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The Quality Oncology Medicare Coordinated Care Demonstration Program After One Year

Final Report

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EXECUTIVE SUMMARY

The Medicare Coordinated Care Demonstration (MCCD), mandated by the Balanced Budget Act of 1997, is testing a range of models aimed at improving the care of chronically ill beneficiaries with Medicare fee-for-service (FFS) coverage. Fifteen programs are participating in the demonstration sponsored by the Centers for Medicare & Medicaid Services (CMS). Mathematica Policy Research, Inc. (MPR) is evaluating the demonstration using both implementation and impact analyses based on a randomized design. This report is one of a series that will describe each program during its first year and will provide estimates of its impact on Medicare service use and costs during the first six months of program operation.

Research during the past decade suggests that successful care coordination usually has several features. These include effective patient identification, highly qualified staff, physician buy-in, and financial incentives aligned with program goals. Successful programs also offer a well-designed, structured intervention that includes:

- A multifaceted assessment whose end product is a ***written care plan*** that can be used to monitor patient progress and that is updated as the patient's condition changes
- A process for providing ***feedback to care coordinators, program leaders, and physicians*** about patient outcomes
- ***Patient education*** that combines the provision of factual information with techniques to help patients change self-care behavior
- Procedures for ***integrating fragmented care***, facilitating ***communication*** among providers, and, when necessary, arranging for ***community services***

The purpose of this report series is to assess the extent to which demonstration programs have these features, as well as to describe early enrollees in the program and their Medicare service use and costs during the first few months after enrollment. Information for the report comes from telephone and in-person contacts with program staff, as well as from analysis of Medicare and program-generated data. The next report series will focus on Medicare service use and costs over a longer time and will include all first-year enrollees.

This report describes Quality Oncology's MCCD project. First, we present an overview of Quality Oncology's MCCD. We then address the following four questions: (1) Who enrolls in the program? (2) To what extent does the program engage physicians? (3) How well is the program implementing its approaches to improving patient health and reducing health care costs? and (4) What were enrollees' Medicare service use and costs during its first months of operation? Finally, we discuss the program's strengths and unique features, as well as potential barriers to program success.

Program Organization and Approaches. Quality Oncology is a cancer disease management company founded in 1993 by a group of South Florida oncologists. Its

headquarters are now in McLean, Virginia, but its MCCD is based at its telephone call center in Sunrise, Florida. The MCCD extends Quality Oncology's ongoing cancer disease management program for members' managed care plans to Medicare beneficiaries in the FFS program. The MCCD project consists of essentially the same services, protocols, and corporate infrastructure that Quality Oncology provides for its usual client health plans. For the most part, the Quality Oncology staff treat MCCD enrollees just like members of another client plan, with its own set of benefits and coverage criteria. Quality Oncology's clients have included two large Florida Medicare managed care plans, for which it served 1,900 beneficiaries with cancer. The company has some data suggesting that it achieved savings for both plans (12 and 6 percent respectively, compared to what costs would have been without its program). Quality Oncology has developed detailed, evidence-based, site- and stage-specific clinical practice guidelines for 42 malignancies. Quality Oncology believes these guidelines have allowed its managed care programs to reduce use of cancer therapies for which there is little evidence of effectiveness and of expensive diagnostic imaging services that have little value. Quality Oncology also encourages oncologists to make less use of expensive, inappropriate hospital facilities for the administration of outpatient chemotherapy and to give more chemotherapy in their own offices.

Several Quality Oncology staff work on the MCCD. Their roles in the MCCD are project director, outreach and enrollment coordinator, medical director, care manager supervisor, quality assurance manager, and care coordinators (called "care managers" by the program). Only the outreach and enrollment coordinator was hired specifically to work full-time on the MCCD. The other staff members have responsibilities across all of Quality Oncology's clients, including the MCCD. All the MCCD staff are in the company's offices in Sunrise, Florida.

Quality Oncology's MCCD has had great difficulty recruiting patients. To try different approaches to increase enrollment, it has hired a succession of outreach and enrollment coordinators with diverse backgrounds and skills. The current enrollment coordinator is the third since the project started in September 2002. The first coordinator was an oncology nurse with a background in clinical trials. The second was a nonclinician with a background in health care administration. The current coordinator has a background in marketing in the hospice industry and had just started in the position in early 2004.

Quality Oncology's care managers are organized into teams supervised by team leaders. Each team serves one client health plan. Quality Oncology originally planned for the MCCD to have its own dedicated team led by an MCCD team leader. At full enrollment, the MCCD team would have 10 care managers, with caseloads of roughly 100 patients each. After a year of operation, however, there were not enough MCCD patients for even one care manager's caseload, and so no separate MCCD team had yet been formed or MCCD team leader designated. All the care managers working with the few MCCD patients were on staff before the demonstration began and so have remained on their usual teams, spending most of their time with patients of their team's health plan.

Quality Oncology's main approaches in the MCCD to improving patient health and reducing health care costs are (1) teaching patients about self-care, and (2) enhancing communication between patients and physicians. Patients who know how to deal with cancer treatment and disease side effects, such as dehydration or pain, can forestall worsening in their condition that might make emergency hospitalization necessary. Quality Oncology believes that patients

themselves are often the best agents for enhancing communication. Patients who understand their treatment options, participate in diagnostic and treatment decisions, call their doctors about their symptoms, and ask questions about their care will naturally improve communication. Improved communication in turn means that providers are notified earlier of patients' impending problems, physicians avoid duplicating tests already ordered by other physicians, and patients choose treatments that are evidence based and match their own desires for aggressiveness of care.

Patient Identification. Quality Oncology's MCCD recruits Medicare beneficiaries from Broward, Dade, and Palm Beach counties in South Florida. All the oncology practices and cancer centers from which the program recruits are within 20 miles of the company's office in central Broward County. To be eligible for the Quality Oncology MCCD, patients must have biopsy-proven cancer and must be receiving or about to begin active treatment for the cancer in the target counties (active treatment includes surgery, chemotherapy, radiation therapy, and biologic therapy). Because of "snowbird" patients who live outside of the service area for a significant portion of the year, the program requires only treatment within the service area, not residence in it (the program is a purely telephonic intervention). The program feels it provides the greatest benefits to patients who have not yet started treatment and would ideally enroll patients as soon as possible after their initial diagnosis of cancer.

Quality Oncology optimistically assumed that the approximately 80 Broward County oncologists with whom it had worked over the years through managed care plans would want to refer their Medicare FFS patients with cancer to the MCCD. As one Quality Oncology staff member put it, physicians *should* welcome a program that relieves them of the chore of repeatedly explaining to patients why their hair is falling out (often a 20-minute conversation). Under the first outreach and enrollment coordinator, the program sent introductory letters to local oncologists describing the MCCD and asking them to notify Quality Oncology of all FFS Medicare beneficiaries newly referred to their care. Contrary to the company's expectations, however, within the first year, only nine oncologists have expressed interest in the MCCD or agreed to allow the program to approach their patients about the program.

Under the second outreach and enrollment coordinator, the program approached local hospitals and cancer centers and expanded to neighboring Dade County in the south. Neither institutional providers nor physicians showed much interest, however. Because the demonstration involved random assignment, the institutions also insisted that Quality Oncology go through the lengthy, time-consuming process of obtaining institutional review board approval.

Shortly after the current outreach and enrollment coordinator arrived, the program expanded its service area to Palm Beach County in the north. The enrollment coordinator also planned to contact seniors' clubs and additional oncology centers and to enlist influential South Florida university- and community-based oncologists who serve on the company's utilization management committee as spokespersons for the demonstration. The program purchased newspaper advertisements in January 2004, but these generated inquiries mostly from beneficiaries ineligible for the MCCD, so the program discontinued them in April 2004. The current enrollment coordinator has shifted to identifying patients during their oncology appointments and meeting them face-to-face. She regularly visits the practices of the participating oncologists, and the practice office managers provide her with lists of potentially

eligible patients with appointments that week. She reviews each patient's record for Medicare and program eligibility and makes a point of being present for each eligible patient's visit. At the conclusion of an eligible patient's visit, the oncologist asks if the patient is willing to speak with the enrollment coordinator. The enrollment coordinator speaks with willing patients in the waiting room, or sometimes even in the infusion room while they are receiving chemotherapy, to explain the program and solicit participation. She was meeting with five to seven patients per recruiting visit to an office. This face-to-face strategy has led to a much higher acceptance rate than previously, but it is time-consuming and labor intensive. The program has identified approximately 75 percent of its enrollees through in-person physician office meetings. Most of the rest have been direct referrals from physicians, physician office staff, or cancer center staff. Only a few were patient self-referrals.

Assessment, Care Planning, and Monitoring. Following random assignment to the treatment group, the care manager is supposed to telephone a new enrollee within one day of enrollment to explain the program in more detail and perform the initial assessment. This assessment covers physical and clinical information, ability to perform self-care activities, psychosocial issues, information on all medications (including those for comorbid conditions), adherence to cancer treatment and other medications, understanding of their diagnosis and treatment, learning readiness, self-management skills, home safety, health care use and access, preventive care, lifestyle information (such as on smoking), and nutrition. Quality Oncology's proprietary, stand-alone electronic health records and care management system—the Integrated Care Management (ICM) system—guides the care manager through the assessment process. The assessment tool, which is embedded in ICM, features branching logic and prompts care managers to ask patients specific questions. Assessments usually take about an hour, and the care manager sometimes contacts patients' family members for information the patient is unsure of or may be hiding (such as not eating). The care manager enters or directly scans into ICM additional clinical information from the copied medical records obtained from the patient's physician. This information includes physical examination results, medical history, pathology reports, stage of cancer, and any other diagnostic imaging or laboratory reports. After the initial contact, the care manager supervisor may assign the patient to another care manager, depending on the primary MCCD care manager's total (MCCD and non-MCCD) caseload and the acuity level of the new enrollee.

After the initial assessment has been completed, ICM helps the care manager develop a care plan. This plan includes a problem list, short- and long-term goals, and planned interventions (including teaching points, community resources, and educational materials). Part of the care plan is standardized and is based on Quality Oncology's treatment guidelines for the patient's stage and type of cancer. Once the patient's cancer type and stage are entered, the system will bring up the recommended chemotherapy, surgery, or radiation therapy, and even the types of cancer specialists the patient should see. The nurse care manager will then enter goals and interventions from "drop-down" lists or as free-form notes. The other portion of the care plan is individualized, developed from the care manager's judgment. Nurse care managers can enter individualized goals and interventions as free-form notes (for example, maintenance of nutrition and referral to meals-on-wheels for a patient unable to cook for herself; ability to describe two methods of dealing with fatigue). Physicians do not receive copies of the care plans.

Care managers monitor patients through regular telephone contacts, with contact frequencies determined by acuity level. The highest level includes, for example, patients who just started chemotherapy or radiation therapy or patients who are having acute symptoms or treatment side effects. These patients are contacted weekly. The lowest-acuity patients, in Level 4, are hospice patients; they are contacted every 45 days. Care managers routinely reassess patients' acuity and readjust monitoring frequency accordingly. Contacts are also supposed to occur around significant clinical milestones, such as after a procedure or at the initiation or completion of a course of treatment. For example, the nurse care manager will call a patient before scheduled outpatient chemotherapy, to "prep" him or her with advice on potential side effects, then will call daily for the first few days after the chemotherapy is completed to check how the patient tolerated it. ICM generates daily tickler lists of contacts and tasks that need to be completed for all the care manager's patients.

During routine monitoring, the care manager assesses the patient's symptoms and health-related quality of life, addresses any side effects or acute problems immediately, updates medication and treatment information, and repeats other assessments based on her judgment. She routinely checks for adverse interactions between patients' cancer-related medications and their other medications and medical conditions. Following each contact, ICM automatically calculates the next contact date for the patient and makes sure there are next-step actions planned, when appropriate—it will not let the care manager exit the patient's record otherwise. The system also helps care managers update the care plan on an ongoing basis, with intervention drop-down lists that change automatically to reflect progress in treatment or achievement of goals.

Finally, care managers provide patients and their families with crucial emotional support and encouragement throughout all phases of treatment, often developing a strong rapport with patients. Quality Oncology staff related stories of how grateful some patients had been for the program's support. In the first six months of operation, more than half of the 12 treatment group enrollees (58 percent) had at least one contact during which the nurse care manager provided emotional support.

Staffing and Management of Program Quality. Quality Oncology care managers must be registered nurses with Florida licenses, and they must have at least five years of nursing experience in oncology, utilization review, case management, home care, or hospice. Certification in oncology or case management is desirable. The company looks for nurses with excellent skills in clinical assessment, communication, and teaching, as well as basic computer skills. A credentialing committee reviews the adequacy and currency of the credentials and licensure of all Quality Oncology clinical staff upon hire and regularly thereafter.

Newly hired care managers undergo a two-week introductory program that includes formal classes, observation of care managers' day-to-day activities, and hands-on experience with ICM. Although they do not receive formal training in patient education, the care managers working on the MCCD have all had patient education experience from several years of working in oncology, and some have additional counseling skills from hospice experience. Care managers also cited the company's full-time educator as a good source of information on counseling and education. The first six months after the initial training are a probationary period for new care managers. Under close supervision by their team leader, they slowly build up to a full caseload of 90 to 100

patients of all acuity levels. They must also complete an oncology self-study course for nurses. The care managers receive continuing education through weekly company-wide teleconferences consisting of a talk, presentations, and discussion of illustrative patient cases, as well as peer networking and exchanging of tips. Cases for presentation are selected successively from each of Quality Oncology's client health plans, including the MCCD. The company also offers other formal and informal continuing education classes and inservices.

Care managers' performance is closely monitored and evaluated in several ways. First, every month, each care manager must complete, and submit to her team leader, structured self-audit forms on ICM records for two of her patients whom her leader has selected for her. These self-audits help care managers and their supervisors assess the completeness and quality of their documentation. Second, every two weeks, team leaders review detailed reports on each of their care managers, produced from the electronic data in ICM. Team leaders can see whether their care managers are making contacts at appropriate frequencies and completing care management tasks within recommended time frames. These data are also fed back to the care managers. Third, every morning the team leaders review the daily tickler lists of each of their care managers. Leaders can gauge from the number of tasks on a care manager's list whether she is keeping up with her workload, and they help those who are falling behind to catch up. Finally, team leaders conduct yearly formal evaluations of their care managers.

At the MCCD program level, the care manager supervisor and the medical director have been regularly monitoring aggregrate electronic reports for rates and types of treatment complications among the MCCD patients. (If the MCCD ever reaches an enrollment comparable to that of Quality Oncology's other health plan clients, it will also be included in other ongoing company-wide quality improvement efforts.) There have been no formal complaints about the MCCD, but Quality Oncology has the same procedures in place for responding to complaints from patients and physicians as it does for its managed care clients. Complaint numbers and time trends will be tracked. Quality Oncology explored obtaining disease management accreditation by one of the national accreditation bodies. It concluded that disease management accreditation programs do not fit cancer disease management well because of their emphasis on routine preventive care, so it did not pursue accreditation. It may seek accreditation for *case* management in the future, however.

WHO ENROLLS IN THE PROGRAM?

The program has encountered several barriers to enrollment. Despite a substantially lower than projected enrollment, however, the program has enrolled patients with high rates of hospitalization and health care expenditures. Staff report that patients are satisfied with the program, and program data show no voluntary disenrollment during its first six months.

Nine physicians in two Broward County oncology practices have allowed the program to recruit their patients. Quality Oncology also overestimated patients' willingness to participate; even patients referred by their oncologists were reluctant to enroll.

Enrollment After One Year. After one year of operation, Quality Oncology had enrolled 32 patients in the demonstration treatment group and 31 in the control group (MPR weekly

enrollment report, week ending September 21, 2003). This does not begin to approach the program's original target of 2,132 beneficiaries in the first year.

The Quality Oncology staff described three main reasons why physicians and patients have been reluctant to participate in the MCCD. First, both physicians and patients have disliked the idea of random assignment—that needy, frightened cancer patients could be randomized to the control group and thus not receive beneficial services. Second, despite Quality Oncology's assurances to the contrary, physicians feared the program would add an intrusive burden to their practices. Since their participation was voluntary, physicians saw little incentive to cooperate, and the one-time $40 payment per patient that Quality Oncology offered for physicians' participation was not enough to overcome their skepticism. Third, physicians were worried that sharing clinical data with Quality Oncology would violate Health Insurance Portability and Accountability Act (HIPAA) regulations. Several months after the program started, CMS provided the program with a letter from Thomas Scully, the CMS administrator at that time, to allay physicians' fears about HIPAA. This letter helped somewhat, but many providers were still anxious about privacy issues and reluctant to participate. A possible fourth factor was its previous contract with one of the local managed care plans to manage its drug replacement program. This program restricted oncologists to obtaining chemotherapy drugs from a single supplier and controlled the quantities of chemotherapy drugs oncologists could keep on hand. Quality Oncology processed oncologists' chemotherapy prescriptions and tracked their inventory. Managed care drug replacement programs are highly unpopular with oncologists, and a few local physicians may have retained a negative impression of Quality Oncology because of this contract. Although Quality Oncology staff did not feel this was a major factor, it may have contributed to the enrollment difficulties.

To estimate the size of the eligible population and the percent that chose to participate, the evaluation simulated the program's eligibility criteria using Medicare enrollment and claims data. This simulation showed that, during the program's first six months of operation—September 2002 through March 2003—slightly less than one percent of the 1,855 eligible beneficiaries enrolled. There were a number of demographic differences between program participants and eligible nonparticipants (Table 1). First, although age 65 years or older was a program eligibility criterion, the program did enroll two people younger than 65. (The evaluation did not include eligible nonparticipants younger than age 65.) The proportion of participants age 85 or older (8 percent) is also half that of the nonparticipants (15 percent). Participants were twice as likely as eligible nonparticipants to be dually eligible for Medicaid. Because the number of participants is so small, none of these differences were statistically significant.

Participants had substantially higher hospitalization rates and total Medicare spending than eligible nonparticipants. In the year before enrollment, about 71 percent of participants had a hospitalization and had monthly Medicare reimbursements of $3,271, compared to a 53 percent hospitalization rate and $2,463 in monthly Medicare reimbursements for eligible nonparticipants. Participants were also three times as likely as nonparticipants to have had a hospitalization in the month before intake (29.2 versus 9.7 percent). (November 15, 2002, the midpoint of the six-month enrollment period for this analysis, was used as a pseudo-enrollment date for nonparticipants.) When developing the cost estimate for the Quality Oncology waiver application, MPR estimated that Medicare reimbursements would average $3,645 per month for

TABLE 1

CHARACTERISTICS OF MCCD PARTICIPANTS AND ELIGIBLE NONPARTICIPANTS DURING FIRST SIX MONTHS OF PROGRAM INTAKE
(Percent, Except as Noted)

	Participants[a]	Eligible Nonparticipants
Age at Intake		
Younger than 65	8.3	0.0[b]
65 to 74	37.5	37.2
75 to 84	45.8	47.8
85 or older	8.3	15.0
Male	33.3	32.0
Nonwhite	8.3	6.5
State Buy-In for Medicare Part A or B	12.5	6.4
Medical Conditions Treated in Past Two Years		
Cancer[c]	100.0	92.2
Coronary artery disease	50.0	49.4
Chronic obstructive pulmonary disease	41.7	39.7
Stroke	37.5	22.7
Diabetes	25.0	23.7
Congestive heart failure	16.7	19.2
Hospital Admission in Past Year	70.8	52.5
Hospital Admission in Past Month	29.2	9.7
Total Medicare Reimbursement per Month During Past Year	$3,271	$2,463
Number of Beneficiaries	**24**	**1,840**

Source: Medicare Enrollment Database and National Claims History.

[a] Participants who do not meet Medicare requirements for the demonstration or who had invalid Health Insurance Claim (HIC) numbers on MPR's enrollment file are excluded from this table because Medicare service use data were not available for them. Participants who are members of the same household as a research sample member are included.

