully does not require applicants to be accredited as DM organizations "in the interest of encouraging proposals from a broad array of organizational models."[34]

Nonetheless, the scope and size of the program suggest that organizations that operate in large markets with population-based models are most likely to be chosen. Large health plans and DM organizations that already provide some chronic care services seem best positioned to meet the program criteria. The contracted CCI programs will need a health data analysis infrastructure (including clinical information, financial systems, performance monitoring) as well as program experience (staff, clinical protocols, relationships with local providers and community organizations). They will also have to have the ability to track and monitor each participating beneficiary across clinical settings (such as home, physician's office, hospital). Operational capacity, record of achievement in the provision of related services, and ability to absorb the financial risk involved will also be considered in the process of soliciting and evaluating bidding organizations.

The RFP instructs applicants to base their proposals on 20,000 beneficiaries in the intervention group.[35] Some health plans and smaller organizations have expressed frustration that this requirement may thwart efforts to bring these practices to rural areas because the geographic areas would need to be quite large (for example, reaching across multiple states). Smaller organizations have raised concerns that such large geographic areas would require them to manage a population that may be too large for them to handle adequately. CMS has been encouraging smaller organizations to form or join consortia to achieve CMS's dual objectives of partnering with a wide variety of organizations and testing scalability.

Some physician group practices have also expressed concern that they may not be able to compete for these contracts. Unlike a prepaid group practice model, the CCI approach allows participants to have complete freedom of choice of physicians. Because the program is testing models that can improve the quality of care and achieve savings with the FFS context, CMS will not allow organizations to steer patients to certain physicians. This freedom makes some physicians reluctant to be held accountable for the outcomes of a predetermined group. Yet, in some areas, most notably California, medical groups and independent practice associations take responsibility for care management of their patient populations. A recent study by Robin Gillies and colleagues found that California physician organizations are much more likely than their non-California counterparts to implement or use care management processes (such as disease registries, care management, and feedback to physicians).[36] Nevertheless, these physician groups seem unlikely to be awarded (or even apply for) a contract, given the size and population requirements of the program.

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How Will the Regions Be Selected?

Related to the types of entities that will be permitted to participate is the consideration of which geographic regions will be selected. The RFP provides specific guidance on this issue.

CMS has determined that there will be approximately 10 pilot projects in different regions around the country. Only one contractor will be selected for any given geographic area. The RFP does not specify exact regions, but it does make clear that size matters and that applications may be rejected if the covered population is not big enough. Several factors will be given preference in considering certain geographic areas (see Appendix):

- Higher-than-average prevalence of CHF and/or diabetes or COPD among FFS Medicare beneficiaries.
- Poor Medicare quality rankings in comparison to national averages.
- Areas that do not conflict with a currently operating FFS chronic care demonstration.

CMS's focus on prevalence and quality suggests a strategy to go where it can get the most "bang for the buck." This is consistent with a desire to achieve results within three years. Providers located in high-quality markets frequently complain that they cannot take advantage of these innovative approaches and new Medicare dollars. On the other hand, given limited resources, it might make more sense to go where the need is greatest.

In order to avoid cross-contamination of control groups, CMS decided not to run a CCI program in the same geographic area where Medicare FFS chronic care demonstrations are currently operating (see Appendix). This determination excludes significant portions of the country from participating in the pilot project. In effect, it penalizes those areas that applied for earlier demonstration projects, even if those efforts were on a much smaller scale. However, CMS does encourage applicants who are interested in proposing an area where a demonstration exists to contact CMS for details on how such a proposal might be structured.[37]

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How Important Is the Physician's Role?

"Improving the quality of care ultimately requires changes in the behavior of individual physicians," according to a recent article by Arnold Epstein, MD. and colleagues.[38] Yet within the chronic care improvement pilot project, the role of physicians is unclear. As Epstein asserts, many quality experts believe strongly that the physician must play a central role in order for care management strategies to be effective. Others argue that strategies focused directly on patients taking responsibility for their own care can be quite effective, with or without physician participation. The answer probably lies somewhere in between.

Most current DM programs focus on the patients. Phone calls from and access to trained staff (such as registered nurses), educational materials,

and individualized care management plans give patients the tools to take better care of themselves.[39] Some commercial programs have little direct involvement with physicians, other than providing patients' health status reports or reminders for follow-up care. Unless a substantial number of a physician's patients are enrolled in a particular program, it can be difficult to get physicians to respond to requests for information, according to DM representatives. Many DM organizations have begun to promote "decision support" services to providers, such as patient registries and physician performance assessments, to gain more physician collaboration.

Physicians, for their part, have reportedly had a mixed reaction to care management tools. As characterized by cardiologist Janet Wright, MD, DM organizations can be viewed as "interveners," helpful to their practice, or as "interferers," impinging on their professional autonomy.[40] Some physicians view dollars paid to a DM company as money that should have been paid directly to physicians. Robert Kolock, MD, recently wrote "some doctors are annoyed when they are inundated by what they perceive as useless or erroneous information."[41] On the other hand, a recent study by the Center for Studying Health System Change found that physicians generally believe care management tools, such as practice guidelines, patient satisfaction surveys, and practice profiling offered by some DM organizations, have a positive effect on the quality and efficiency of care they provide.[42]

Proponents of greater physician involvement in this pilot project have suggested that CCI programs could pay physicians through a subcapitated arrangement. Individual doctors could therefore be rewarded for collaborating with the care management plan (for example, reading and responding to CCI reports). Whereas payment might be one strategy, researchers note that it is difficult to identify the main financial drivers that promote physician involvement.

In the RFP, CMS expresses a particular interest in programs that have a "track record of success in engaging beneficiaries' physicians and other providers for information sharing."[43] Applicants are required to demonstrate "adequate mechanisms for ensuring physician integration with the program."[44]

Nevertheless, many experts agree that if the delivery system is truly to move from its traditional acute-care emphasis toward one focused on chronic care, physicians must be rewarded for doing so. This program may not be the vehicle for that kind of systemic change. Its focus seems to be on patients and self-management as change agents, rather than physicians. Proponents of this approach seem content just to make a difference where they can.

Many experts agree that if the delivery system is truly to move from its traditional acute-care emphasis toward one focused on chronic care, physicians must be rewarded for doing so.

How Will CCI Programs Be Integrated with Prescription Drug Plans?

The primary objective of the new Medicare law was to provide a prescription drug benefit to Medicare beneficiaries. The new prescription drug plans (PDPs)—intended to deliver the Medicare drug benefit to FFS beneficiaries—are required to have in place "medication therapy management programs" to improve medication use and reduce the risk of adverse events. The law specifically targets individuals with "multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and [CHF])" as primary beneficiaries.

Historically, DM programs have also sought to reduce adverse reactions and improve compliance with drug regimens. Pharmaceutical benefit management (PBM) firms have also played this role, but their emphasis has been on reducing *drug* costs. DM programs, on the other hand, have sometimes been identified with increasing drug costs when enrollees are encouraged to take specific medications as prescribed or when drugs are substituted for more costly interventions in the later stages of a disease. How these two approaches interact (or clash) in the marketplace may be a critical determinant of the CCI program's success. For example, diabetes drugs are reportedly in the top five cost drivers for a PDP. The legislation requires the DHHS secretary to establish guidelines for the coordination of any medication therapy management plan with a CCI program. Aligning these contradictory objectives may be easier said than done.

Moreover, the Medicare drug discount card (in June 2004) and Part D pharmacy benefit (in January 2006) will be implemented during the course of the three-year CCI study period. If participants in the program and the control group enroll equally in these programs, then comparisons of the two groups should be valid. However, if one group enrolls more than the other, cost accounting will be complicated. The RFP specifies that Medicare drug expenditures will be included in the calculation of total Medicare expenditures, beginning in 2006 when beneficiaries will be given the opportunity to purchase Medicare prescription drug benefits.

How Much Will Information Technology Be Encouraged or Rewarded?

Throughout the Medicare legislation, there are incentives for investments in information technology (IT). For example, the legislation establishes an electronic prescribing program to be used by all physicians. It also extends a program that rewards physicians' offices with a monetary bonus if they have certain IT systems (such as electronic medical records) in place.

Many quality experts have suggested that information technology can improve care for patients with chronic conditions. Indeed, the IOM's landmark quality report stated "[IT] must play a central role in the redesign of