[b] Although age 65 years or greater was a program eligibility criterion, the program did enroll two people younger than 65. The evaluation did not include eligible nonparticipants younger than age 65.

[c] All eligible nonparticipants in this table meet Quality Oncology's definition for cancer, as simulated in Medicare claims data. However, not all eligible nonparticipants are shown as having cancer in this section because these conditions were identified through standard definitions developed by MPR for use across *all* of the MCCD programs, and this standard definition for cancer does not contain the procedure codes used by Quality Oncology.

eligible beneficiaries who did not participate in the program. With average monthly reimbursements of $3,271 before enrollment, it appears that the program has enrolled patients who are as costly as planned.

Quality Oncology staff report that, anecdotally, patients are very satisfied with the program. One patient attributed her living as long as she had to her care manager. Another patient, overwhelmed by the burdens of caring for his wife and going through his own treatment, told his care manager she was "sent from heaven." Patients may stay in the Quality Oncology MCCD for the duration of the demonstration (that is, until April 2006). Quality Oncology plans to discharge only patients who die or move away from the program's MCCD service area.

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

Recognizing physicians' desire to avoid additional burden on their practices, the Quality Oncology MCCD requires little of physicians. It only requests that physicians tell suitable patients about it. Under the third outreach and enrollment coordinator, the original referral process, which included asking physicians' offices to copy and forward medical records, has changed so that the enrollment coordinator has been collecting that information herself. As mentioned, oncologists have not viewed the program's $40 per patient payment as enough of an inducement to participate.

Care managers have no regularly scheduled communication with physicians or their offices. A care manager will call physicians for worrisome symptoms reported by a patient, and she might send an occasional update form to a physician's office with information she considers important. These updates were infrequent during the program's first year, but program staff said they planned to increase the number of ICM-generated progress reports sent to physicians to improve physician engagement. Program staff guessed that care managers might contact a physician once a month, on average, for the typical patient and once per week for the more complex patient.

It is difficult to gauge the success of Quality Oncology's efforts to engage those physicians who have agreed to participate, since only nine physicians have done so. These physicians, especially with the efforts of the current project director, have been cooperating with the MCCD by allowing access to their offices and medical records. The Quality Oncology staff did feel that communication with these physicians could be better— for example, they wish physicians would notify the care managers about hospitalizations. Often, the chemotherapy nurses are the most helpful people in the oncology practices. After the MCCD outreach and enrollment coordinator has developed a relationship with a chemotherapy nurse in a practice, that nurse will generally return telephone calls from the Quality Oncology care managers, give the care managers additional information on enrollees, or make sure that patients receive needed tests or appointments.

Unlike its programs for managed care plans, Quality Oncology's MCCD does not have improving provider practice as a major goal. Care managers are to inform the medical director if an enrollee's treatment plan deviates from Quality Oncology's practice guidelines, and the medical director may contact the treating physician. In the first year of the MCCD, however, the medical director has not felt it necessary to contact any physicians. The program is cautious

about offering treatment recommendations that patients' physicians may not welcome or even about advising patients to question their physicians' decisions.

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

Improving Patient Self-Care. Care managers' main patient education task is generally to help patients get through the rigors of treatment as best they can by teaching them how to anticipate and deal with the effects of cancer and the predictable complications of treatment. Patients often fail to understand that cancer pain can and should be controlled and do not inform their providers about their pain. Undertreated pain may escalate to a crisis, leading to avoidable suffering, emergency room visits, and hospitalizations. Care managers explain to patients the importance of communicating and getting treatment for the pain and help make sure that they have a plan and adequate analgesics for pain control. Dehydration from treatment-induced nausea, vomiting, and diarrhea is another common problem for cancer patients that, if not managed properly at home, can lead to preventable hospitalizations. For patients receiving chemotherapy that lowers white blood cell counts and causes immune suppression, nurses can also explain when the maximum immune suppression will occur, what signs and symptoms of infection to look out for, and when to call the doctor. ICM allows care managers to order educational pamphlets directly from the American Cancer Society and the National Cancer Institute, or the National Coalition for Cancer Survivorship's Cancer Survival Toolbox, to be mailed to patients. ICM keeps a record of the educational literature that each patient has been sent. Finally, Quality Oncology has its own cancer support website, www.cancerpage.com. This is not only a resource for cancer information—it also has an interactive decision support tool for exploring treatment options, online support group chatrooms, an interface to send questions to care managers, and a tool for patients and family members to track physician visits, interactions with care managers, and treatment complications.

Care managers assess patients' understanding and retention of educational messages using ICM standardized question sets, to which care managers add their own questions. Examples of such questions are: "What did you learn?" "Did you try the protein shakes I suggested?" "How many did you try?" and "Is there something you would like me [the care manager] to research for the next time we talk?" Nurse care managers also use routine contacts to answer patients' commonly asked questions (for example, the chemotherapy and hair loss question). This saves physicians' and patients' time and lets patients make the most of their physician visits.

The program does not enroll cognitively impaired patients, but care managers must still work with patients who develop depression (which often impairs memory) after entering the program or suffer acute cognitive declines as a result of treatment. Among the 12 patients enrolled in Quality Oncology's MCCD during its first six months, only half (50 percent) had received at least one contact for disease-specific or self-care education. This relatively low percentage may be due to only 58 percent of patients having had an initial assessment or because the program provides patient self-care education around the patient's schedule for receiving chemotherapy or radiation therapy.

Improving Communication and Coordination. The Quality Oncology MCCD facilitates communication between patients and their physicians in several ways. One way is by giving

patients the knowledge and skills they need to make informed decisions about their cancer treatment. Patients often are frightened and anxious after learning they have cancer, and they have difficulty absorbing all the detailed information about treatment options they are initially bombarded with. The care manager assesses how well the patient has understood his or her doctor's proposed treatment plan. She often has more time than busy oncologists and oncology nurses to explain diagnosis and treatment to the patient, and the patient is often better able to grasp this information and formulate questions at home than in the physician's office. Fifty-eight percent of enrolled patients had one or more contacts in which care managers explained tests or procedures.

One of the care managers' first communication and coordination tasks may be to counsel patients on where to seek care. Some patients' initial reaction to a cancer diagnosis is to seek treatment from distant academic, tertiary-care centers. Care managers help explain that, for common cancers, community facilities provide state-of-the-art care and that traveling to a tertiary-care center often disrupts patients' natural support systems, imposes stress on patients and their families, complicates arrangements for follow-up, rehabilitative, and home care, and, because of longer hospital stays, increases risk of hospital-acquired infections. (In addition, tertiary-care centers often are much more expensive than community centers, without clear advantages.) Another situation in which care managers help communication is when patients are dying. Family members' guilt often is channeled into obtaining more treatment, regardless of outcome or emotional and physical impact on the patient. Care managers can help the well-meaning family members, the patient, and physicians communicate better, often allowing the patient to express his or her desire to not be subjected to more futile treatment efforts and to explore hospice as an option.

As a rule, care managers try to have patients make their own calls to physicians, since it is the program's goal to teach and empower patients to contact and communicate with physicians when appropriate. For example, a patient was unsure whether to contact her doctor about shortness of breath. The care manager, suspecting anemia, told the patient to call. The patient was found to have a low blood oxygen level, and the situation was addressed in a timely manner. To prepare patients for visits with their oncologists, the care manager may help them list specific questions, such as what side effects to expect from chemotherapy or radiation therapy. Sometimes care managers instead serve as "information conduits" between patients and their physicians. Patients often will not bring up important symptoms or worries during time-pressured doctor visits because they think these are not worth bothering the physician with, but they will tell their care manager about them. As another example, a care manager detected symptoms of depression in a patient's initial assessment and described this in the report she faxed to the patient's physician, prompting the physician to prescribe an antidepressant. Care managers also will call physicians' offices directly for emergencies, such as severe vomiting. For example, an elderly woman with arthritis and colon cancer living alone was threatened with dehydration because of chemotherapy-induced nausea and diarrhea. The care manager alerted the patient's physician, who ordered an anti-emetic to be delivered to the patient's home and home health care to give intravenous fluids. In addition, the care manager taught the patient how to record fluid intake and output and how to improve home safety, and arranged for a home care aide and meals-on-wheels. Care managers sometimes will help patients with their comorbid conditions, such as diabetes or heart disease, if their cancers have become quiescent (as may

happen with slow-growing cancers like prostate cancer), and the other conditions require attention.

The medical director described the care managers as skilled at not becoming embroiled in disputes between patients' physicians over difficult treatment choices or becoming a "referee" between physicians. The typical example is a patient with newly diagnosed prostate cancer for whom the urologist often will recommend surgery and the radiation oncologist radiation therapy. Care managers will tell the patient that both options are acceptable since both are considered within treatment guidelines. They may still help patients by providing factual information, however. One of the care managers described a patient who was very grateful to her for having suggested that he have a CAT scan. Care managers also aim to improve coordination by tracking patients' unexpected health care events, such as hospitalizations or trips to the emergency room. With the patient and his or her caregiver, the care manager tries to develop a plan to prevent future occurrences. She will also try to learn diagnostic findings or therapeutic decisions from the hospital stay and whether the patient is on any new medications or seeing any new physicians. The Quality Oncology staff did note that, compared to their usual managed care patients, for whom they are notified of admission almost immediately, it was harder for them to find out when their MCCD participants had been hospitalized. Quality Oncology must learn of an MCCD enrollee's hospitalization through the patient or the physician.

Increasing Access to Services. Although increasing access to services is not a primary intervention approach for Quality Oncology's MCCD, the program does refer patients to a wide variety of services, and, if necessary, arranges services on their behalf. Elderly patients starting chemotherapy often are afraid of driving, and the care managers will arrange transportation to chemotherapy and other medical appointments for patients without friends or family to drive them. The care managers will schedule follow-up calls to make sure the arrangements are working. Other services that the program refers to include durable medical equipment (particularly canes and walkers), meals, home health care, personal or companion care, respite care, hospice care, and mental health counseling. The primary MCCD care manager had compiled a large binder of local resources specifically for Medicare FFS beneficiaries that the other care managers had nicknamed the "bible."

Quality Oncology's MCCD does not pay for any non-Medicare covered services. Care managers refer patients who have difficulty affording oral prescription drugs, medical equipment, or supplies (for either cancer-related problems or comorbid conditions) to medication assistance programs, and the care managers help patients complete the application forms. The program encourages patients to participate in clinical trials of cancer therapies, especially if conventional treatment options have been exhausted. (Trial sponsors often provide the experimental drugs to participants for free, and Medicare now covers doctor visits and tests that are part of a clinical trial.) During the first six months of the program, Quality Oncology did not purchase any goods or services for the 12 enrollees, nor did care managers identify any needs for Medicare- or non-Medicare-covered services among them.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

There are too few enrollees on whom data were available (9 treatment group members and 10 control group members during the first four months of intake) to develop even preliminary

estimates of the short-term effect of the Quality Oncology MCCD on Medicare service use and costs. Average Medicare reimbursements for the 9 treatment group patients, exclusive of demonstration costs, were $13,701 ($6,851 per month) during the first two months after enrollment, compared to $10,700 ($5,350 per month) for the 10 control group members over the same period. Again, these data are far too small a sample to permit any conclusions about early program effects.

CONCLUSIONS

Quality Oncology's MCCD is unique among the 15 demonstration programs nationwide in its exclusive focus on cancer. Advances in treatment have made a few types of cancer into chronic illnesses that are incurable but controllable over many years with medications and monitoring. Most cancers, however, differ from the common prototypical chronic illnesses targeted in the MCCD—diabetes, heart failure, and coronary artery disease. Much of what happens to cancer patients in the initial period after diagnosis is done *to* them. In contrast, much of what happens to patients over the course of "usual" chronic illnesses depends on what is done *by* them—adhering to medications, making long-term changes in lifestyle, and performing self-monitoring.

Most cancer patients need to just "get through" the physically and emotionally demanding period immediately following the initial diagnosis, during which they undergo harsh, toxic treatments (chemotherapy, surgery, and/or radiation therapy) over a period of a few months. After the initial period, an assessment is made of tumor response, with next steps dependent on treatment success or failure. This time course is quite different than in typical chronic illnesses, for which patients' conditions tend to fluctuate between exacerbations and remissions throughout the rest of their lifetimes.

Not surprisingly, then, compared to the other MCCD programs, Quality Oncology's MCCD program focuses less on effecting long-term behavioral changes in patients (although it does focus on improving self-care to help manage side effects). The program's emphasis is on helping patients avoid predictable treatment complications in the short term. To a lesser degree, the program also tries to provide patients with knowledge and confidence to participate more fully in treatment decisions with the goal of reducing use of toxic, expensive treatments whose harms may exceed their benefits and use of costly diagnostic tests that provide little or marginal information.

Another unique aspect of cancer and Quality Oncology's program is that cost impacts, if any, should appear relatively early after patients' enrollment, compared to the targeted conditions and interventions in the other MCCD sites. Quality Oncology believes most of its effectiveness will be through reduction of preventable hospitalizations from poorly managed treatment side effects and, to a lesser extent, through controlling inappropriate use of diagnostic imaging and second- or third-line cancer treatments, all of which usually occur in patients' first several months of treatment. In contrast, improved management of other chronic illnesses may not pay off in reductions of adverse events and health care utilization for many months, or even years.

Despite these differences from the other MCCD demonstration programs, many features of the general framework that MPR has developed to describe coordinated care programs still apply

to Quality Oncology's MCCD. According to this framework, the program has several commendable characteristics:

- The program enrolls patients being actively treated for cancer, a ***target population with high expected health care costs*** (and enrolled patients so far indeed have had very high costs).

- Nurse care managers conduct a ***multifaceted, individualized assessment*** appropriate for cancer patients. The assessment is guided by Quality Oncology's electronic decision support and medical record system. The system also helps to create an ***individualized patient care plan with goals*** that monitors patient progress and is updated in response to patients' symptoms and completions of treatment milestones. Patient monitoring is tailored to patients' acuity, which is periodically reassessed. The system provides electronic tickler lists and tracking of interventions.

- The ongoing audits of the quality of nurse care managers' documentation and sharing of nurse care manager-level reports constitute a sophisticated ***system for providing ongoing feedback on patient outcomes*** to team leaders and nurse care managers.

- Quality Oncology's MCCD seems to have developed an ***effective patient education program.*** Care managers can order educational materials to be mailed to patients from within ICM, and the system tracks what patients have been sent. The care managers seem very skilled in counseling patients on how to deal with common treatment complications, and they follow up with questions to assess patients' understanding. ***Providing emotional support*** also is a central aspect of nurse care managers' functions.

- The program tries to ***reduce care fragmentation and facilitate communication*** between providers and patients by teaching and empowering patients to call their oncologist when appropriate. Care managers work to uncover modifiable factors that can cause repeated unexpected hospitalizations, and they facilitate difficult end-of-life discussions. They also help ***improve access to services*** by arranging transportation and referring patients to community services, cancer support programs, and medication assistance programs.

- ***Nurse care managers are highly qualified and experienced nurses.*** Quality Oncology has designed a rigorous initial training, mentoring, and supervision program for new care managers, as well as extensive continuing education efforts for regular care managers.

- Finally, MCCD staff have been performing regular ***quality monitoring.*** The computer system contains a wealth of up-to-date data for assessing program performance that the care manager supervisor and medical director have been routinely reviewing. If the MCCD's enrollment ever approaches that of Quality Oncology's other health plan programs, the MCCD will become part of the company's regular, systematic quality monitoring and improvement processes.

Potential Barriers to Program Success. The program's extremely slow enrollment is a concern. (The cumulative enrollment as of February 21, 2005—29 months after start of enrollment—is 202, with 101 in the treatment group.) Small sample sizes clearly limit the evaluation's ability to detect impacts. The new outreach and enrollment manager's approach of recruiting patients through face-to-face meetings seems to be working better than previous approaches, but it is time-consuming and labor intensive. In addition, because of the small size of Quality Oncology's MCCD, it does not yet have its own team, with dedicated care managers supervised by a team leader. To the extent that a team's performance improves with development of expertise in its patient population, the MCCD is not enjoying the advantages of such specialization. The MCCD is also not yet large enough to benefit from the regular quality assurance reviews of computerized data that Quality Oncology's programs for other health plan clients undergo.

The enrollment is too small to detect any real trends. As of the cutoff date for the care manager contact data included in this report, however, 42 percent of enrollees had not had an assessment contact, and, among those with an assessment, 57 percent were not contacted for their initial assessment until two or more weeks after random assignment. Enrollment records show that most enrollees had been randomized several weeks before the cutoff date for the contact data. Since cancer treatments and cancer symptoms may both progress fairly rapidly, program delays in initial assessment, care planning, and implementation of interventions may lead to missed opportunities for program benefits.

Lack of physician support also may be a barrier to program success. Only a few physicians in the counties served by the MCCD currently participate, and reception of the program among the larger oncology community seems to have been lukewarm at best. Reportedly, physicians have not perceived the one-time $40 per patient payment for participation to be much of an incentive. Physicians who do not support the program are unlikely to (1) keep MCCD nurse care managers up-to-date about hospitalizations, lab tests, alterations in treatment, and changes in patient status; (2) be receptive to care managers' reports and suggestions; or (3) reinforce nurse care manager advice to patients. To the extent that these physician behaviors contribute to program effectiveness, this apparent lack of physician support may be an impediment to program success.

Quality Oncology may have underestimated the extent to which its program for health plan clients relies upon managed care features that are absent in the Medicare FFS program. In contrast to its managed care programs, in the MCCD, Quality Oncology has little control over oncologists' choice of cancer treatment regimens, selection of treatment facilities for chemotherapy administration, or use of diagnostic tests. It is unclear how much of Quality Oncology's reported cost savings for its client health plans depends on controlling inappropriate physician utilization. If it is a substantial portion, Quality Oncology may find it difficult to replicate these results in the FFS setting and will have to substitute savings from hospitalizations prevented through patient education and monitoring for any diminished effects on physician practice. Quality Oncology staff also complained about how the lack of managed care information and notification systems hampered their ability to find out about enrollees' hospitalizations or other events. If Quality Oncology's success in managed care depends heavily on timely data on patients' health care utilization, this lack of data in the MCCD may also blunt the program's effects.

Obviously, it is too early, and samples are too small, to draw any inferences about program impacts. For all demonstration programs, savings in hospitalizations and other expensive Medicare services will have to be large enough to cover not only direct program fees, but also any higher Part B expenses incurred as nurse care managers refer treatment group patients for Medicare-covered services that may contribute to better short- or long-term outcomes for enrollees.

INTRODUCTION

The Medicare Coordinated Care Demonstration (MCCD), mandated by the Balanced Budget Act of 1997, is testing a range of models aimed at improving the care of chronically ill beneficiaries with Medicare fee-for-service (FFS) coverage. Fifteen programs are participating in the demonstration sponsored by the Centers for Medicare & Medicaid Services (CMS). The programs—hosted by organizations as diverse as hospital systems, disease management providers, and retirement communities—are serving patients in 17 states and the District of Columbia. Mathematica Policy Research, Inc. (MPR) is evaluating the national demonstration through both impact and implementation analyses.[1]

This report is one of a series that describes each program during its first year of implementation and provides preliminary estimates of its impact on Medicare service use and costs. First, it briefly describes the data and methodology used in this series of reports and presents an overview of the program that is the focus of this report. It then addresses the following questions: Who enrolls in the program? To what extent does the program engage physicians? How well is the program implementing its approaches to improving patient health and reducing health care costs? What were enrollees' Medicare service use and costs during its first months of operation? The report concludes with a discussion of the program's strengths and unique features, as well as potential barriers to program success.