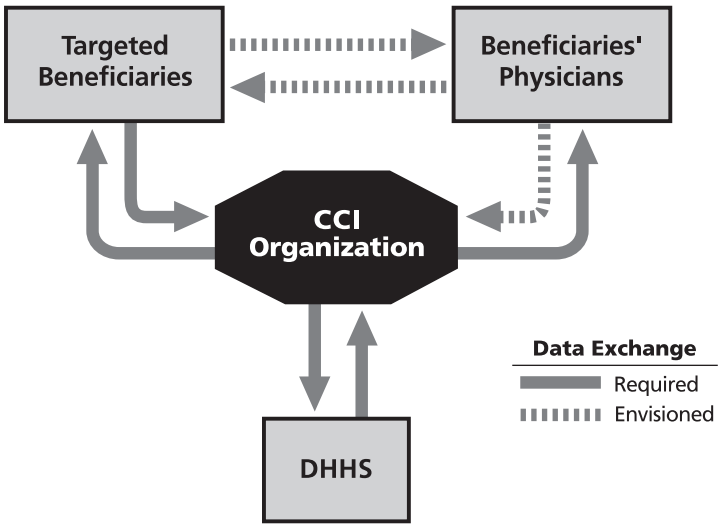
DM programs have sometimes been identified with increasing drug costs when enrollees are encouraged to take specific medications as prescribed.

the health care system if a substantial improvement in quality is to be achieved over the coming decade."[45]

Some analysts have suggested that IT systems may ultimately replace DM organizations by providing many of the same services (such as reminders about preventive visits or medications prescribed and/or drug interaction information) directly to patients and physicians.[46] A study by Lawrence Casalino and colleagues found that clinical IT is significantly associated with the use of care management processes (such as clinical practice guidelines, physician feedback, and patient self-management training) by physician organizations.[47]

The extent to which the use of information technology will be encouraged or rewarded under the new CCI program is not clear. The legislation simply requires CCI programs to "develop a clinical information database to track and monitor each participant across settings."[48] The RFP recognizes the potential of integrative information infrastructures and new applications of information and communication technologies. CMS solicits applications from organizations that have proven to be successful in applying these tools to meet the needs of participants and their providers. Thus, while sophisticated IT systems are not required, the pilot program presents an important opportunity to test their effectiveness in improving chronic care on a large scale. It might also encourage increased connectivity among regional providers and CCI programs (Figure 2).

FIGURE 2
Data Flow Envisioned by the New Chronic Care Improvement Program Under the MMA of 2003



Based on a presentation by Sandra Foote, Director, Health Insurance Reform Project, at the American Enterprise Institute on March 22, 2004.

How Will CMS Measure Success?

The legislation requires that each CCI program be evaluated on the basis of cost, quality, and patient satisfaction. However, some have expressed concern that the legislation appears to have a definite formula for paying for cost-savings results but not for quality. How much will cost concerns outweigh quality in the evaluation of these programs?

Measuring cost effectiveness may prove difficult enough. Whereas some commercial programs have demonstrated improved clinical performance or patient outcomes, clear evidence of a consistent cost savings is lacking. When cost effectiveness is shown, it is often difficult to determine which interventions caused the effect.[49] The Congressional Budget Office was skeptical enough about potential cost savings in the new CCI program that it estimated its cost at $500 million over 10 years. Though the program itself is mandated to be budget neutral, Congress did provide start-up funding not to exceed $100 million (net of savings) over three years to get the systems and the contracts up and running. Because savings will be measured against expenditures in a randomized control group, the program does give a real opportunity to test cost effectiveness.

Measurement of quality may prove even more problematic than costs. The actual methodology is not defined in the legislation. CMS has identified a core set of clinical quality indicators, but the RFP specifies that "detailed definitions of the indicators, measures, and calculation methods" will be agreed on between CMS and the individual contractors. As problematic as it may be to achieve consensus on the metrics, the requisite data sources and manner in which they are collected may be even more contentious. Assuring the comparability of the intervention and control group can be extremely difficult. Some quality measurement experts have suggested that CMS should have a strong preference for measures that can be evaluated through existing administrative data wherever possible, rather than requiring additional collection by CCI programs. On the other hand, neither beneficiary satisfaction nor clinical outcomes are available from Medicare claims data.

Questions have been raised about whether all of the programs will be held accountable to the same standard or allowed to differ. With the exception of a core set, standards appear to be allowed to vary across CCI programs. As stated earlier, different interventions may make it more difficult to prove effectiveness. Too much emphasis on the study design, however, could stifle innovation and thwart the multidisciplinary content of many of the successful programs.

For its part, CMS has indicated that the measurement standards will be routine, transparent, and explicit. At the same time, however, CMS officials have suggested that they would like "real time" ongoing evaluations to allow them to make adjustments to increase chances of success.

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CONCLUSION

The new CCI pilot program clearly signals congressional intent to expand Medicare's role in improving chronic care. Though many questions will need to be answered, the new program offers one of the first opportunities for quality management within the FFS environment. The extent to which this program might be leveraged to achieve more fundamental change is not yet apparent. Nonetheless, it will provide an important test of the notion that improved chronic care management will yield cost savings and improve quality and patient satisfaction for Medicare beneficiaries.