This report describes Quality Oncology's MCCD project. Quality Oncology, Inc. is a cancer disease management firm whose clients are commercial and Medicare managed care

[1]The CMS Medicare Case Management Demonstration for Congestive Heart Failure and Diabetes Mellitus is also part of the MPR evaluation. Appendix Table A.1 lists all demonstration programs and locations.

plans.[2] The Quality Oncology MCCD, which began enrollment in September 2002, enrolls Medicare FFS beneficiaries in South Florida who have newly diagnosed cancer.

DATA SOURCES AND METHODOLOGY

Implementation Analysis. The evaluation's implementation analysis uses information gathered during telephone interviews with program staff conducted approximately three months after the program began enrolling patients, as well as during in-person interviews conducted about six months later. For each program, one of three MPR implementation team members conducted the telephone and in-person interviews using semistructured protocols. The protocols covered the following topics: organization and staffing; targeting and patient identification; program goals; care coordination activities (such as assessment, patient education, and service arranging); physician attitudes toward the program and program interventions with physicians; quality management; record keeping and reporting; and financial monitoring. Use of the protocols ensured that each interviewer collected as consistent a set of information for each program as possible, while allowing the interviewer to explore specific issues of importance to each program. The structure of the protocols also will make synthesizing findings across programs more efficient. MPR staff reviewed written materials each program provided, including the program's proposal to CMS, its operational protocol, materials it provided to patients and physicians, and the forms used in its operation. (Appendix Table A.2 contains a full list of documents reviewed for this report.) This analysis also includes an examination of data each program collected specifically for the evaluation, describing care coordinator contacts with

[2] In this report, "client" refers to the managed care organizations and health plans that contract with Quality Oncology to provide cancer disease management services.

patients, patient disenrollment, and any goods and services the program purchased for patients during its first six months of operation.

Participation Analysis. The evaluation uses Medicare claims and eligibility data to estimate the number of beneficiaries in the Quality Oncology service area who were eligible for the program and the percentage that enrolled during the program's first six months of operation. Beneficiaries are identified as eligible if, for any month from September 2002 through March 2003, they (1) lived in the program's service area,[3] (2) were enrolled in Medicare Parts A and B, (3) had Medicare as the primary payer, (4) were not in a Medicare managed care (Medicare + Choice) plan, and (5) met the program's target diagnosis and service use requirements (described in detail in Appendix B). The approximate midpoint of the six-month enrollment period examined in this analysis—November 15, 2002—is used as a pseudo-enrollment date for nonparticipants; the actual enrollment date is used for participants. We then compared participants and eligible nonparticipants with respect to demographic characteristics, diagnoses, and utilization histories to determine the extent to which participants are typical of the pool of eligible beneficiaries.

Impact Analysis. This report also presents early impact estimates based on key study outcomes. The evaluation's impact analysis is based on the random assignment of consenting, eligible Medicare beneficiaries to receive (1) the program intervention in addition to their regular Medicare benefits, or (2) only their regular Medicare benefits as usual. Comparison of outcomes for the two groups will yield unbiased estimates of the impact of care coordination. Disenrollees

[3] This is different than Quality Oncology's geographic inclusion criterion, which does not require beneficiaries to reside in the service area, but only to be receiving active treatment from an oncologist in the service area. The evaluator used residence in the service area as the closest approximation, however, as searching physician claims for all beneficiaries in the nation for the Medicare provider identification numbers (UPINs) of Broward County oncologists would have been impracticable.

are not excluded from the analysis sample because doing so would introduce unmeasured, preexisting differences between the treatment and control groups that random assignment is meant to avoid.

The report provides two types of comparisons of estimated treatment and control group means for Medicare-covered service use and costs. The first uses outcomes measured over the first two months after random assignment for beneficiaries who enrolled in the program during its first four months. The second compares treatment and control group means for each calendar month after program startup, using all sample members enrolled through the end of each month, to observe any trends in treatment-control differences over time.

In this report, the impact of the program's intervention is estimated as the simple difference in mean outcomes between treatment and control patients. T- and chi-squared tests are used to establish whether differences are statistically significant. The next round of site-specific reports will use regression to adjust for any chance baseline differences between the two groups that arose despite random assignment. (Appendix B describes in more detail the methods used to obtain Medicare data, construct variables, and choose analysis samples.)

The treatment-control comparisons presented in this report may not reflect the true long-term impacts of the program, for several reasons. First, the comparisons are based on a relatively small sample (only patients enrolling during the first four months of program operation). Second, the outcomes are measured too soon after patient enrollment to expect programs to be able to have sizable impacts. (The timetable for the evaluation's first report to Congress defined the observation period for this report.) Third, program interventions may change as staff gain more experience with the specific patients they have enrolled. Finally, if programs change their eligibility criteria or the type of outreach they conduct, they may enroll different types of patients over time.

Despite these shortcomings, we present the treatment-control differences to provide some limited feedback to the programs on how the two groups compare. Later analyses will examine Medicare service use and cost impacts over a longer time and will include all enrollees during the program's first 12 months.

OVERVIEW OF THE QUALITY ONCOLOGY MCCD

Quality Oncology's MCCD is an extension of its ongoing cancer disease management program for members of commercial and Medicare managed care plans to Medicare beneficiaries in the FFS program. The MCCD project consists of essentially the same services, protocols, and corporate infrastructure that Quality Oncology provides for its usual client health plans. For the most part, the Quality Oncology staff treat MCCD enrollees just like members of another client plan, with its own set of benefits and coverage criteria.

There are a few differences between Quality Oncology's main program and the MCCD, however, which we point out in this report. The MCCD has yet to use some features of Quality Oncology's main program because the number of enrollees is too few, but the company intends to apply them when there are enough enrollees. A few features of Quality Oncology's regular programs were developed for the managed care environment and do not translate well into the Medicare FFS setting of the MCCD. Finally, for the MCCD, Quality Oncology decided not to do the surveys of patients that it routinely does for its other client health plans, because it knew MPR was going to be conducting patient surveys for the evaluation.[4]

Program Organization and Relationship to Physicians. Quality Oncology was founded in 1993 by a group of South Florida oncologists. Originally a subsidiary of LifeMetrix, Inc., it

[4] However, MPR did not survey program sites whose total enrollment (treatment and control groups combined) by 12 months after the program had started recruiting patients was much lower than the target of 686, so Quality Oncology's patients were not surveyed.

was acquired in September 2002 by Matria Healthcare, Inc., a publicly held disease management vendor headquartered in Marietta, Georgia (Matria Healthcare 2002).[5] According to the Quality Oncology staff, Matria very much wants the MCCD to succeed. Quality Oncology is currently headquartered in McLean, Virginia, and its MCCD is based at its telephone call center in Sunrise, Florida.[6]

Since its founding, Quality Oncology has provided cancer disease management services to 14 health plans (Quality Oncology 2004), including two large Florida Medicare managed care plans. Between 1997 and 2000, the company served 1,900 Florida Medicare beneficiaries with cancer enrolled in these two plans, and claims to have saved 12 percent in costs for one plan, and 6 percent for the other, compared to what costs would have been without its program (Quality Oncology 2000; Kirsh and Lee 1999). Besides providing cancer disease management services, Quality Oncology also managed the drug replacement program for one of its clients.[7]

At least part of the positive results Quality Oncology has achieved for its health plan clients appears to have come from improving physicians' practice. Contracting health plans often delegate utilization management to Quality Oncology, so treating oncologists must first submit

[5] In addition to cancer disease management programs, Matria Healthcare offers disease management programs for high-risk obstetrics, diabetes, respiratory disorders, cardiovascular disease, chronic pain, and depression.

[6] Quality Oncology has six call centers in Virginia, Florida, California and Texas.

[7] In managed care organizations' drug replacement programs, also known as mandatory vendor imposition programs, oncologists must use chemotherapy and associated drugs that are prepared and shipped by a remote third-party supplier that the health plan selects. Quantities of medication supplied are tightly controlled to prevent oncologists from accumulating doses that could be used for other patients. Each shipment is designated for a specific patient and contains only a few doses. The oncologist must notify the drug replacement program when a dose has been administered or discarded. Quality Oncology's role was to take the medication orders from oncologists and track medications shipped and used. Most oncologists strongly dislike these programs, for several reasons. First, they make it difficult for oncologists to modify chemotherapy dosages and regimens at the time of infusion based on patient condition, which often is necessary. Rather than being able to administer the modified dose from their own stores right away, they must send the patient home and order the new dose to be delivered. Second, oncologists prefer acquiring chemotherapy drugs from trusted suppliers and preparing the mixtures in their own practices. They fear drug preparations from unknown suppliers may be of low quality, or even diluted or

their proposed diagnostic and treatment plans to Quality Oncology for approval. Over 10 years, with the input of more than 20,000 hours by approximately 25 community and academic oncologists, Quality Oncology has developed detailed, evidence-based, site- and stage-specific clinical practice guidelines for 42 malignancies. Quality Oncology's utilization management committee update these guidelines monthly. The guidelines are embedded in the nurse care managers' software so they can compare the proposed plans with the ones that Quality Oncology's guidelines recommend. The care managers refer cases in which there are substantial deviations of proposed tests or treatments from those suggested by Quality Oncology to the medical director for review and possible peer-to-peer discussions with the treating oncologist.

Quality Oncology feels that much of its impact in improving cancer treatment is through reduction of inappropriate regimens for patients who have failed initial treatment or have recurrent cancer. In the experience of the Quality Oncology staff, most plans for the initial treatment of cancers are within guidelines. For patients who do not respond, or whose cancer recurs, however, oncologists often feel pressured to try expensive, toxic regimens that lack evidence for effectiveness and offer little chance of meaningful benefits. Pressure comes from family members and patients who want to keep fighting, pharmaceutical industry "hype" about new therapies, oncologists' difficulty in telling patients and families that the cancer is terminal, and oncologists' own emotions about stopping active treatment and conceding to death. The Quality Oncology medical director can help treating oncologists recognize and resist these pressures. Through education and counseling, the nurse care managers can help patients and their family members appreciate clinical facts and possible underlying emotional issues. Quality

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(continued)
contaminated. Finally, shipping delays may lead to delayed chemotherapy administration, and improper shipping conditions may cause deterioration in unstable drug mixtures.

Oncology and the health plan client have the ultimate choice of not covering treatments they consider inappropriate.

Quality Oncology has also curbed use of other unnecessary health care services in its managed care programs. By using the American Society of Clinical Oncology's evidence-based guidelines, the company has successfully reduced inappropriate use of expensive diagnostic tests, such as nuclear bone scans, to check for cancer recurrence. For many of these tests, there is no evidence that they are useful for detecting cancer recurrence however, patients may be anxious about not having them done. The care managers have allayed patients' anxiety through empathetic education and reassurance and referral to cancer support groups. The medical director can remind the patients' oncologists about the scientific basis for not performing many of these tests. Quality Oncology also encourages oncologists to make less use of expensive, inappropriate hospital facilities for the administration of outpatient chemotherapy and to give more chemotherapy in their own offices. Again, Quality Oncology and the managed care plan client can, as a last resort, choose to not cover tests or services they do not agree with.

Several Quality Oncology staff work on the MCCD. Their roles in the MCCD (with their Quality Oncology corporate titles in parentheses) are (1) project director (Vice-President for Account Management); (2) outreach and enrollment coordinator (Medicare Project Director); (3) medical director (Chief Medical Officer); (4) care manager supervisor (Director of Care Management Operations, Southeast); (5) quality assurance manager (Director of Quality Management); and (6) care coordinators (called "care managers" by the program). Only the outreach and enrollment coordinator was hired specifically to work full-time on the MCCD.[8]

[8] Although the company title of this person is Medicare Project Director, her responsibilities are to recruit patients and physicians and to build relationships with physician practices and cancer centers.

The other staff members have responsibilities across all of Quality Oncology's clients, including the MCCD. All the MCCD staff are in the company's offices in Sunrise, Florida.

The current outreach and enrollment coordinator is the program's third. Quality Oncology's MCCD has had great difficulty recruiting patients. To match its various approaches to increase enrollment, it has hired different outreach and enrollment coordinators with diverse backgrounds and skills. The first coordinator was an oncology nurse with a background in clinical trials. The second was a nonclinician with a background in health care administration. The current coordinator has a background in marketing in the hospice industry and had just started in the position a few months before MPR's site visit in May 2004.

Quality Oncology's care managers are organized into teams supervised by team leaders. Each team serves one client health plan. Quality Oncology originally planned for the MCCD to have its own dedicated team led by an MCCD team leader. At full enrollment, the MCCD team would have 10 care managers, with caseloads of approximately 100 patients each. After a year of operation, however, there were not enough MCCD patients for even one care manager's caseload, so no separate MCCD team had yet been formed or MCCD team leader designated. All the care managers working with the few MCCD patients were on staff at Quality Oncology before the demonstration began and so remained on their usual teams, spending most of their time with patients of their team's health plan. One care manager, whom we refer to in this report as the primary MCCD care manager, handled most of the MCCD patients, and four other care managers served a few patients each.

Quality Oncology's MCCD recruits patients from Broward, Dade, and Palm Beach counties in South Florida. There is a high population of elderly Medicare beneficiaries in the area. Through its long experience with two Medicare+Choice (now called Medicare Advantage) plans in South Florida, Quality Oncology had established working relationships with all the local

oncology practices and cancer centers. All the oncology practices and cancer centers from which the program recruits are within 20 miles of the company's office in central Broward County.

Primary Approaches. Quality Oncology's main approaches in the MCCD to improving patient health and reducing health care costs are (1) teaching patients about self-care, and (2) enhancing communication between patients and physicians. Patients who know how to deal with treatment or disease side effects, such as dehydration or pain, can forestall worsening in their condition that might make emergency hospitalization necessary. Quality Oncology believes that patients themselves are often the best agents for enhancing communication. Patients who understand their treatment options, participate in diagnostic and treatment decisions, call their doctors about their symptoms, and ask questions about their care will naturally make communication easier. Improved communication in turn means that providers are notified earlier of patients' impending problems, physicians avoid duplicating tests already ordered by other physicians, and patients choose treatments that are evidence based and match their own desires for aggressiveness of care.

Quality Oncology cites hospice care as an important area in which it seeks to improve communication and, thus, patient decision making. Alternative treatment options often are limited for patients whose cancers are not responding to initial treatments or who are having difficulty tolerating treatment. Quality Oncology care managers begin educating these patients and their families on the chances of response, and the potential impacts of side effects on quality of life, with these second- or third-line treatments. They also begin explaining palliative care and hospice.[9] Patients and their families who understand these options early on have time to discuss them with their physicians and to weigh continued active treatment against comfort care

[9] On the other hand, Quality Oncology states that it will help patients who clearly want active treatment, and for whom reasonable treatment options have not been exhausted, to obtain such treatment.

and palliation. There is uniform consensus among oncology experts that cancer patients who would benefit from hospice care are generally offered these services too late, often shortly before death, and are thus deprived of the advantages that hospice care can bring to the end of life. Quality Oncology seeks to *increase* length of stay in hospice.

One approach that Quality Oncology uses in its managed care contracts but does *not* in the MCCD is ensuring that patients' cancer treatment follows evidence-based guidelines. Unlike its client managed care plans, in the MCCD, Quality Oncology does not have direct leverage over participants' oncologists of pre-authorization of cancer treatment plans.

Target Criteria and Patient Identification. To be eligible for the Quality Oncology MCCD, patients must have biopsy-proven cancer and be receiving or about to begin active treatment for the cancer in the South Florida counties of Broward, Dade, or Palm Beach.[10] Active treatment includes surgery, chemotherapy, radiation therapy, and biologic therapy (such as interferon or interleukin-2). The program feels it provides the greatest benefits to patients who have not yet started treatment and would ideally enroll patients as soon as possible after their initial diagnosis of cancer.

As in all 16 demonstration programs, beneficiaries must meet CMS's insurance payer and coverage requirements for the demonstration: (1) be enrolled in Medicare Parts A and B, (2) not be in a Medicare managed care plan of any kind, and (3) have Medicare as their primary payer. The program excludes patients who are already in hospice care or who live in a nursing home; have end-stage renal disease; have *in situ* cancer of the cervix, prostate, bladder, or colon; have basal or squamous cell skin cancers; are taking maintenance hormonal therapies; or are enrolled in the United Mine Workers or Railroad retirement programs.

[10] Because many patients ("snowbirds") live outside the service area for a significant portion of the year, the program requires treatment within the service area, rather than residence in it.

Unlike the managed care environment that Quality Oncology is accustomed to, in the FFS environment, there are no health plans to identify patients and to provide the mechanism through which program staff gain the attention of treating physicians. Quality Oncology assumed that the approximately 80 Broward County oncologists with whom it had worked over the years through managed care plans would see the advantages of identifying and referring their Medicare FFS patients with cancer to the MCCD. In presentations to oncologists, Quality Oncology highlighted how the MCCD would benefit patients (as described under "Primary Approaches" above) and physicians as well. The presentation pointed out how the MCCD reinforces the treatment plan with patients, helps arrange services through its familiarity with Medicare benefits and community resources, facilitates communication across multiple providers and settings, provides care managers available around the clock to answer cancer patients' questions, and informs physicians of patients' new developments at home that they might not be aware of. As one Quality Oncology staff member put it, physicians *should* welcome a program that relieves them of the chore of repeatedly explaining to patients why their hair is falling out (often a 20-minute conversation).

Under the first outreach and enrollment coordinator, the program sent introductory letters and distributed flyers and pamphlets to physicians' offices. The letter briefly described the MCCD, asked oncologists to notify Quality Oncology of all FFS Medicare beneficiaries newly referred to their care by filling out a referral form (Appendix C), and alerted them that they might be asked to provide additional clinical information. Quality Oncology planned to then telephone the patients referred by the oncologists, explain the study, mail information and consent forms, and conduct follow-up calls to solicit enrollment.

Unfortunately for the program, Quality Oncology's initial assumptions about the willingness of oncologists to participate appear to have been overly optimistic. Contrary to the company's

expectations, few oncologists expressed interest in the MCCD or agreed to allow the program to approach their patients about it. Nine physicians in two Broward County oncology practices have allowed the program to recruit their patients. Quality Oncology also overestimated patients' willingness to participate—even patients referred by their oncologists were reluctant to enroll. The section on enrollment ("Who Enrolls in the Program?") describes in further detail the recruitment challenges the program has encountered.

Under the second outreach and enrollment coordinator, the program approached local hospitals and cancer centers and expanded to neighboring Dade County in the south. The initial response of many institutional providers to the project was that they already provided the cancer care management services that Quality Oncology offered, so they saw no need to refer patients. In addition, because the demonstration involved random assignment, the institutions insisted on institutional review board approval, a lengthy, time-consuming process for Quality Oncology. In Dade County, providers and physicians showed little interest in the project because of a high Medicare managed care penetration.

The current outreach and enrollment coordinator has shifted the patient recruitment strategy from one that waited for oncologists to refer patients, and then relied on letters and telephone calls to referred patients, to one that identifies patients during their oncology appointments and engages them in face-to-face meetings. She regularly visits the practices of participating oncologists, and the practices' office managers provide her with lists of potentially eligible patients with appointments that week. She reviews each patient's record for Medicare and program eligibility and plans to be in the oncology practice at the time of each eligible patient's visit. At the conclusion of an eligible patient's visit, the oncologist will ask if the patient is willing to speak with the enrollment coordinator.

The enrollment coordinator speaks with willing patients in the waiting room, or sometimes even in the infusion room while they are receiving chemotherapy, to explain the program and solicit participation. If the patient consents to participate, the enrollment coordinator later submits the patient's information to MPR for random assignment. To minimize burden on oncologists' office staff, the enrollment coordinator often will copy consenting patients' records in the office, even before randomization. The enrollment coordinator discusses the program with five to seven patients per recruiting visit to an office.

Of the 70 people the enrollment coordinator had approached so far, only 2 had refused to participate, apparently a much higher acceptance rate than previously. This face-to-face approach is time-consuming and labor intensive, however. The program has identified approximately 75 percent of its enrollees through in-person physician office meetings. Most of the rest have been direct referrals from physicians, physician office staff, or cancer center staff. Only a few have been patient self-referrals. Because it demands that she be in the field constantly, the program has started providing the enrollment coordinator with some clerical support in the Quality Oncology office to open the new cases in its electronic records system.