This paper draws on insights gained from discussions with many national experts on chronic care improvement in fee-for-service Medicare, including, in particular, those who participated in a meeting sponsored by the Health Insurance Reform Project (HIRP) on January 26–27, 2004.

ENDNOTES

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2. MMA, Title I, Sec. 101, Subpart 1, Sec. 1860D-4(c)(2).

3. MMA, Title VII, Subtitle D, Section 649.

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20. Foote, W3-351.

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22. CMS-5004-N, 22068.

23. Foote, W3-344.

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25. Horvath and Berenson, 2.

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27. Lisa Sprague, "Disease Management to Population-Based Health: Steps in the Right Direction?" Issue Brief No. 791, National Health Policy Forum, May 16, 2003, 2–3.

28. George A. Taler, MD, on behalf of the American Geriatrics Society, statement before the House Ways and Means Committee, Subcommittee on Health, U.S. House of Representatives, Washington, DC, February 25, 2003.

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49. For a thorough description of the evaluation of DM programs, see Sprague, 7–8.

APPENDIX

Factors Considered in Selecting Regions for Chronic Care Improvement Program

STATE	FFS BENEFICIARIES	DIABETES (%)	CHF (%)	COPD (%)	QUALITY RANK	CONFLICTING DEMOS
AL	661,747	20	14	15	42	———
AK	45,728	9	6	6	33	———
AZ	474,227	12	9	10	29	AZ
AR	436,271	15	13	12	48	Northwestern AR
CA	2,557,305	7	5	5	44	CA
CO	339,159	12	11	12	7	CO
CT	454,662	18	12	12	9	South-central CT
DE	114,806	22	14	12	14	———
DC	73,382	11	7	4	37	DC
FL	2,240,227	18	12	15	41	Northern FL
GA	927,667	20	13	13	47	———
HI	116,160	2	2	1	16	———
ID	158,301	13	10	9	22	———
IL	1,535,043	17	13	11	46	Rural / Eastern IL
IN	854,548	19	14	14	27	Central / Western IN
IA	474,090	16	11	11	6	Northeastern IA, Northwestern IA
KS	371,539	15	12	11	30	———
KY	622,181	19	13	16	40	———
LA	543,327	20	15	12	51	Corridor I-49
ME	225,477	16	11	14	3	ME
MD	651,698	18	12	11	25	Montomery Co., DC Suburbs, Baltimore
MA	768,883	17	12	12	15	———
MI	1,376,774	22	14	14	26	MI
MN	596,098	14	10	8	10	Eastern rural MN, South-central MN
MS	430,625	19	13	11	50	———
MO	764,550	17	14	13	28	Southwestern MO, St. Louis
MT	142,428	11	10	11	13	Southeastern MT
NE	251,062	15	12	10	12	———

(continued)

APPENDIX – Chronic Care Improvement Program *(continued)*

STATE	FFS BENEFICIARIES	DIABETES (%)	CHF (%)	COPD (%)	QUALITY RANK	CONFLICTING DEMOS
NV	176,387	12	9	11	35	———
NH	176,330	16	11	12	1	Southwestern NH
NJ	1,089,135	21	16	13	43	———
NM	221,363	14	9	11	36	NM
NY	2,327,080	21	16	12	24	New York City
NC	1,141,084	20	12	12	23	Northwestern NC
ND	104,775	14	10	9	4	———
OH	1,497,640	20	15	14	38	———
OK	473,529	16	14	13	45	———
OR	336,477	10	7	7	11	———
PA	1,623,162	20	14	13	31	Eastern PA, Central Northeastern PA
RI	117,890	19	13	13	17	———
SC	597,582	22	13	12	32	———
SD	122,324	13	11	10	20	SD
TN	829,852	19	13	14	39	Northeastern TN
TX	2,112,410	19	14	12	49	Houston, Urban / Southern TX
UT	210,115	15	11	6	5	———
VT	92,798	15	10	11	2	Eastern VT
VA	914,745	19	12	11	18	Southwestern VA, Richmond
WA	616,018	13	10	9	19	West-central WA
WV	324,294	22	14	17	34	———
WI	769,142	16	11	9	8	North-central WI
WY	67,139	13	11	13	21	Northern WY
US Total	**34,717,973**	**17**	**12**	**12**	———	———

Source: Federal Register, *69, no. 79 (April 23, 2004): 20068–20069.*