More recently, the current enrollment coordinator began to give presentations in area retirement communities, and she planned to give additional talks at seniors' clubs and oncology centers in fall 2004. Since her arrival, the program expanded its service area to adjacent Palm Beach County in the north and began marketing itself to oncologists there. It also hoped to soon enlist the eight or nine influential South Florida university- and community-based oncologists who serve on the company's utilization management committee to be spokespersons for the demonstration. This committee meets monthly to incorporate the latest medical evidence into Quality Oncology's clinical guidelines and to review interventions and denial decisions by the company's medical director. The local oncologists who sit on the committee have been

enthusiastic about Quality Oncology in general. The project director was scheduled to give a presentation to the committee about the MCCD in June.

The program had also placed advertisements in newspapers in January (Appendix C). Program staff report that these generated high interest in the program among individual patients and a large number of calls. Unfortunately, about 75 percent of these calls were from patients ineligible for the MCCD, so the program discontinued the newspaper advertisements in April 2004. Program staff have been referring interested patients to information about the MCCD on the Quality Oncology website (Quality Oncology 2004). Although many patients in the targeted population do not use the Internet, their family members can visit the website to learn more about demonstration participation.

Assessment, Care Planning, and Monitoring. Following random assignment to the treatment group, the primary MCCD care manager is supposed to telephone patients within three to seven days of enrollment (ideally, within a day) to explain the program in more detail, including the services that will be provided, the role of the care manager, and the goals of care coordination. She explains to patients that, even though the program will contact them periodically, they may also call their care manager directly through a toll-free number whenever they have concerns or questions. Quality Oncology is a purely telephonic intervention, however, and does not make any in-person contacts.

The care manager also performs an assessment during the initial contact. This assessment covers physical and clinical information, ability to perform self-care activities, psychosocial issues, information on all medications (including those for comorbid conditions), and adherence to cancer treatment and other medications. It also covers patients' understanding of their diagnosis and treatment, learning readiness, self-management skills, home safety, health care use

and access, preventive care, lifestyle information (such as on smoking), and nutrition. This assessment is the same, regardless of the patient's specific cancer or severity of illness.

Quality Oncology's proprietary, stand-alone computer system—the Integrated Care Management (ICM) system—guides the care manager through the assessment. The assessment tool is embedded in ICM and prompts care managers to ask patients specific questions based on their prior responses. Assessments usually take about an hour, and the care manager sometimes contacts patients' family members for information the patient is unsure of or suspects the patient is hiding (such as not eating). The care manager enters into ICM additional clinical information from the copied medical records obtained from the patient's physician, including physical examination results, medical history, pathology reports, stage of cancer, and any other diagnostic imaging or laboratory reports. Care managers can scan documents directly into ICM, thus eliminating the need for paper copies of records and allowing all information to be stored electronically. Only care managers have access to ICM, and only to the records of their team's patients. After the initial contact, the care manager supervisor may assign the patient to another care manager, depending on the primary MCCD care manager's total (MCCD and non-MCCD) caseload and the acuity level of the new enrollee.

After the initial assessment is completed, ICM helps the care manager develop a care plan. The care plan contains a problem list, short- and long-term goals, and planned interventions (including teaching points, community resources, and educational materials). Part of the care plan is standardized to some extent in ICM and based on Quality Oncology's treatment guidelines for the patient's stage and type of cancer. After the patient's cancer type and stage are entered, ICM will bring up the recommended chemotherapy, surgery, or radiation therapy and even the types of specialists the patient should see (such as oncology subspecialists, urologists, or gynecologists). The nurse care manager then enters goals and interventions from drop-down

lists or as free-form notes on the appropriate services screens. For example, for a patient who is receiving chemotherapy, the nurse care manager documents the patient's needs and goals under the chemotherapy screen.

The other portion of the care plan is individualized, developed from the care manager's judgment after review of the initial assessment. Nurse care managers can enter individualized goals and interventions as free-form notes in ICM (for example, maintenance of nutrition and referral to meals-on-wheels for a patient unable to cook for herself. Another goal might be that the patient will be able to describe two methods of dealing with fatigue. Physicians do not receive copies of the care plans.

The initial assessment data are also used to assign the patient to one of four acuity levels, with Level 1 being the highest. Acuity levels are used to guide monitoring frequency and assess nurse care managers' caseloads. For example, criteria for Level 1 include patients who are new, or who have had a recent or current hospitalization, initiation of chemotherapy or radiation therapy, a bone marrow transplantation, or acute symptoms or treatment side effects. The lowest-acuity patients, in Level 4, are hospice patients.[11]

Care managers monitor patients through regular telephone contacts, with frequency determined by acuity. The highest-acuity patients (those in Level 1) are contacted weekly. Level 2 patients are contacted every other week, Level 3 patients monthly, and Level 4 patients every 45 days. Contacts are also supposed to occur around significant clinical milestones, such as after a procedure or at the initiation or completion of a course of treatment. For example, the

[11] Guidelines for the intermediate-acuity levels are: Level 2—elderly with comorbidities, head and neck cancers, participants in clinical trials, and prostate cancers after implantation of radioactive seeds; Level 3: stable disease and minimal side effects after two cycles of chemotherapy and/or two weeks of radiation therapy, prostate cancer on hormonal treatment before implantation of radioactive seeds, newly diagnosed patients in whom treatment is not being started for several weeks, and patients after surgery with no additional chemotherapy or radiation therapy planned.

nurse care manager will call a patient before scheduled outpatient chemotherapy, to provide information and advice on potential side effects, then will call daily for the first few days after the chemotherapy is completed to see how the patient tolerated it. ICM generates daily tickler lists of contacts that must be made and tasks that must be completed for all the care manager's patients. By default, the tickler lists are prioritized by the dates of planned contacts, with the oldest date first. However, the care manager may re-sort the list by other criteria if she wishes (for example, by acuity, or by grouping together all calls to physicians).

During routine monitoring, the care manager assesses the patient's symptoms and health-related quality of life and immediately addresses any side effects or acute problems. As in the initial assessment, when patients are too sick to talk or seem reluctant to disclose problems they may be having, the care managers will speak with family members or caregivers. The care manager updates the patient's medication and treatment information and repeats other assessments from ICM based on her judgment. As of spring 2004, Quality Oncology was working on having additional assessments automatically pop up in ICM based on entered information (for example, if the patient's functional status fell below a certain level), but these changes had not yet been implemented.

Nurse care managers also use routine contacts to answer questions that patients frequently ask (for example, the chemotherapy and hair loss question) so that patients do not need to ask their physician. Answering these questions saves physicians' time and lets patients make the most of their physician visits.

After each contact, ICM automatically calculates the next contact date for the patient. For many activities, the care manager must complete "next-step" fields before ICM will let her exit the patient's record. This ensures that every patient has next-step actions planned, when appropriate.

ICM also allows care managers to update the care plan on an ongoing basis. As the nurse care manager documents a patient's completion of steps in his or her treatment, the intervention drop-down list in ICM changes to reflect this progress, as well as any common problems that might be anticipated. The drop-down list also changes with the documentation of previous symptoms or problems resolving or of new ones developing. Similarly, goals can be changed, if patients have accomplished them.

Care managers also take into account patients' comorbid conditions. First, they routinely check for adverse interactions between patients' cancer-related medications and their other medications and medical conditions. Second, patients' comorbid conditions can sometimes become more pressing than their cancers, particularly with slow-growing cancers, like prostate cancer. In these circumstances, the care managers also help coordinate care for these other medical problems, such as heart problems or diabetes.

Care managers use ongoing monitoring to routinely reassess patients' acuity. Patients whose acuity level falls do not need as close or frequent monitoring; conversely, patients who become more acute receive greater attention. In this way, Quality Oncology tries to allocate its care manager efforts most efficiently.

Finally, care managers provide patients and their families with crucial emotional support and encouragement throughout all phases of treatment, often developing a strong rapport with patients. One elderly man in the MCCD was struggling with his cancer while continuing to be his wife's primary caregiver. His children had remained uninvolved. He told his care manager, "You're sent from heaven—I have no one else to talk to." Another MCCD enrollee's husband and daughter had both died of cancer, and now she had cancer. The care manager gave her the only opportunity she had to "unload" all of her emotions, as she said her other family members

"think I'm crazy." One care manager encouraged all her patients to call with questions or even when they just felt lonely or felt the need to ventilate.

Quality Oncology provided examples of how the nurses monitored MCCD enrollees and worked with them. In one case, an 80-year-old woman with arthritis and colon cancer was living alone, unable to cook for herself, and at high risk for dehydration because of chemotherapy-induced nausea and diarrhea (Quality Oncology 2000). The care manager educated her on recording fluid intake and output, home safety issues, and the importance of waiting for assistance to accomplish activities at home. The care manager also arranged for meals-on-wheels and notified the patient's physician of the situation. The physician ordered an anti-emetic to be delivered to her home and home health care to give intravenous fluids. The next contact was scheduled for one week's time, and the care manager's next steps were to follow up on how meals-on-wheels was going, conduct a home safety assessment, and arrange for home care for assistance with activities of daily living.

In another case, a patient in his mid- to late 80s receiving radiation and chemotherapy for esophageal cancer was suffering from debilitating fatigue and nocturnal insomnia. Although nothing seemed very effective, the care manager continued working with him and his wife, successively trying hydration, nutrition, high-protein powder supplements, curtailment of daytime naps, and physical activity.

Between September 2002 and March 2003, the first six months of program operation, 12 patients enrolled and were randomly assigned to Quality Oncology's treatment group (Table 1). Among those patients, only seven (58 percent) had at least one contact for assessment, and, among those contacted for assessment, only three enrollees had their first contact within two weeks of random assignment. The program's goal is to assess all newly enrolled patients within three days to a week of random assignment, preferably within one day. The care managers noted

that delays in performing the initial assessment were due to difficulty scheduling the handful of patients who were under age 65 and still working.

Of these 12 patients, 9 had at least one contact with a care manager (Table 1). Those patients averaged three contacts during this period. Care managers initiated most contacts (92 percent), and all contacts were conducted by telephone. Although these contacts include those for assessment, nine enrollees (75 percent) had a contact for routine monitoring. Seven enrollees (58 percent) had one or more contacts in which they received emotional support.

Staffing and Management of Program Quality. Effective programs require (1) qualified, well-trained staff; (2) periodic evaluations of staff performance; and (3) collection and use of program-level performance data for program management and quality improvement. Quality Oncology has sophisticated processes to ensure that it has all three program features.

Quality Oncology care managers must be registered nurses with Florida licenses and have at least five years of nursing experience in oncology, utilization review, case management, home care, or hospice. Certification in oncology or case management is desirable. The company looks for nurses with excellent skills in clinical assessment, communication, and teaching, as well as with basic computer skills.

A credentialing committee regularly reviews the adequacy and currency of the credentials and licensure of all Quality Oncology clinical staff. This committee checks all clinical staff members' credentials for compliance with regulatory and accreditation standards upon initial hire and then every three years. It verifies quarterly that each clinical staff member's licensure is current.

Quality Oncology has a rigorous, structured training and orientation process for newly hired nurse care managers. The company has a full-time educator responsible for both the initial training and continuing education of care managers. New hires first undergo a two-week

TABLE 1

CARE MANAGER CONTACTS WITH PATIENTS DURING FIRST SIX MONTHS

Number of Patients Enrolled[a]	12
Number of Patients with at Least One Care Manager Contact[b]	9
Total Number of Contacts for All Patients	24
Among Patients with at Least One Care Manager Contact, Average Number of Contacts per Patient	2.7
Number of Care Managers Contacting Patients	4
Among Those Patients with at Least One Contact:	
Percentage of contacts care manager initiated	91.7
Percentage of contacts in person at patient's residence	0.0
Percentage of contacts by telephone	100.0
Percentage of contacts in person elsewhere	0.0
Of All Patients Enrolled, Percentage with Assessment Contact	58.3
Among Those Patients with an Assessment, Percentage of Patients Whose First Assessment Contact Was:	
Within a week of random assignment	0.0
Between one and two weeks after random assignment	42.9
More than two weeks after random assignment	57.1
Of All Patients Enrolled, Percentage of Patients with Contacts for:	
Routine patient monitoring	75.0
Providing emotional support	58.3
Providing disease-specific or self-care education	50.0
Explaining tests or procedures	58.3
Explaining medications	33.3
Monitoring abnormal results	25.0
Identifying need for non-Medicare service[c]	0.0
Identifying need for Medicare service	0.0
Monitoring services	50.0
Among Patients with at Least One Care Manager Contact, Average Number of Patients Contacted per Care Manager	2.3
Average Number of Patient Contacts per Care Manager	6

Source: Quality Oncology program data received April 2003 and updated July 2003. Covers six-month period beginning September 18, 2002, and ending March 16, 2003.

[a] Number of patients enrolled in the treatment group as of March 16, 2003.

[b] Contacts described in this table include those made by care manager, social worker, and chaplain.

[c] Includes transportation; meals and/or food sources; help applying for medication assistance and public programs; personal care; homemaker, companion, or respite care; mental health counseling and spiritual care; dental services; adult day care; housing resources; diabetic and heart failure education classes; and wound and pain clinics.

introductory program. The program includes formal classes, observation of care managers' day-to-day activities, and hands-on experience with ICM. The classes cover the company's approach toward care management and its policies and procedures, ICMS and other basic computer skills, HIPAA compliance, and American Healthcare Accreditation Council (URAC) requirements.[12]

Although care managers do not receive formal training on patient education skills, the ones working on the MCCD have all had patient education experience from several years' experience in oncology. The two care managers with the most MCCD enrollees have each developed additional counseling skills from hospice experience. Care managers also cited the company's full-time educator as a good source of information on counseling and education.

Quality Oncology did provide some training specific to the MCCD for the care managers who would be working on the demonstration. This consisted mainly of how to record the nurse care manager-patient contact information that the demonstration programs are collecting for MPR as part of the evaluation (see Appendix C for the training agenda).

The next three months after the initial training are a probationary period for new care managers. They start by managing a small number of low-acuity patients under close supervision by their team leader and slowly build up to a full caseload of 90 to 100 patients of all acuity levels. They also must complete an oncology self-study course for nurses from Western Schools (Western Schools 2004). After three months, if they have received satisfactory monthly evaluations, the new care managers become permanent employees. After six months, they become full-fledged care managers and start participating in the ongoing quality monitoring processes, described below.

[12] HIPAA mandates certain privacy protections for personal health information. URAC is a nonprofit organization that accredits and certifies health care organizations and programs. In particular, it has a program for accrediting disease management programs (URAC 2004).

The care managers also receive extensive continuing education. Each of the call center offices takes turns hosting a weekly, company-wide, hour-long teleconference attended by care managers from all the offices, as well as the medical director. The first 40 minutes are devoted to a talk by the medical director or another speaker on an important topic (for example, fatigue, or multiple coexisting psychosocial or physical problems), followed by a presentation and discussion of two illustrative patient cases. Cases are selected successively from each of Quality Oncology's client health plans, including the MCCD. The last 20 minutes of the conference are for peer networking and exchanging of tips. (Care managers said this was another valuable resource for learning about patient education and counseling techniques.) Other continuing education opportunities include a Saturday oncology review class that Quality Oncology offers to help care managers gain oncology certification and lunchtime inservices by pharmaceutical company representatives to discuss new cancer drugs. Care managers also receive two educational days per year to attend conferences.

Care managers' performance is closely monitored and evaluated in several ways. First, every month, each care manager must complete, and submit to her team leader, structured self-audit forms on the electronic ICMS records for two of her patients whom her leader has selected for her. The purpose of these self-audits is to assess the completeness of the care managers' documentation of patient information in ICM and how well they are interpreting and recording information in a standardized fashion.[13] The care managers often correct deficiencies in their records as they do the self-audits; the team leaders do not mind them doing this, however, since the ultimate goal is to improve the quality of patients' records.

[13] The form asks, for example, whether the patient's goals have been clearly stated and recorded within the specified time frame. If the nurse care manager has listed as a goal that that she will follow up with the patient after the completion of a diagnostic test, the supervisor will point out that this is not the *patient's* goal; the patient's goal is to undergo the test.

Second, every two weeks, team leaders review detailed Intervention Activity Reports (IARs) on each of their care managers, produced from the electronic data in ICM. Team leaders can see whether their care managers are making contacts at appropriate frequencies, completing care management tasks within recommended time frames, and keeping their patients' records up-to-date. The IAR data are also fed back to the care managers.

Third, every morning the team leaders review the daily tickler lists of each of their care managers. Leaders can gauge from the number of tasks on a care manager's list whether she is keeping up with her workload. The daily review allows the team leaders to detect care managers who are falling behind early so they can help them catch up before problems get worse. Finally, team leaders conduct yearly formal evaluations of their care managers.

Quality Oncology also conducts several quality monitoring and improvement activities at the MCCD program level. To recognize any problematic trends quickly, the care manager supervisor and the medical director regularly monitor the IARs aggregrated to the MCCD program level for rates and types of treatment complications among the MCCD patients. If the MCCD ever reaches an enrollment comparable to that of Quality Oncology's other health plan clients, the MCCD's IARs will become part of the regular company schedule in which each health plan's IARs are reviewed every two weeks by Quality Oncology's director of care management operations, director of quality management, and other senior management.[14]

In addition, when the MCCD becomes large enough, it will be reviewed along with Quality Oncology's other health plan clients by the company's standing quality management committee.

[14] The routine health plan IARs show treatment status (numbers of cases receiving active cancer treatment, in post-treatment phase, or in hospice); health care utilization (physician office visits, emergency room visits, hospital admissions and readmissions, and admissions to skilled nursing facility and hospice); symptoms (self-reported pain scores, intractable nausea); cases that do not conform to company treatment guidelines; patients with involvement by multiple physicians; and potentially preventable complications of cancer treatment (such as hospitalizations for pain or dehydration). Appendix C contains examples of these reports.

This committee is made up of several senior company officers and department managers. It meets every other month to review interim data from the IARs, and, once a year, it thoroughly assesses program performance for the entire preceding year.

There have been no formal complaints about the MCCD, but Quality Oncology has in place the same procedures for responding to complaints from patients and physicians as it does for its managed care clients. The introductory packets that MCCD enrollees receive contain instructions on how to register a complaint. The Quality Oncology staff member receiving the complaint completes a report form, which is then sent to the quality assurance manager (the company director of quality management) for review. Complaint numbers and time trends will be tracked.

Quality Oncology explored, but did not pursue, obtaining disease management accreditation, such as by the National Committee on Quality Assurance (NCQA).[15] The company concluded that disease management accreditation programs do not fit cancer disease management well because they include many standards for routine preventive care that are not relevant for cancer patients (such as performance of eye exams in diabetes, or controlling cholesterol levels in coronary artery disease). For oncology patients, "prevention" consists primarily of preventing hospitalizations for the side effects of chemotherapy, and, in some cases, death may be the expected outcome. As one Quality Oncology staff member put it, "Cancer can't be tied to a lab value." Quality Oncology may seek accreditation for *case* management in the future, however.

[15] Matria has NCQA accreditation for disease management, but this accreditation does not include Quality Oncology, which was acquired after NCQA's review.

WHO ENROLLS IN THE PROGRAM?

The program has encountered several barriers to enrollment. Despite a substantially lower than projected enrollment, however, the program has enrolled patients with high rates of hospitalization and health care expenditures. Staff report that patients are satisfied with the program, and program data show no voluntary disenrollment during its first six months.

Enrollment After One Year. After one year of operation, Quality Oncology had enrolled 32 patients in the demonstration treatment group and 31 in the control group (MPR weekly enrollment report, week ending September 21, 2003). This does not begin to approach the program's original target of 2,132 beneficiaries in the first year.

The Quality Oncology staff described three main reasons (and one potential reason) why physicians and patients have been reluctant to participate in the MCCD. First has been the negative reaction of both physicians and patients to random assignment. Oncologists dislike the idea that that needy, frightened cancer patients could be randomized to the control group and, thus, denied services perceived as beneficial. Likewise, patients refuse to participate because they do not want to be in the control group.

Second, despite Quality Oncology's assurances that the program would retrieve all clinical information from office records and provide all administrative support, physicians feared the program would add an intrusive burden to their practices. Since their participation was voluntary, physicians saw little incentive to cooperate, and the one-time payment of $40 per patient that Quality Oncology offered for physicians' participation was not enough to overcome their skepticism.

Third, physicians were worried that sharing clinical data with Quality Oncology would violate HIPAA regulations. Several months after the program started, CMS provided the program with a letter from Thomas Scully, the CMS administrator at that time, to allay

physicians' fears about HIPAA. This letter helped somewhat, but many providers were still reluctant to participate because they were anxious about patient privacy.

A possible fourth factor that may have hampered Quality Oncology's recruitment efforts was Quality Oncology's previous connection with Blue Cross/Blue Shield of Florida's drug replacement program. The drug replacement program was unpopular among oncologists, and a few local physicians may have retained a negative impression of Quality Oncology from its association with the program. Program staff, however, did not feel this was a major factor behind the enrollment difficulties.

Percent of Eligible Beneficiaries Participating. To estimate the size of the eligible population and the percent that chose to participate, the evaluation simulated the program's eligibility criteria using Medicare enrollment and claims data. (Appendix B contains a detailed description of the simulation.) This simulation identified 1,855 beneficiaries eligible for the program between September 2002 and March 2003, the program's first six months of operation (see Table B.4). That is, they lived in the program's service area, met CMS's demonstration-wide eligibility criteria, and met the program's clinical eligibility criteria.[16] During the same six months, 15 eligible beneficiaries enrolled in the demonstration (about 0.8 percent of the 1,855 eligible beneficiaries).[17] (See Tables B.2 and B.3.)

[16] From September 2002 through March 2003, 253,016 beneficiaries were living in the program's service area. Of those, 128,330 (51 percent) would have been ineligible for the program because they did not meet one of CMS's demonstration-wide criteria. Of the remaining 124,686 beneficiaries who met these criteria, 1,855 (1.5 percent) also met the program's diagnostic and service use criteria at some point during the six-month intake window, and they had none of its exclusion criteria (to the extent they could be simulated with the Medicare data). (See Table B.2.)

[17] In fact, 25 beneficiaries actually enrolled in the program during its first six months. When estimating the participation rate, the evaluation excludes enrollees who did not meet the Medicare demonstration-wide criteria or the program's geographic, diagnostic, or exclusion criteria (as measured using Medicare data). These enrollees were excluded from the participation analyses in order to use consistent definitions of eligibility for the numerator and denominator of the ratio. This leaves 15 known *eligible* participants. Most of the reduction was due to failure to have had a claim for cancer during the year before the program started or during the six-month enrollment window. The comparison of participants to eligible nonparticipants in Table 2, however, excludes only one participant who

Comparison of Participants and Eligible Nonparticipants. According to an analysis of Medicare enrollment and claims data, program participants and eligible nonparticipants were demographically similar. The average age of participants was 76, one-third were male, and most (92 percent) were white (Table 2).[18] Participants were more likely to be poor, as reflected by their eligibility for Medicaid, and more likely to be entitled to Medicare through the disability or ESRD categories, but none of these differences were statistically significant.

Participants and eligible nonparticipants also had similar chronic conditions. During the two years before enrolling, all participants had been treated for cancer, the target diagnosis for Quality Oncology.[19] Participants also had several comorbidities that the program did not target. About half of participants and nonparticipants had coronary artery disease, 40 percent had chronic obstructive pulmonary disease, and one-quarter had diabetes. Thirty-eight percent of participants and 23 percent of nonparticipants had been treated for stroke.

Participants had substantially higher hospitalization rates and total Medicare spending than eligible nonparticipants. In the year before enrollment, about 71 percent of participants had a hospitalization and had monthly Medicare reimbursements of $3,271, compared to a 53 percent hospitalization rate and $2,463 in monthly Medicare reimbursements for eligible nonparticipants.

(continued)
did not meet Medicare-wide requirements, leaving 24 participants. Thus, that comparison more closely reflects the differences between all actual participants and those who might have participated.

[18] Although the program's exclusion criteria list age less than 65, it has enrolled two participants younger than age 65 (apparently through an oversight).

[19] All eligible nonparticipants in Table 2 meet Quality Oncology's definition for cancer, as operationalized in Medicare claims data. However, in the section in Table 2 entitled "Medical Conditions Treated During Two Years Before Month of Intake," not all eligible nonparticipants are shown as having cancer, because these conditions were identified through standard definitions the evaluator developed for use across *all* the MCCD programs, and the standard definition for cancer differs from Quality Oncology's. For example, it does not contain the procedure codes that Quality Oncology uses.

TABLE 2

CHARACTERISTICS OF ALL PARTICIPANTS AND ELIGIBLE NONPARTICIPANTS DURING THE FIRST SIX MONTHS OF PROGRAM ENROLLMENT
(Percentages, Unless Otherwise Noted)

	Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Age at Intake			
Average age (in years)	75.7	77.2	
Younger than 65[b]	8.3	0.0[b]	***
65 to 74	37.5	37.2	
75 to 84	45.8	47.8	
85 or older	8.3	15.0	
Male	33.3	32.0	
Nonwhite	8.3	6.5	
Original Reason for Medicare: Disabled or End Stage Renal Disease (ESRD)	12.5	5.4	
State Buy-In for Medicare Part A or B	12.5	6.4	
Newly Eligible for Medicare (Eligible Less than Six Months)	0.00	0.65	
Enrolled in Fee-for-Service Medicare Six or More Months During Two Years Before Intake	100.0	97.6	
Medical Conditions Treated During Two Years Before Month of Intake[c]			
Coronary artery disease	50.0	49.4	
Congestive heart failure	16.7	19.2	
Stroke	37.5	22.7	*
Diabetes	25.0	23.7	
Cancer	100.0	92.2[c]	
Chronic obstructive pulmonary disease	41.7	39.7	
Dementia (including Alzheimer's disease)	4.2	3.0	
Peripheral vascular disease	8.3	10.2	
Renal disease	4.2	5.2	
Total number of diagnoses (number)	2.9	2.7	
Days Between Last Hospital Admission and Intake Date[d]			
No hospitalization in past two years	16.7	34.6	*
0 to 30	29.2	9.7	***
31 to 60	8.3	5.2	
61 to 180	20.8	17.3	
181 to 365	12.5	20.3	
366 to 730	12.5	12.8	

TABLE 2 *(continued)*

	Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Annualized Number of Hospitalizations During Two Years Before Month of Intake[d,e]			
0	20.8	36.3	
0.1 to 1.0	66.7	41.9	**
1.1 to 2.0	8.3	14.0	
2.1 to 3.0	4.2	4.4	
3.1 or more	0.0	3.5	
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[d]			
Part A	$867	$979	
Part B	$2,404	$1,484	***
Total	$3,271	$2,463	
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[d]			
$0	0.0	0.5	
$1 to 500	0.0	18.5	**
$501 to 1,000	8.3	15.0	
$1,001 to 2,000	25.0	20.2	
More than $2,000	66.7	45.9	**
Number of Beneficiaries	**24**	**1,840**	

Source: Medicare Enrollment Database and National Claims History File.

Note: The intake date used in this table is the date of enrollment for participants. For eligible nonparticipants, the intake date is November 15, 2002, roughly the midpoint of the six-month enrollment period examined.

[a] Participants who do not meet CMS's demonstration-wide requirements for the demonstration or who had an invalid HIC number on MPR's enrollment file are excluded from this table because we do not have Medicare data showing their reimbursement in the fee-for-service program. Members of the same households as the research sample members are included.

[b] Although the program's exclusion criteria lists age less than 65 (and thus all eligible nonparticipants are age 65 or older), it has enrolled two participants younger than age 65.

[c] All eligible nonparticipants in this table meet Quality Oncology's definition for cancer, as reproduced using diagnosis and procedure codes in Medicare claims data. However, not all eligible nonparticipants are shown as having cancer in this section because these conditions were identified through standard definitions developed by the evaluator for use across *all* of the MCCD programs, and the standard definition for cancer does not contain the procedure codes used by Quality Oncology.

[d] Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. (See Note, above, concerning intake date definition.)

[e] Calculated as 12 x (number of hospitalizations during two years before month of intake) / (number of months eligible). For example, if a beneficiary was in fee-for-service all 24 months and had two hospitalizations during that time, they would have one hospitalization per year [(12 x 2) / 24]. If another beneficiary was in fee-for-service eight months during the previous two years, and had two hospitalizations during those eight months, they would have [(12 x 2) / 8], or three hospitalizations per year. The estimate of the proportion with

TABLE 2 *(continued)*

no hospitalization in the two years before the month of intake may differ slightly from the proportion with no hospitalization in the two years before the date of intake because the two measure slightly different periods. Someone enrolled on September 20, 2003, whose only hospitalization in the preenrollment period occurred on September 5, 2003, would not be counted as hospitalized during the 24 months before the month of intake. Conversely, someone hospitalized on September 25, 2001, would be captured in the measure defined by month of enrollment but not in the measure based on the day of enrollment.

*Difference between participants and eligible nonparticipants significantly different from zero at the .10 level, two-tailed test.

**Difference between participants and eligible nonparticipants significantly different from zero at the .05 level, two-tailed test.

***Difference between participants and eligible nonparticipants significantly different from zero at the .01 level, two-tailed test.

Participants were also three times as likely as nonparticipants to have had a hospitalization in the month before intake (29.2 versus 9.7 percent).[20]

When developing the cost estimate for the Quality Oncology waiver application, MPR estimated that Medicare reimbursements would average $3,645 per month for eligible beneficiaries who did not participate in the program.[21] With average monthly reimbursements of $3,271 before enrollment, it thus appears that the program has enrolled patients who are as costly as planned.

Satisfaction and Voluntary Disenrollment. Quality Oncology staff report that, anecdotally, patients are very satisfied with the program. One patient attributed her living as long as she had to her care manager. Another patient, overwhelmed by the burdens of caring for his wife and going through his own treatment, told his care manager she was "sent from heaven."

Patients may stay in the Quality Oncology MCCD for the duration of the demonstration (that is, until April 2006). Quality Oncology plans to only close cases or discharge patients who die or move away from the program's MCCD service area. Among the 12 patients receiving the Quality Oncology MCCD intervention who enrolled over the first six months of operation, 42 percent (five patients) were enrolled 10 weeks or less, 16 percent (two patients) were enrolled between 11 and 20 weeks, and 42 percent (five patients) were enrolled 21 or more weeks (Table 3). No patients voluntarily disenrolled during the first six months of the program.

[20] November 15, 2002, is used as a pseudo-enrollment date for nonparticipants.

[21] Waiver cost calculations for all the demonstration projects assume that each project will reduce Medicare costs by 20 percent. If the assumptions are correct, the project will save Medicare an average of $377 per patient, per month, or approximately $15,648,869 over the four-year life of the demonstration, assuming 1,426 beneficiaries will be randomly assigned to the treatment group. These estimates are net of the demonstration's costs of $117 per patient, per month (the fee paid by CMS to the project) but do not include the costs of the evaluation.

TABLE 3

DISENROLLMENT FOR PATIENTS ENROLLED DURING FIRST SIX MONTHS

Number of Treatment Group Patients Enrolled[a]	12
Length of Enrollment as of March 16, 2002 (Percentage of Patients Enrolled)	
10 weeks or less	42.0
11 to 20 weeks	16.0
21 or more weeks	42.0
Mean Length of Enrollment (Weeks)	15.2
Number of Patients Who Disenrolled	3
Number Who Disenrolled Because:	
Patient died	2
Patient lost program eligibility[b]	1
Patient initiated disenrollment	0
Number Disenrolling:	
Within a week after random assignment	0
Between 1 and 4 weeks	1
Between 5 and 12 weeks	0
More than 12 weeks	2

Source: Quality Oncology program data received April 2003 and updated July 2003. Covers six-month period beginning September 18, 2002, and ending March 16, 2002.

[a]Number of patients ever enrolled in the treatment group through March 16, 2002.

[b]Patients can lose program eligibility for the following reasons: Medicare no longer primary payer; joined a managed care plan; entered a nursing home, long-term care facility, or hospice; or moved out of the program's service area.

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

Physician engagement appears to be a central feature of successful care coordination programs (Schore et al. 1999; Chen et al. 2000).

Relationship Between Physicians and Care Managers. Recognizing physicians' desire to avoid additional burden on their practices, the Quality Oncology MCCD requires little of physicians. It only requests that physicians keep the program in mind for suitable patients and tell them about it. The original referral process asked physicians to fill out a half-page form (see Appendix C) with the type and stage of cancer and names of all treating physicians they know of and to forward selected medical records (pathology and operative reports, oncology consultation reports, cancer-related diagnostic studies, and treatment plan) to the program. In practice,

however, to minimize the burden on physicians' practices, the MCCD outreach and enrollment coordinator has been collecting as much of this information as possible from the physicians' patient charts herself. The Quality Oncology MCCD is sensitive to physician concerns about extra work for their office staff—one physician became highly irritated after he received a written request for information because he felt the program was imposing on his practice. When the MCCD needs follow-up medical records on enrollees who have been hospitalized or undergone tests or procedures, it again relies as much as possible on the MCCD outreach and enrollment coordinator gathering this data on her next recruitment visit to the practice.

Care managers have no regularly scheduled communication with physicians or their offices. Care managers will call physicians about worrisome symptoms that patients report. A care manager might send an occasional update form to a physician's office if she has information she considers important to convey. As mentioned, ICM allows the nurse care managers to fax forms and letters directly to doctors' offices. These updates were infrequent, but program staff informed the evaluator at its site visit in May 2004 that, to improve physician engagement, they planned to increase the number of ICMS-generated progress reports sent to physicians. Program staff guessed that care managers might contact a physician once a month, on average, for the "typical" patient and once a week for the more complex patient.

It is difficult to gauge how well Quality Oncology's efforts to engage physicians are succeeding, since only nine physicians are participating in the program. These physicians, especially with the efforts of the current project director, have been cooperating with the MCCD by allowing access to their offices and medical records. The Quality Oncology staff did feel that communication with physicians could be better. For example, they wished that physicians would notify the care managers about hospitalizations. Often, the most helpful people in the oncology practices are the chemotherapy nurses. After the MCCD outreach and enrollment coordinator

has developed a relationship with a chemotherapy nurse in a practice, that nurse will generally return telephone calls from the Quality Oncology care managers, provide them with additional information on enrollees, or make sure that patients receive needed tests or appointments.

Improving Practice. Unlike in its programs for managed care plans, Quality Oncology's MCCD does not have improving provider practice as a major goal. Care managers are to inform the medical director if an enrollee's treatment plan deviates from Quality Oncology's practice guidelines, and the medical director may contact the treating physician. In the first year of the MCCD, however, the medical director has not felt it necessary to contact any physicians.

The Quality Oncology MCCD is aware that it clearly does not have the clout with patients' oncologists in the Medicare FFS environment that it does in the managed care setting. Therefore, the program is cautious about offering treatment recommendations that patients' physicians may not welcome or even about advising patients to question their physicians' decisions.

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

Quality Oncology's MCCD is emphasizing (1) patient education and empowerment, and (2) communication and coordination between patients and their physicians as the two primary approaches to improving participants' health and reducing unnecessary health care utilization and costs.

Improving Patient Self-Care. Care managers' main patient education task is generally to help patients get through the rigors of treatment as best they can by teaching them how to anticipate and deal with the effects of cancer and the predictable complications of treatment. Patients often fail to understand that cancer pain can and should be controlled and do not inform their providers about their pain. Undertreated pain may escalate to a crisis, leading to avoidable

suffering, emergency room visits, and hospitalizations. Care managers explain to patients the importance of communicating and getting treatment for their pain and help make sure that they are equipped with a plan and adequate analgesics for pain control. Dehydration from treatment-induced nausea, vomiting, and diarrhea is another common problem for cancer patients that, if not managed properly at home, can lead to preventable hospitalizations.

Because ICM stores important dates and milestones in patients' treatment and reminds the nurse care managers of them through the daily ticklers, the nurse care managers can "prep" their patients for upcoming chemotherapy and radiation therapy when they most need the information. The nurses instruct patients in strategies to counter dehydration, nausea, vomiting, or diarrhea and to manage fatigue and weakness. As mentioned earlier, the nurses also call daily for the first two days *after* chemotherapy to see how the patient is doing. For patients receiving chemotherapy that lowers white blood cell counts and causes immune suppression, nurses can explain at the time that the white blood count "nadirs" or reaches its lowest point (usually about 7 to 10 days after chemotherapy), what signs and symptoms of infection patients should look out for, and when to call the doctor.

ICM contains embedded tools to determine patients' specific educational needs in standard education topics. The care managers working with MCCD patients have also begun using an educational assessment form developed by the primary MCCD care manager specifically for MCCD enrollees. From within ICM, care managers can order educational pamphlets directly from the American Cancer Society and the National Cancer Institute, or the National Coalition for Cancer Survivorship's Cancer Survival Toolbox, to be mailed to patients. ICM also keeps a record of the educational literature that each patient has been sent. Finally, care managers refer patients and family members to Quality Oncology's cancer support website, www.cancerpage.com. This website is a resource for cancer information. In addition, it has an

interactive decision support tool for exploring treatment options, online support group chatrooms, an interface to send questions to care managers, and a tool for patients and family members to track physician visits, interactions with care managers, and treatment complications.

Care managers assess patients' understanding and retention of educational messages using ICM standardized question sets, to which care managers add their own questions. Examples of such questions are: "What did you learn?" "Did you try the protein shakes I suggested?" "How many did you try?" and "Is there something you would like me [the care manager] to research for the next time we talk?" Care managers address comorbidities and lifestyle issues mainly as they relate to the patient's cancer. The program does not enroll cognitively impaired patients, but care managers must still work with patients who develop depression (which often impairs memory) after entering the program or who suffer acute cognitive declines as a result of treatment. The program has served few non-English speaking patients. Bilingual care managers are available, however, including the main care manager for the MCCD, who speaks English and Spanish (translation services are also available). Care managers report that the MCCD patients "really listen and follow directions . . . they say 'OK, I'll try it' [care managers' suggestions] and they really do try it."

Among the 12 patients enrolled in Quality Oncology's MCCD during its first six months, half (50 percent) had received at least one contact for disease-specific or self-care education, and one-third (33 percent) of patients had at least one contact during which the nurse care manager explained medications (Table 1). The relatively low proportion of enrollees receiving contacts for disease-specific or self-care education may be related to only 58 percent of enrollees having had an initial assessment contact to start with or perhaps to the timing of patient education depending on the patient's schedule for chemotherapy or radiation therapy.

Enhancing Communication and Coordination. The Quality Oncology MCCD makes communication between patients and their physicians easier in several ways. One way is by conveying the knowledge and skills patients need to make informed decisions about their cancer treatment. Patients often are frightened and anxious after learning they have cancer and have difficulty absorbing all of the detailed information about treatment options they are initially bombarded with. The nurse care manager assesses how well the patient has understood his or her doctor's proposed treatment plan. She often has more time than busy oncologists and oncology nurses to explain diagnosis and treatment to the patient, and the patient often is better able to grasp this information and formulate questions at home than in the physician's office.

One of the care managers' first coordination tasks may be to counsel patients to receive care locally. Some patients' initial reaction to a cancer diagnosis is to seek treatment from distant academic, tertiary-care centers, but such journeys disrupt patients' natural support systems, impose stress on patients on their families, and complicate arrangements for follow-up, rehabilitative, and home care. Cancer patients' immune systems are often already suppressed, and prolonged hospitalizations at distant tertiary-care centers increase risk of hospital-acquired infections. Care managers help patients understand that, for common cancers, local facilities often are perfectly capable of delivering state-of-the-art care. For these common cancers, tertiary-care centers provide care whose quality is no higher than that of community facilities but at much greater cost.

The company says that its care managers have become skilled in helping families maintain communication during the emotional upheavals that a dying cancer patient can precipitate. A common problem, for example, is that family members' guilt is channeled into obtaining more treatment, regardless of outcome or emotional and physical impact on the patient. Care managers can help the well-meaning family members and the patient communicate better—often

allowing the patient to express his or her desire to not be subjected to more futile treatment efforts and to explore hospice as an option.

As a rule, care managers try to have patients make their own calls to physicians, since it is one of the program's goals to teach and empower patients to contact and communicate with physicians when appropriate. For example, a patient reported to her care manager that she was having shortness of breath while performing daily tasks such as grocery shopping. The care manager, suspecting anemia, told the patient that her symptoms were serious and advised her to call her physician to have the oxygen level in her blood measured. The patient telephoned her physician, was given an appointment, and was indeed found to have a low blood oxygen level. Although the patient required hospitalization, the problem was addressed quickly, and she is now home with portable oxygen. To prepare patients for visits with their oncologists, the care manager may help them list specific questions, such as what side effects to expect from chemotherapy or radiation therapy.

Depending on the situation, however, the care managers may take a more active role. They may serve as "information conduits" between patients and their physicians. Patients often do not bring up important symptoms or worries during time-pressured doctor visits because they think they are not worth bothering the physician with. Nurse care managers often uncover these problems through frequent contact, empathetic listening, and gentle probing during reassessments, then convey them to the physicians. One nurse care manager, for example, found symptoms of depression during a patient's initial assessment and described this in the report she faxed to the patient's physician. At her next contact with the patient a few days later, the nurse care manager learned that the physician had started the patient on an antidepressant.

Care managers also will call physicians' offices directly for emergencies such as severe vomiting. For example, a patient experiencing dizziness was having trouble getting past her

physician's answering machine. The care manager got through to the physician's office and had the physician telephone the patient directly. The patient was seen for an appointment that day. In another instance, a patient with memory problems living in an assisted-living facility was at risk from dehydration from chemotherapy. The MCCD care manager made sure a nurse's aide at the assisted-living facility knew to call her if the patient's condition worsened acutely but the patient forgot how to call.

The medical director described the care managers as skilled at not becoming embroiled in disputes between patients' physicians over difficult treatment choices or becoming a "referee" between physicians. The typical example is a patient with newly diagnosed prostate cancer for whom the urologist often will recommend surgery and the radiation oncologist radiation therapy. Care managers will tell the patient that both options are acceptable, since both are considered within treatment guidelines. They may still help patients by providing factual information, however. One of the care managers described a patient who was very grateful to her for having suggested that he have a CAT scan.

Care managers also aim to improve coordination by tracking patients' unexpected health care events, such as hospitalizations or trips to the emergency room. With the patient and his or her caregiver, the care manager tries to develop a plan to prevent future occurrences. She will also try to learn diagnostic findings or therapeutic decisions from the hospital stay and whether the patient is on any new medications or seeing any new physicians. If the hospital admission was cancer related, the care manager will most likely call the patient's oncologist or the oncologist's office for details. If the admission was completely unrelated to the cancer, however, the nurse might not pursue contacting other specialists, such as endocrinologists.

The Quality Oncology staff noted that, compared to their usual managed care patients, for whom they are notified of admission almost immediately, it was harder for them to find out

when their MCCD participants had been hospitalized. Quality Oncology must learn of an MCCD enrollee's hospitalization through the patient or the physician.

Care managers generally do not get involved in the details of making sure that events occur in the appropriate order, such as reminding patients to fast for a test, or checking to see that laboratory results are available at the time of a physician visit. However, they do try to ensure that patients receive the treatments and follow-up care specified in the care plan. A care manager would call a patient due for a follow-up scan to make sure he or she had received the scan and would get a copy of the results for the patient's ICMS record.

Increasing Access to Services. Although increasing access to services is not a primary intervention approach for Quality Oncology's MCCD, the program does refer patients to a wide variety of services, and, if necessary, arranges services on their behalf. Elderly patients starting chemotherapy often are afraid of driving, and the care managers will arrange transportation to chemotherapy and other medical appointments for patients without friends or family to drive them. The care managers will schedule follow-up calls to make sure the arrangements are working. Other services that the program refers to include durable medical equipment (particularly canes and walkers), meals, home health care, personal or companion care, respite care, hospice care, and mental health counseling. The primary MCCD care manager had compiled a large binder of local resources specifically for Medicare FFS beneficiaries that the other care managers had nicknamed the "bible."

Quality Oncology's MCCD does not pay for any non-Medicare-covered services. Care managers refer patients who have difficulty affording oral prescription drugs, medical equipment, or supplies (for either cancer-related problems or comorbid conditions) to medication assistance programs, and the care managers help patients complete the application forms. The

program encourages patients to participate in clinical trials of cancer therapies, especially if conventional treatment options have been exhausted.[22]

During the first six months of the program, Quality Oncology did not purchase any goods or services for participants. Care managers did not identify any needs for Medicare- or non-Medicare-covered services among the 12 patients enrolled during that period (Table 1).

WHAT WERE ENROLLEES' SERVICE USE AND COSTS?

This report provides preliminary estimates of the effect of Quality Oncology on Medicare service use and expenditures. These early estimates must be viewed with caution, as they are not likely to be reliable indicators of the true effect of the program over a longer period. Due to lags in data availability, analysis for this report included only an early cohort of enrollees (those enrolling during the first four months of program operation) and allowed observation of their experiences during their first two months in the program. The estimates thus include patients' experiences only during the program's first six months of operation, when staff still may have been fine-tuning the intervention. Moreover, the program enrolled few patients over the first four months and may enroll patients with quite different characteristics in the future.

Total Medicare Part A and B reimbursements for the treatment group, exclusive of demonstration payment, were $13,701 ($6,851 per month), on average, during the first two months after enrollment, compared with $10,700 ($5,350 per month) for the control group (Table 4). This treatment-control difference of $3,000 ($1,500 per month), or 14 percent, is not statistically significant ($p = 0.60$), due to the small sample size. The CMS per-member, per-

[22] Clinical trial sponsors often will provide experimental drugs to participants for free, and Medicare now covers doctor's visits and tests that are part of a clinical trial.

TABLE 4

MEDICARE-COVERED SERVICE USE DURING THE TWO MONTHS AFTER THE MONTH OF RANDOMIZATION, FOR EARLY ENROLLEES

	Treatment Group	Control Group	Difference[a]	
Inpatient Hospital Services				
Any admission (percent)	11.1	10.0	1.1	
Mean number of admissions	0.11	0.20	–0.09	
Mean number of hospital days	1.00	4.00	–3.00	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	0.0	10.0	–10.0	
Not resulting in admission	0.0	0.0	0.0	
Total	0.0	10.0	–10.0	
Mean number of emergency room encounters				
Resulting in admission	0.00	0.10	–0.10	
Not resulting in admission	0.00	0.00	0.00	
Total	0.00	0.10	–0.10	
Skilled Nursing Facility Services				
Any admission (percent)	11.1	10.0	1.1	
Mean number of admissions	0.11	0.10	0.01	
Mean number of days	4.78	0.80	3.98	
Hospice Services				
Any admission (percent)	0.0	10.0	–10.0	
Mean number of days	0.00	1.30	–1.30	
Home Health Services				
Any use (percent)	22.2	20.0	2.2	
Mean number of visits	6.33	12.00	–5.67	
Outpatient Hospital Services[b]				
Any use (percent)	22.2	30.0	–7.8	
Physician and Other Part B Services[c]				
Any use (percent)	77.8	80.0	–2.2	
Mean number of visits or claims	30.0	19.2	10.8	
Mortality Rate (Percent)	0.0	20.0	–20.0	
Total Medicare Reimbursement[d]				
Part A[e]	$2,608	$3,561	–$953	
Part B	$11,093	$7,139	$3,954	
Total	$13,701	$10,700	$3,000	
Reimbursement for Care Coordination[f]	$207	$0	$207	***
Number of Beneficiaries	**9**	**10**		

TABLE 4 *(continued)*

Source: Medicare National Claims History File.

Note: Sample includes those enrolled during the first four months of program operations. Participants were excluded from this table if they had an invalid HIC number on MPR's enrollment file, were identified as a member of the same household as a research sample member, or did not meet Medicare coverage and payer requirements (defined as having Medicare as a secondary payer, being in Medicare managed care plan, or not having Part A and Part B coverage) during the month of randomization. Patient-months were excluded if the participant did not meet the above Medicare coverage and payer requirements that month or had died in a previous month.

"Percents with any medical encounter type" are the percent of treatment or control group members who have at least one encounter of a particular type; "mean numbers of medical encounter types" are the average number of encounters of a particular type per treatment or control group member.

[a] These estimates are based on preliminary data and will be updated in the second site-specific report.

The direction of the treatment-control difference does not by itself signify whether the program is "effective." That is, for some outcomes, a statistically significant negative difference (such as lower hospitalization rates for the treatment group than for the control group) suggests that the program is working as intended. However, a positive difference for other outcomes, such as number of physician visits, does not necessarily mean the program is ineffective or having adverse effects, because the program may encourage patients to see their physician more regularly for preventive care or to obtain recommended laboratory tests for their target conditions than they would have in the absence of the demonstration.

Due to rounding, the difference column may differ slightly from the result when the control column is subtracted from the treatment column.

[b] Includes visits to outpatient hospital facilities, as well as emergency room visits that do not result in an inpatient admission. Laboratory and radiology services are also included.

[c]Includes diagnostic laboratory and radiology services (including pathologist and radiologist services) from nonhospital providers, suppliers and devices, mammography, ambulance, covered medications, blood, and vaccines.

[d]Does not include reimbursement for care coordination services provided by demonstration programs.

[e]Includes reimbursement for inpatient, skilled nursing facility, hospice, and all home health care (including that paid under Medicare Part B). Excludes reimbursement for care coordination services provided by demonstration programs.

[f]This is the average amount paid to the program as recorded in the Medicare claims data for the two months following randomization. The difference between the recorded amount and two time the amount the program was allowed to charge per member per month may reflect billing errors, delays, or payment adjustments for patients who disenrolled.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.

**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.

***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

month payment to the program averaged $207 (or $104 per month).[23] The sample enrolled during the first four months is too small to allow the evaluation to draw even preliminary conclusions about early program effects.

The evaluation also examined monthly trends in treatment-control differences from September 2002 through February 2003, the first six months of program operation (Table 5). Again, the sample enrolled in each of these months is too small to draw inferences. The table is included only to demonstrate the types of analyses the evaluation will conduct in the future.

CONCLUSION

Research during the past decade suggests, but is by no means conclusive, that successful care coordination has many features. These include effective patient identification, a well-designed and structured intervention, highly qualified staff, physician buy-in, and financial incentives aligned with program goals.

First, to generate net savings over a relatively short period, effective programs tend to target high-risk people. These people may include those with recognized high-cost diagnoses, such as heart failure (or cancer, in this case), but also those with prevalent geriatric syndromes, such as physical inactivity, falls, depression, incontinence, misuse of medications, and undernutrition (Rector and Venus 1999; and Fox 2000).

Second, successful programs tend to have a comprehensive, structured intervention that can be adapted to individual patient needs. One key feature is a multifaceted assessment whose end product is a written care plan that can be used to monitor patient progress toward specific long-

[23] The per-member, per-month fee the program charges is $140, or $280 over the two-month period. The lower means in Tables 4 and 5 may have resulted from delays in assessments, billing errors, payment delays, or payment adjustments for patients who disenrolled or died.

TABLE 5

MONTHLY MEDICARE SERVICE USE FOR PARTICIPANTS WHO ENROLLED DURING THE FIRST SIX MONTHS OF PROGRAM OPERATIONS

	Group	Sep 02	Oct 02	Nov 02	Dec 02	Jan 03	Feb 03
Cumulative Enrollment Through Month End	Treatment	4	5	5	6	9	10
	Control	4	7	7	7	9	9
Mean Number of Beneficiaries Enrolled Who Meet Medicare Coverage and Payer Requirements and Are Alive That Month	Treatment	4	5	5	6	9	9
	Control	4	7	6	6	6	6
Average Medicare Reimbursement During the Month[a]	Treatment	$13,659	$7,879	$6,988	$5,900	$4,310	$3,420
	Control	$10,064	$6,637	$8,780	$10,819	$3,521	$4,990
Average Reimbursement for Care Coordination During the Month[a,b]	Treatment	$180	$148	$140	$117	$118	$82
Whether Admitted to Hospital This Month[a] (Percentage)	Treatment	25.0	0.0	0.0	16.7	22.2	33.3
	Control	50.0	28.6	16.7	16.7	16.7	16.7
Treatment-Control Difference[c]							
Average Medicare Reimbursement[a]		$3,596	$1,242	–$1,792	–$4,920	$789	–$1,569
Average Reimbursement for Medicare plus Care Coordination[a]		$3,776	$1,390	–$1,652	–4,803	$907	–$1,487
Percentage Hospitalized[a]		–25.0	–28.6	–16.7	0.0	5.6	16.7

Source: Medicare National Claims History File.

[a] Participants were excluded if they died in a previous month or failed to meet the Medicare coverage and payer requirements during the month of randomization or the month examined—that is, if they were in a Medicare managed care plan, had Medicare as a secondary payer, or did not have both Part A and Part B coverage. Participants were also excluded entirely from this table if they had an invalid HIC number on MPR's enrollment file.

[b] This is the average amount paid to the program as recorded in the Medicare claims data. The difference between the recorded amount and the program's approved per member per month fee may reflect billing errors, delays, or payment adjustments for patients who disenrolled.

TABLE 5 *(continued)*

[c] These estimates are based on preliminary data and will be updated in the second site-specific report.

The direction of the treatment-control difference does not by itself signify whether the program is "effective." That is, for some outcomes a statistically significant negative difference (such as lower hospitalization rates for the treatment group than for the control group) suggests that the program is working as intended. However, a positive difference for other outcomes, such as number of physician visits, does not necessarily mean the program is ineffective or having adverse effects, because the program may encourage patients to see their physician more regularly for preventive care or to obtain recommended laboratory tests for their target conditions than they would have in the absence of the demonstration.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.
**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.
***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

and short-term goals and that is updated and revised as the patient's condition changes (Chen et al. 2000). Another is a process for providing aggregate- and patient-level feedback to care managers, program leaders, and physicians about patient outcomes (Chen et al. 2000). A third key feature is patient education that combines the provision of factual information with techniques to help patients change self-care behavior and better manage their care and that addresses affective issues related to chronic illness (Williams 1999; Lorig et al. 1999; Vernarec 1999; Roter et al. 1998; Aubry 2000). Finally, successful programs tend to have structures and procedures for integrating fragmented care and facilitating communication among providers, to address the complexities posed by patients with several comorbid conditions, and, when necessary, to arrange for community services (Chen et al. 2000; Bodenheimer 1999; Hagland 2000).

The third and fourth characteristics that have been associated with successful programs are having highly trained staff and actively involved providers. Strong programs typically have care managers who are baccalaureate-prepared nurses or who have case management or community nursing experience. They also tend to have the active support and involvement of patients' physicians (Chen et al. 2000; Schore et al. 1999).

Finally, periodic feedback during the demonstration period can motivate providers and care managers and enable the program to modify or intensify the intervention if it appears that it is not having the expected effect on intermediate or ultimate outcome indicators. Financial incentives can help encourage physicians and program staff look for creative ways to meet patient goals and reduce total health care costs (Schore et al. 1999).

Program Strengths and Unique Features. Quality Oncology's MCCD is unique among the 16 demonstration programs nationwide in its exclusive focus on cancer. Advances in

treatment have made a few types of cancer into chronic illnesses that, like diabetes or heart failure, are incurable but controllable over many years with medications and monitoring.

Most cancers, however, differ from the most common prototypical chronic illnesses targeted in the MCCD—diabetes, heart failure, and coronary artery disease. Much of what happens to cancer patients in this initial period is done *to* them. Much of what happens to patients suffering from other chronic conditions over the course of the illness depends on what is done *by* them—adhering to medications, making long-term changes in lifestyle, and performing self-monitoring.

The most important difference is in the time frame and nature of disease treatment and progression. Most cancer patients need to just "get through" the physically and emotionally demanding period immediately following the initial diagnosis, during which they undergo a set of harsh, toxic treatments (chemotherapy, surgery, and/or radiation therapy) over a period of a few months. After the initial period, an assessment is made of tumor response, with next steps dependent on treatment success or failure. This time course is quite different than in typical chronic illnesses, for which patients' conditions tend to fluctuate between exacerbations and remissions over the rest of their lifetimes (patients with coronary artery disease may have an initial flurry of procedures with coronary bypass surgery or coronary angioplasty, but then they, too, settle down to a more chronic course).

Not surprisingly, then, compared to the other MCCD programs, Quality Oncology's MCCD program focuses less on effecting long-term behavioral changes in patients (although it does focus on improving self-care to help manage side effects). The program's emphasis is on helping patients avoid predictable treatment complications in the short term. To a lesser degree, the program also tries to provide patients with knowledge and confidence to participate more fully in treatment decisions with the goal of reducing use of toxic, expensive treatments whose

harms may exceed their benefits and use of costly diagnostic tests that provide little marginal information.

Another unique aspect of cancer and Quality Oncology's program is that cost impacts, if any, should appear relatively early after patients' enrollment, compared to the targeted conditions and interventions in the other MCCD sites. Quality Oncology believes most of its effectiveness will be through reduction of preventable hospitalizations, with some possible effects on inappropriate use of diagnostic imaging and second- or third-line cancer treatments, all of which usually occur in patients' first several months of treatment. In contrast, improved management of other chronic illnesses may not pay off in reductions of adverse events and health care utilization for many months, or even years.

Despite these differences from the other MCCD demonstration programs, many features of the general framework that MPR has developed to describe coordinated care programs still apply to Quality Oncology's MCCD. According to this framework, the program has several commendable characteristics:

- The program enrolls patients being actively treated for cancer, a ***target population with high, expected health care costs,*** and enrolled patients do indeed have the expected high costs.
- Nurse care managers conduct a ***multifaceted, individualized assessment*** appropriate for cancer patients. The assessment is guided by Quality Oncology's electronic decision support and medical record system. The system also helps to create an ***individualized patient care plan with goals*** that monitors patient progress and is updated in response to patients' symptoms and completions of treatment milestones. Patient monitoring is tailored to patients' acuity, which is periodically reassessed. The system provides electronic tickler lists and tracking of interventions.
- The ongoing audits of the quality of nurse care managers' documentation and sharing of nurse care manager-level reports constitute a sophisticated ***system for providing ongoing feedback on patient outcomes*** to team leaders and nurse care managers.
- Quality Oncology's MCCD seems to have developed an ***effective patient education program***, using educational needs assessment. Care managers can order educational materials to be mailed to patients from within ICM, and the system tracks what

patients have been sent. The care managers seem very skilled in counseling patients on how to deal with common treatment complications. ***Providing emotional support*** is also a central aspect of nurse care managers' functions.

- The program tries to ***reduce care fragmentation and facilitate communication*** among providers and patients by teaching patients to call their oncologist when appropriate and empowering them to do so. Care managers work to uncover modifiable factors that can prevent repeated unexpected hospitalizations. They also help ***improve access to services*** by arranging transportation and referring patients to community services, cancer support programs, and medication assistance programs.

- ***Nurse care managers are highly qualified and experienced nurses.*** Quality Oncology has designed a rigorous initial training, mentoring, and supervision program for new care managers, as well as extensive continuing education efforts for regular care managers.

- Finally, the MCCD is undergoing regular ***quality monitoring***. The system contains a wealth of up-to-date data for assessing program performance, which senior management review every two weeks. Should the MCCD ever reach enrollment comparable to that of Quality Oncology's other health plan clients, it will undergo the same systematic quality monitoring and improvement reviews as the other programs.

Potential Barriers to Program Success. Although Quality Oncology's MCCD has many features associated with successful programs, the program's slow enrollment is a concern. Small sample sizes clearly limit the evaluation's ability to detect impacts. The new outreach and enrollment manager's approach of recruiting patients through face-to-face meetings seems to be working better than previous approaches, but it is time-consuming and labor intensive. The small size of Quality Oncology's MCCD has also meant that it does not yet have its own team, with dedicated care managers supervised by a team leader. To the extent that a team's performance improves with development of expertise in its patient population, the MCCD is not enjoying the advantages of such specialization. The MCCD is also not yet large enough to benefit from the regular quality assurance reviews of computerized data that Quality Oncology's programs for other health plan clients undergo.

Although the enrollment is too small to detect any real trends, 42 percent of enrollees had not had an assessment contact as of the cutoff date for the care manager contact data presented in

Table 1, and among those with an assessment, 57 percent were not contacted for their initial assessment until two or more weeks after random assignment. The program guidelines are for initial assessment to occur within three to seven days and, ideally, within one day. Enrollment records show that most enrollees had been randomized several weeks before the cutoff date for the data in Table 1. Care managers reported that these delays were due to scheduling difficulties with the few patients who were still working. Since cancer treatments and cancer symptoms may both progress fairly rapidly, program delays in initial assessment, care planning, and implementation of interventions may lead to missed opportunities for program benefits.

Lack of physician support may also be a barrier to program success. Only a few physicians in the counties served by the MCCD currently participate, and reception of the program among the larger oncology community seems to have been lukewarm at best. Reportedly, physicians have not considered the $40 per patient payment for participation to be much of an incentive. Without physicians' support of the program, physicians are unlikely to keep MCCD nurse care managers up-to-date about hospitalizations, lab tests, alterations in treatment, and changes in patient status; be receptive to care managers' reports and suggestions; or reinforce nurse care manager advice to patients. To the extent that these physician behaviors contribute to program effectiveness, this apparent lack of physician support may be an impediment to program success.

Quality Oncology may have underestimated the extent to which its program for health plan clients relies upon managed care features that are absent in the Medicare FFS program. In contrast to its managed care programs, in the MCCD, Quality Oncology has little control over oncologists' choice of cancer treatment regimens, selection of treatment sites for chemotherapy administration, or use of diagnostic tests. It is unclear how much of Quality Oncology's cost savings for its client health plans depends upon controlling inappropriate physician utilization. If it is a substantial portion, Quality Oncology may find it difficult reproduce the same results in

the FFS setting and will have to substitute savings from prevented hospitalizations through patient education and monitoring for any diminished effects on physician practice. Quality Oncology staff also complained about how the lack of managed care information and notification systems hampered their ability to find out about enrollees' hospitalizations or other events. If Quality Oncology's success in managed care depends heavily on timely data on patients' health care utilization, this lack of data in the MCCD may also blunt the program's effects.

It is too early, and samples are too small, to draw any inferences yet about program impacts. For all programs participating in the demonstration, savings in hospitalizations and other expensive Medicare services will have to be large enough to cover not only direct program fees, but also any higher Part B expenses incurred as care managers refer treatment patients for Medicare-covered services that may contribute to better short- or long-term outcomes for enrollees.

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APPENDIX A

ADDITIONAL TABLES

TABLE A.1

DEMONSTRATION PROGRAMS PARTICIPATING IN THE EVALUATION

Host Organization	Organization Type	Service Area	Targeted Diagnoses
Avera Research Institute/Avera McKennan Hospital and University Health Center	Hospital	49 counties in South Dakota and 22 contiguous counties in Minnesota, Nebraska, and Iowa	CHF
Carle Foundation	Integrated delivery system	11 counties in east central Illinois and 2 counties in west central Indiana	Heart conditions Diabetes Chronic lung disease
CenVaNet	Provider of care coordination services owned by hospitals and physicians	Richmond, Virginia, metropolitan area	Heart conditions Diabetes Chronic lung disease Cerebrovascular disease
Charlestown Retirement Community	Part of Erickson Retirement Communities	2 retirement communities in the Baltimore, Maryland, metropolitan area[a]	Heart conditions Diabetes COPD
CorSolutions	Provider of disease management services	Harris, Fort Bend, Bruzoria, and Montgomery counties, Texas (Houston area)	CHF
Georgetown University Medical School	Academic institution in partnership with Medstar, owner of Georgetown University Hospital and Washington Hospital Center	Washington, DC, and parts of Maryland and Virginia	CHF
Health Quality Partners	Provider of quality improvement services	Four counties in eastern Pennsylvania	Heart conditions Diabetes Asthma Moderate to severe hyperlipidemia or hypertension
Hospice of the Valley	Hospice	Maricopa County, Arizona (greater Phoenix)	CHF COPD Cancer Neurological conditions

TABLE A.1 *(continued)*

Host Organization	Organization Type	Service Area	Targeted Diagnoses
Jewish Home and Hospital Lifecare System	Long-term care provider, in partnership with the medical practices of St. Luke's and Mt. Sinai hospitals as referral sources	Manhattan and the Bronx, New York City	Heart conditions Diabetes Chronic lung disease Cancer Liver disease Stroke or other cerebrovascular disease Psychotic disorder Major depressive or anxiety disorder Alzheimer's or other cognitive impairment
Lovelace Health Systems	Integrated delivery system	Albuquerque metropolitan statistical area (Bernalillo, Valencia, and Sandoval counties in New Mexico)	CHF Diabetes
Medical Care Development	Consortium of 17 Maine hospitals hosted by a health services research organization	Rural areas of Maine	Heart conditions
Mercy Medical Center/North Iowa	Hospital	Rural areas of Iowa	CHF Chronic lung disease Liver disease Stroke Vascular disease Renal failure
QMed	Provider of disease management services	2 counties in northern California	CAD
Quality Oncology, Inc.	Provider of disease management services	Broward county, Florida	Cancer
University of Maryland Medical School	Academic institution	Baltimore, Maryland, metropolitan area, two counties in western Maryland, four in eastern Maryland, and two in Pennsylvania	CHF
Washington University School of Medicine	Academic institution in partnership with American Healthways, a disease management services provider	St. Louis, Missouri, metropolitan area	No specific diagnoses targeted[b]

TABLE A.1 *(continued)*

Note: Each program's service area and targeted diagnoses refer to its first year of operations.

Heart conditions may include congestive heart failure (CHF); coronary artery disease (CAD); atrial fibrillation; and ischemic, hypertensive, or other heart diseases. Chronic lung disease includes asthma and chronic obstructive pulmonary disease (COPD). Neurological conditions include stroke, Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis.

[a]Charlestown added a third retirement community in April 2003.

[b]Washington University uses an algorithm developed by its demonstration partner, American Healthways, to target Medicare beneficiaries who are likely to become clinically unstable and to require hospitalization during the next 12 months.

TABLE A.2

LIST OF DOCUMENTS REVIEWED FOR THIS REPORT

Quality Oncology, Inc., Medicare Coordinated Care Demonstration (MCCD) proposal to the Health Care Financing Administration (now Centers for Medicare & Medicaid Services), dated October 2000.
LifeMetrix/Quality Oncology orientation checklist for newly hired Nurse care managers
PowerPoint slides prepared for Mathematica site visit May 2004
PowerPoint slides for physician presentation
Newspaper advertisement for MCCD
MCCD Patient Reference Guide (patient information brochure)
Patient invitation letter
Introductory letter to physicians
Fax transmission cover sheet for request for pathology report and treatment plan
Care management update form for physicians
Care management records request
Telephone script for Medicare+Choice disenrolled beneficiaries
Follow up letters to introductory calls to potential enrollees (cover letter for informed consent form and letter acknowledging receipt of signed consent form)
Unable to reach letter
Samples of member resources (brochures and informational booklets from American Cancer Society, Individual Cancer Assistance Network/Bristol-Meyers Squibb Foundation, National Cancer Institute, and so on, about support groups and services, and about specific cancers)
Selected policies from Quality Oncology Policies and Procedures manual
Sample reports from Integrated Care Management System (ICMS)
Materials from www.qualityoncology.com
Materials from www.cancerpage.com
Quality Oncology 2002-2003 Quality/Utilization/Care Management Program Description
Care Coordinator Training Materials
Care management review tool
New care manager record review tool
Assessment “cheat sheet”
New member assessment form
“Quality Oncology’s Tools”—brief summary of ICMS and clinical practice guidelines
Quality Oncology provider satisfaction survey
Quality Oncology, Inc., Medicare Coordinated Care Demonstration

APPENDIX B

METHODS USED TO ANALYZE PARTICIPATION AND PROGRAM IMPACTS

This appendix describes the methods and data sources used to analyze participation and treatment-control service use and reimbursement differences using Medicare data.

METHOD FOR CALCULATING PARTICIPATION RATE AND PATTERNS

We measured the proportion and types of beneficiaries attracted to the program by calculating the participation rate and patterns. The participation rate was calculated as the number of beneficiaries who met the program's eligibility criteria and actually participated during the first six months of the program's operations, divided by the number who met the eligibility criteria. The six-month window spanned 179 days, from September 18, 2002, through March 16, 2003. We explored patterns of participation by comparing eligible participants and eligible nonparticipants, noting how they differed on demographics, reason for Medicare eligibility, and costs and use of key Medicare services during the previous two years.

Approximating Program Eligibility Criteria

We began by identifying the program's eligibility criteria, reflecting CMS's insurance coverage and payer criteria for all programs and The Quality Oncology Inc. (Quality Oncology MCCD) specific criteria. CMS excluded beneficiaries from the demonstration who were not at risk for incurring full costs in the fee-for-service (FFS) setting because they (1) were enrolled in a Medicare managed care plan, (2) did not have both Part A and B coverage, or (3) did not have Medicare as the primary payer.

In addition to the Medicare coverage and payer requirements, Quality Oncology MCCD applied program-specific criteria to identify the target population. Table B.1 summarizes these criteria, which were approved by CMS and by the Office of Management and Budget (Brown et al. 2001). The program confirmed these criteria in spring 2003. To be considered for the program's demonstration, beneficiaries must be receiving active treatment for their cancer.

TABLE B.1

ELIGIBILITY CRITERIA

Inclusion Criteria	Patients receiving active treatment for their cancer. Active treatment is defined as surgery, radiation therapy, or chemotherapy. Patients receiving biologic therapy are eligible for participation but only if this treatment is in conjunction with radiation therapy or chemotherapy. Codes: ICD-9 code 140-17299, 174-17819, 1983-20899 **plus** CPT4 19120, 19125, 19126, 19140, 19160, 19162, 19180, 19182, 19200, 19220, 19240, 19357, 19361, 19364, 19366, 19367, 19368, 19369, 31360, 31365, 32110, 32440, 32442, 32445, 32480, 32482, 32484, 32485, 32486, 32488, 38230, 38231, 38240, 38241, 44140, 44141, 44143, 44144, 44145, 44146, 44147, 44150, 44151, 44152, 44153, 44155, 44156, 44160, 44320, 44322, 44340, 44345, 44346, 45135, 47480, 47490, 50340, 51550, 51555, 51565, 51570, 51575, 51580, 51585, 51590, 51595, 51596, 52339, 52340, 53220, 54530, 54535, 55801, 55810, 55812, 55815, 55821, 55831, 55840, 55845, 57460, 58150, 58152, 58951, 60220, 60225, 60252, 60254, 61510, 61518, 61520, 61521, 61526, 61530, 61545, 77261, 77262, 77263, 77280, 77285, 77290, 77295, 77299, 77300, 77305, 77310, 77315, 77321, 77326, 77327, 77328, 77331, 77332, 77333, 77334, 77336, 77370, 77399, 77401, 77402, 77403, 77404, 77406, 77407, 77408, 77409, 77411, 77412, 77413, 77414, 77416, 77417, 77419, 77420, 77425, 77430, 77431, 77432, 77470, 77499, 77600, 77605, 77610, 77615, 77620, 77750, 77761, 77762, 77763, 77776, 77777, 77778, 77781, 77782, 77783, 77784, 77789, 77790, 77799, 96400, 96405, 96406, 96408, 96410, 96412, 96414, 96420, 96422, 96423, 96425, 96440, 96445, 96450, 96520, 96530, 96542, 96545, 96549, HCPCS J9000, HCPCS J9010, HCPCS J9015, HCPCS J9020, HCPCS J9031, HCPCS J9040, HCPCS J9045, HCPCS J9050, HCPCS J9060, HCPCS J9062, HCPCS J9065, HCPCS J9070, HCPCS J9080, HCPCS J9090, HCPCS J9091, HCPCS J9092, HCPCS J9093, HCPCS J9094, HCPCS J9095, HCPCS J9096, HCPCS J9097, HCPCS J9100, HCPCS J9110, HCPCS J9120, HCPCS J9130, HCPCS J9140, HCPCS J9150, HCPCS J9165, HCPCS J9181, HCPCS J9182, HCPCS J9185, HCPCS J9190, HCPCS J9200, HCPCS J9202, HCPCS J9208, HCPCS J9209, HCPCS J9211, HCPCS J9213, HCPCS J9214, HCPCS J9215, HCPCS J9216, HCPCS J9217, HCPCS J9218, HCPCS J9230, HCPCS J9245, HCPCS J9250, HCPCS J9260, HCPCS J9265, HCPCS J9266, HCPCS J9268, HCPCS J9270, HCPCS J9280, HCPCS J9290, HCPCS J9291, HCPCS J9293, HCPCS J9295, HCPCS J9320, HCPCS J9340, HCPCS J9360, HCPCS J9370, HCPCS J9375, HCPCS J9380, HCPCS J9390, HCPCS J9999, ICD9 DXV580 , ICD9 DXV581 , ICD9 Surg 012, ICD9 Surg 0125, ICD9 Surg 0159, ICD9 Surg 064, ICD9 Surg 303, ICD9 Surg 304, ICD9 Surg 323, ICD9 Surg 324, ICD9 Surg 325, ICD9 Surg 4100, ICD9 Surg 4101, ICD9 Surg 4102, ICD9 Surg 4103, ICD9 Surg 4104, ICD9 Surg 4573, ICD9 Surg 4575, ICD9 Surg 4576, ICD9 Surg 461, ICD9 Surg 5122, ICD9 Surg 5732, ICD9 Surg 5749, ICD9 Surg 602, ICD9 Surg 6029, ICD9 Surg 603, ICD9 Surg 604, ICD9 Surg 605, ICD9 Surg 6062, ICD9 Surg 6069, ICD9 Surg 622, ICD9 Surg 623, ICD9 Surg 673, ICD9 Surg 684, ICD9 Surg 685, ICD9 Surg 686, ICD9 Surg 687, ICD9 Surg 8520, ICD9 Surg 8521, ICD9 Surg 8522, ICD9 Surg 8523, ICD9 Surg 8524, ICD9 Surg 8525, ICD9 Surg 8541, ICD9 Surg 8542, ICD9 Surg 8543, ICD9 Surg 8544, ICD9 Surg 8545, ICD9 Surg 8546, ICD9 Surg 8547, ICD9 Surg 8548, ICD9 Surg 857, ICD9 Surg 8587, ICD9 Surg 9224, ICD9 Surg 9225, ICD9 Surg 9226, ICD9 Surg 9227, ICD9 Surg 9228, ICD9 Surg 9229, ICD9 Surg 9925, Revenue Code 331, Revenue Code 333, Revenue Code 335

TABLE B.1 *(continued)*

Exclusion Criteria	Patients will be excluded if they are Under 65 Hospice patient Patients in nursing homes ESRD Patients enrolled in United Mine Workers or Railroad retirement programs Patients with in situ cancer of cervix (233.1) , prostate (233.4), bladder (233.7) or colon (230.3) Patients with basal or squamous cell skin cancers (232.9) Patients taking maintenance hormonal therapies
Providers/Referral Sources	Broward County oncologists
Geographic location	Broward County, FL *In 4/2003, the site has added Dade County, FL, and in March 2004, the site added Palm Beach County, FL.*

Active treatment is defined by the program as having surgery, radiation therapy, or chemotherapy. Patients receiving biologic therapy are eligible for participation but only if this treatment is in conjunction with radiation therapy or chemotherapy. Along with meeting the diagnosis criteria, at the time of enrollment beneficiaries could not: (1) be under the age of 65, (2) be a hospice patient, (3) live in a nursing home, (5) be enrolled in the United Mine Workers or Railroad Retirement program, (6) have in situ cancer of the cervix, prostate, bladder, or colon, (7) have basal or squamous cell skin cancer, or (8) be taking maintenance hormonal therapies.[1]

We could approximate most of Quality Oncology MCCD's criteria using Medicare data with some exceptions. We implemented Quality Oncology MCCD's requirement that a patient must have been receiving, active treatment for their cancer, by examining whether a beneficiary had an encounter for the specified conditions, treatments, or procedures at any point during the 18-month period beginning October 1, 2001, one year before enrollment began, and ending six months after enrollment started (March 31, 2003). We were unable to observe the complete diagnostic history for beneficiaries who had not been in FFS Medicare during the full two years before the 6-month enrollment window.[2] In addition, we did not limit eligible beneficiaries to people who had used the specific doctors who refer patients to the program, making our estimates potentially overstate the true number of people Quality Oncology MCCD would have approached about participating. We did not approximate three of Quality Oncology MCCD's

[1] Despite stating that it excludes beneficiaries under age 65, Quality Oncology MCCD enrolled patients under the age of 65. For the analysis, we used our understanding of the target criteria, which indicated that they intended to exclude patients under the age of 65.

[2] Among the 24 who enrolled in the first six months, who had valid Health Insurance Claim (HIC) numbers reported and who met CMS's insurance requirements at intake, 3 participants were enrolled in Medicare FFS less than a year before they enrolled in the demonstration; no participants were in FFS fewer than 6 of the 12 months before enrolling.

exclusion criteria using Medicare data: (1) living in a nursing home, (2) enrolled in the United Mine Workers or Railroad Retirement program or (3) taking maintenance hormonal therapies.

Identifying Health Insurance Claim (HIC) Numbers and Records of Participants and All Beneficiaries

Medicare claims and eligibility data and data submitted by the program were used to identify participants and eligible nonparticipants. For all participants, we used the Medicare enrollment database (EDB) file to confirm the HIC numbers, name, and date of birth submitted by the program when beneficiaries were randomized. We identified potentially eligible nonparticipants by identifying the HIC numbers of all Medicare beneficiaries who were alive and living in the catchment counties during the six-month enrollment window. Initially, two years of Denominator records (2000-2001) and one year of HISKEW records (2002) were used to identify people living in the catchment counties at any time in the 2000-2002 period. HIC numbers of potentially eligible nonparticipants and all participants together formed a "finder file." The finder file was used to gather data on the beneficiary's state and county of residence during the 6-month enrollment period, as well as to obtain eligibility information from the EDB. Using this information, we limited the sample to people living in the catchment area at any point during the six-month enrollment window. This finder file was also used to make a "cross-reference" file to ensure that we obtained all possible HIC numbers the beneficiary may have been assigned. This was done using Leg 1 of CMS's Decision Support Access Facility. At the end of this step, we had a list of HIC numbers for all participants, as well as all beneficiaries living in the catchment area during the six-month enrollment period.

Creating Variables from Enrollment and Claims Data

We obtained eligibility information from the EDB and diagnostic and utilization data from the National Claims History (NCH). All claims files were accessed through CMS's Data Extract

System. At the end of June 2003, we requested Medicare claims from 2000 through 2003. We received all claims that were updated by CMS through March 2003. This did not allow for a lag between a patient's receipt of a Medicare-covered service in the last month we examined—March 2003—and the appearance of the claim on the Medicare files. Because of lags to when the NCH is updated, it is likely we do not have fully complete claims for January, February, or March 2003. We therefore expect that the estimates we present in this interim report will understate the actual service use and cost for both the treatment and control groups, to a similar extent. Future analyses will allow for a longer lag time, ensuring that the data are essentially complete for the followup period examined.

Medicare claims and eligibility information were summarized as monthly variables from October 2000 through March 2003, for a total of 30 months. This enabled us to look at the eligibility status and the use of Medicare-covered services during any month in the two years before the program's start, to analyze participation in the first six months of program operation and to analyze treatment-control differences in Medicare service use and reimbursement following enrollment.

The EDB file provided us the information with which to construct measures of beneficiaries' demographic characteristics (age, sex, race), dates of death, original reason for Medicare entitlement, Medicare managed care enrollment, Part A and B coverage, whether Medicare was the primary payer, and the state buy-in proxy measure for enrollment in Medicaid.

The Medicare claims data in the NCH files were used to construct measures of Medicare-covered service use and reimbursement by type of service (inpatient hospital, skilled nursing facility, home health, hospice, outpatient hospital, and physician and other Part B providers). When the services spanned months, the monthly variables were allocated based on the number of days served in that month, as documented in the CLAIM FROM and CLAIM THRU dates. The

length of stay for a month represented actual days spent in the facility in that month; costs were prorated according to the share of days spent in each month. Ambulatory visits were defined as the unique counts of the person-provider-date, as documented in the physician/supplier and hospital outpatient claims. Durable medical equipment (DME) reimbursements were counted in other Part B reimbursement. A small number of negative values for total Part A and Part B reimbursements during the past two years occurred for some of the demonstration programs. Any negative Part A and Part B amounts were truncated to zero. The few patients with a different number of months in Part A and Part B were dropped from the analysis of reimbursement in the two years before intake.

When we examined a beneficiary's history from the month during which they were randomized, we used the actual date of randomization for participants and a simulated date of randomization for nonparticipants, picked to be November 15, 2002.

Defining Eligible Nonparticipants and Eligible Participants

We used target criteria information to whittle the group of beneficiaries who lived in the catchment area down to those who met the program's eligibility criteria, which we could measure using the Medicare data. Tables B.2 and B.3 illustrate the exclusions used to identify the sample of eligible participants and nonparticipants used to analyze participation patterns.

We identified 253,016 beneficiaries who lived in Quality Oncology MCCD's catchment area at some point during the first six months of enrollment (Table B.2). We then excluded 128,330 people (51.0 percent) who did not meet the insurance requirements set by CMS for participation in the program during one or more months during the six-month enrollment window. Another 122,356 of the remaining people (48.4 percent of all area beneficiaries) were dropped from the sample, as they did not have any claims for the target diagnoses that the

TABLE B.2

SAMPLE OF ALL ELIGIBLE BENEFICIARIES FOR PARTICIPATION ANALYSIS

Sample	Number
Full Sample of Eligible Beneficiaries Who Live in Catchment Area One or More Months During the First Six Months of Enrollment	253,016
Minus Those Who:	
During 6-month enrollment period, either (1) were always in a Medicare managed care plan, or (2) never had Medicare Part A coverage, or (3) never had Medicare Part B coverage, or (4) Medicare was not primary payer during one or more months	–128,330
Did not have one or more of the target diagnoses on any claim during the year before the program started or during the six-month enrollment window	–122,356
Met at least one of the exclusion criteria during the 18 months from October 2001 through March 2003	–475
Eligible Sample	**1,855**

program identified as necessary for inclusion during the year before the program began or the first six months of enrollment. Finally, 475 people were identified as having at least one of Quality Oncology MCCD's exclusion criteria, leaving us with a sample of 1,855 beneficiaries we estimated would have been eligible to participate in Quality Oncology MCCD's program.

Quality Oncology MCCD randomized 25 beneficiaries who enrolled in the demonstration program during the first six months of operation (Table B.3). All beneficiaries reported valid HIC numbers and could be matched to their Medicare claims data. Quality Oncology MCCD randomized three beneficiaries who had an address on the EDB that was outside its catchment area. We excluded these cases from the participation analysis to maintain comparability to the eligible nonparticipant sample. All of the remaining participants met CMS's insurance requirements for participation in the program during the month of intake. We also dropped five beneficiaries from the participation analyses for not having one or more of the target diagnoses

TABLE B.3

SAMPLE OF ELIGIBLE PARTICIPANTS FOR PARTICIPATION ANALYSIS

Sample	Treatment Group	Control Group	All
Full Sample of Participants Randomized During the First Six Months of Enrollment	12	13	25
Minus Those Who:			
Had an invalid HIC number on MPR's enrollment file	–0	–0	–0
Not in geographic catchment area during the month of intake	–1	–2	–3
In a Medicare managed care plan, or did not have Medicare Part A and B coverage, or Medicare is not primary payer during the month of intake	–0	–0	–0
Did not have one or more of the target diagnoses on any claim during the 12 months before the program started or during the six-month enrollment window	–1	–4	–5
Met at least one of the exclusion criteria during the 18 months from October 2001 through March 2003	–2	–0	–2
Eligible Sample	**8**	**7**	**15**

Note: The number of sample members reported as excluded at each point reflects *people in the previous line* who did not meet the additional eligibility criteria according to Medicare data. Thus, the table applied sequential criteria. The program actually used patient self-reports of diagnosis and service use.

on any claim and two beneficiaries because they met one of the program's medical exclusion criteria during the 18-month period, October 1, 2001 through March 2003. Thus, among the 25 participants randomized by Quality Oncology MCCD into the program, after exclusions, 15 people are included in the participation analyses as eligible participants.

Quality Oncology MCCD's participation rate for the first six months of enrollment is therefore calculated as the number of participants who met the eligibility requirements (15), divided by the number of eligibles who live in the catchment area (1,855), or 0.8 percent.

Table B.4 describes the characteristics of the 15 participants who were enrolled by Quality Oncology MCCD during the first six months and who appear to meet Quality Oncology MCCD's eligibility requirements, as measured in Medicare data, and the 1,840 eligible nonparticipants. This table is identical to Table 2 in the text, except that the participant sample has been restricted to the beneficiaries who meet the eligibility criteria according to Medicare claims data. The results are similar to those in Table 2, although they do significantly differ on a few dimensions at baseline. As mentioned in footnote 1, despite stating that it excludes beneficiaries under age 65, Quality Oncology MCCD enrolled patients under the age of 65, thus, the age distribution differs between the participant samples. Additionally, a smaller proportion of eligible participants had no hospitalizations during the two years before the month of intake and, as a result, eligible participants had higher Medicare reimbursement per month in Fee-for-Service during the year prior to intake.

METHOD FOR CALCULATING TREATMENT-CONTROL DIFFERENCES

Sample sizes are too small, and the follow-up period too short, to estimate program impacts. Comparing the treatment and control groups on mean outcomes, however, provides an early indication of potential effects. The analysis draws on the data and the variables constructed for the participation analysis but is restricted to the program's participants (treatments and controls). The cost of the intervention was estimated as the amount CMS paid to Quality Oncology MCCD for the treatment group patients, using G-coded claims in the physician claims file.

Treatment – Control Differences

We used two approaches to estimate treatment-control differences in Medicare-covered service use and cost outcomes. First, we estimated differences over a two-month follow-up period for all people Quality Oncology MCCD randomized during the first four months of

TABLE B.4

CHARACTERISTICS OF ELIGIBLE PARTICIPANTS AND ELIGIBLE NONPARTICIPANTS DURING THE FIRST SIX MONTHS OF PROGRAM ENROLLMENT
(Percentages, Unless Otherwise Noted)

	Eligible Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Age at Intake			
Average age (in years)	77.5	77.2	
Younger than 65	0.0	0.0	
65 to 74	40.0	37.2	
75 to 84	53.3	47.8	
85 or older	6.7	15.0	
Male	20.0	32.0	
Nonwhite	6.7	6.5	
Original Reason for Medicare: Disabled or ESRD	6.7	5.4	
State Buy-In for Medicare Part A or B	6.7	6.4	
Newly Eligible for Medicare (Eligible Less than Six Months)	0.00	0.65	
Enrolled in Fee-for-Service Medicare 6 or More Months During Two Years Before Intake	100.0	97.6	
Medical Conditions Treated During Two Years Before Month of Intake[b]			
Coronary artery disease	46.7	49.4	
Congestive heart failure	20.0	19.2	
Stroke	40.0	22.7	
Diabetes	26.7	23.7	
Cancer	100.0	92.2	
Chronic obstructive pulmonary disease	46.7	39.7	
Dementia (including Alzheimer's disease)	6.7	3.0	
Peripheral vascular disease	13.3	10.2	
Renal disease	6.7	5.2	
Total Number of Diagnoses	3.1	2.7	
Days Between Last Hospital Admission and Intake Date[b]			
No hospitalization in past two years	6.7	34.6	**
0 to 30	40.0	9.7	***
31 to 60	6.7	5.2	
61 to 180	26.7	17.3	
181 to 365	13.3	20.3	
366 to 730	6.7	12.8	

TABLE B.4 *(continued)*

	Eligible Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
0	13.3	36.3	*
0.1 to 1.0	66.7	41.9	*
1.1 to 2.0	13.3	14.0	
2.1 to 3.0	6.7	4.4	
3.1 or more	0.0	3.5	
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[b]			
Part A	$1,130	$979	
Part B	$2,693	$1,484	***
Total	$3,823	$2,463	**
Distribution of Total Medicare Reimbursement per Month Fee-for-Service During One Year Before Intake[b]			
$0	0.0	0.5	
$1 to 500	0.0	18.5	*
$501 to 1,000	6.7	15.0	
$1,001 to 2,000	20.0	20.2	
More than $2,000	73.3	45.9	**
Number of Beneficiaries	**15**	**1,840**	

Source: Medicare Enrollment Database and National Claims History File.

Note: The intake date used in this table is the date of enrollment for participants. For eligible nonparticipants, the intake date is November 15, 2002, roughly the midpoint of the six-month enrollment period examined.

[a]Participants who do not meet CMS's demonstration-wide requirements for the demonstration, or who had an invalid HIC number on MPR's enrollment file, are excluded from this table because we do not have Medicare data showing their reimbursement in the fee-for-service program. Members of the same households as the research sample members are included.

[b]Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. (See Note, above, concerning intake date definition.)

[c]Calculated as 12 x (number of hospitalizations during two years before month of intake) / (number of months eligible). For example, if a beneficiary was in fee-for-service all 24 months and had two hospitalizations during that time, they would have one hospitalization per year [(12 x 2) / 24]. If another beneficiary was in fee-for-service eight months during the previous two years, and had two hospitalizations during those eight months, they would have [(12 x 2) / 8], or three hospitalizations per year. The estimate of the proportion with no hospitalization in the two years before the month of intake may differ slightly from the proportion with no hospitalization in the two years before the date of intake because the two measure slightly different periods. Someone enrolled on September 20, 2003, whose only hospitalization in the preenrollment period occurred on September 5, 2003, would not be counted as hospitalized during the 24 months before the month of intake. Conversely, someone hospitalized on September 25, 2001, would be captured in the measure defined by month of enrollment but not in the measure based on the day of enrollment.

TABLE B.4 *(continued)*

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*Difference between eligible participants and eligible nonparticipants significantly different from zero at the .10 level, two-tailed test.

**Difference between eligible participants and eligible nonparticipants significantly different from zero at the .05 level, two-tailed test.

***Difference between eligible participants and eligible nonparticipants significantly different from zero at the .01 level, two-tailed test.

enrollment. The four-month enrollment window covers September 18, 2002 through January 15, 2003. The follow-up time covered the two calendar months after the month of randomization. For example, for a beneficiary randomized on September 30, we examined outcomes in October and November.

Second, we estimated treatment – control differences by calendar month over the first six months of Quality Oncology MCCD's enrollment to look at how cost-effectiveness might vary over the life of a program. One might expect programs to have little effect at first, since it takes time for patients to be assessed, the program to become fully functional, the patients to adopt case managers' recommendations, and these behavior changes to affect the need for health care. Analyzing costs by program month will allow us to examine such patterns. For each month from September 2002 through February 2003, we identified the patients who were enrolled in Quality Oncology MCCD's coordinated care program and analyzed their Medicare-covered service use. For example, a person randomized in September would be present in September through February, provided that person is eligible and alive in each month.[3] Someone randomized in October would not be part of the calculations for September but would be included in October through February, again provided that the person is eligible during those months.

The sample used to analyze treatment – control differences in outcomes differs from that used to analyze participation. We excluded one person in the six-month sample who enrolled but was ineligible for the demonstration according to CMS's insurance criteria (as determined from data on the EDB). In contrast to the participation analyses, participants who did not meet the program's target criteria according to the claims and EDB data were not excluded from the outcomes analyses. Given this, the sample for analyzing treatment-control differences contained

[3] Patients were excluded as ineligible during months when we could not observe their full costs (when they were enrolled in a Medicare managed care plan for the full month).

all 19 people randomized in the first four months of Quality Oncology MCCD's demonstration. For the six-month sample, 24 of the 25 randomized people were included in the final sample (Table B.5). In addition to excluding beneficiaries, we excluded months during which we could not observe the beneficiaries' full costs in fee-for-service (described in footnote 3).

Integrity of Random Assignment

Eligible applicants to the program were randomly assigned to the treatment or control group. To assess whether random assignment successfully produced treatment and control groups with similar baseline characteristics, we used two-tailed t-tests and chi-squared tests to compare the two research groups. Table B.6 presents the baseline characteristics for both the four-month and the six-month sample.

TABLE B.5

SAMPLES FOR TREATMENT-CONTROL COMPARISONS

	First Four Months	First Six Months
Number of Beneficiaries Who Were Randomized	19	25
Minus Those Who:		
Were members of the same household as research sample members	–0	–0
Had invalid HIC numbers on MPR's enrollment file	–0	–0
In a Medicare managed care plan, or did not have Medicare Part A and B coverage, or Medicare is not primary payer during the month of intake	–0	–1
Number of Usable Sample Members	**19**	**24**

TABLE B.6

CHARACTERISTICS OF TREATMENT AND CONTROL GROUPS IN THE RESEARCH SAMPLE ENROLLED DURING THE FIRST FOUR MONTHS AND SIX MONTHS OF PROGRAM ENROLLMENT

	Four-Month Sample			Six-Month Sample		
	Treatment Group	Control Group	Total Research Sample	Treatment Group	Control Group	Total Research Sample
Age at Intake						
Average age (in years)	73.9	77.9	76.0	75.0	76.5	75.8
Younger than 65	22.2	0.0	10.5	16.7	0.0	8.3
65 to 74	33.3	30.0	31.6	33.3	41.7	37.5
75 to 84	44.4	60.0	52.6	41.7	50.0	45.8
85 or older	0.0	10.0	5.3	8.3	8.3	8.3
Male	33.3	20.0	26.3	33.3	25.0	29.2
Nonwhite	0.0	10.0	5.3	0.0	8.3	4.2
Original Reason for Medicare: Disabled or ESRD	22.2	10.0	15.8	16.7	8.3	12.5
State Buy-In for Medicare Part A or B	11.1	10.0	10.5	8.3	8.3	8.3
Newly Eligible for Medicare (Eligible Less than Six Months)	0.0	0.0	0.0	0.0	0.0	0.0
Enrolled in Fee-for-Service Medicare Six or More Months During Two Years Before Intake	100.0	100.0	100.0	100.0	91.7	95.8
Medical Conditions Treated During Two Years Before Month of Intake[a]						
Coronary artery disease	55.6	40.0	47.4	58.3	45.5	52.2
Congestive heart failure	11.1	30.0	21.1	8.3	27.3	17.4
Stroke	44.4	30.0	36.8	41.7	36.4	39.1
Diabetes	22.2	30.0	26.3	25.0	27.3	26.1
Cancer	100.0	100.0	100.0	100.0	100.0	100.0
Chronic obstructive pulmonary disease	66.7	30.0	47.4	50.0	27.3	39.1
Dementia (including Alzheimer's disease)	11.1	0.0	5.3	8.3	0.0	4.3
Peripheral vascular disease	11.1	10.0	10.5	8.3	9.1	8.7
Renal disease	11.1	0.0	5.3	8.3	0.0	4.3
Total number of diagnoses (number)	3.3	2.7	3.0	3.1	2.7	2.9

TABLE B.6 *(continued)*

	Four-Month Sample			Six-Month Sample		
	Treatment Group	Control Group	Total Research Sample	Treatment Group	Control Group	Total Research Sample
Days Between Last Hospital Admission and Intake Date[a]						
No hospitalization in past two years	22.2	10.0	15.8	16.7	9.1	13.0
0 to 30	44.4	10.0	26.3	50.0	9.1 **	30.4
31 to 60	11.1	0.0	5.3	16.7	0.0	8.7
61 to 180	11.1	30.0	21.1	8.3	36.4	21.7
181 to 365	11.1	20.0	15.8	8.3	18.2	13.0
366 to 730	0.0	30.0 *	15.8	0.0	27.3 *	13.0
Annualized Number of Hospitalizations During Two Years Before Month of Intake[a,b]						
0	22.2	20.0	21.1	16.7	18.2	17.4
0.1 to 1.0	66.7	60.0	63.2	75.0	63.6	69.6
1.1 to 2.0	0.0	20.0	10.5	0.0	18.2	8.7
2.1 to 3.0	11.1	0.0	5.3	8.3	0.0	4.3
3.1 or more	0.0	0.0	0.0	0.0	0.0	0.0
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]						
Part A	$940	$835	$885	$897	$913	$905
Part B	$2,469	$2,663	$2,571	$2,458	$2,467	$2,462
Total	$3,409	$3,498	$3,456	$3,355	$3,380	$3,367
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]						
$0	0.0	0.0	0.0	0.0	0.0	0.0
$1 to 500	0.0	0.0	0.0	0.0	0.0	0.0
$501 to 1,000	11.1	10.0	10.5	8.3	9.1	8.7
$1,001 to 2,000	44.4	10.0	26.3	33.3	9.1	21.7
More than $2,000	44.4	80.0	63.2	58.3	81.8	69.6
Location During Program Intake Period						
Florida						
Broward	100.0	100.0	100.0	91.7	91.7	91.7
Outside catchment area	0.0	0.0	0.0	8.3	8.3	8.3
Number of Beneficiaries	**9**	**10**	**19**	**12**	**12**	**24**

Source: Medicare Enrollment Database and National Claims History File.

Notes: The intake date used in this table is the date of enrollment for participants. For eligible nonparticipants, the intake date is November 15, 2002, roughly the midpoint of the six-month enrollment period examined.

Participants who do not meet CMS's demonstration-wide requirements, had an invalid HIC number on MPR's enrollment file, or were identified as a member of the same household as a research sample member were excluded from this table.

[a] Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. (See Note, above, concerning intake date definition.)

[b] Calculated as 12 x (number of hospitalizations during two years before month of intake) / (number of months eligible). For example, if a beneficiary was in fee-for-service all 24 months and had two hospitalizations during that time, they would have one hospitalization per year [(12 x 2) / 24]. If another beneficiary was in fee-for-service eight months during the previous two years, and had two hospitalizations during those eight months, they would have [(12 x 2) / 8], or three hospitalizations per year. The estimate of the proportion with no hospitalization in the two years before the month of intake may differ slightly from the proportion with no hospitalization in the two years before the date of intake because the two measure slightly different periods. Someone enrolled on September 20, 2003, whose only hospitalization in the preenrollment period occurred on September 5, 2003, would not be counted as hospitalized during the 24 months before the month of intake. Conversely, someone hospitalized on September 25, 2001, would be captured in the measure defined by month of enrollment, but not in the measure based on the day of enrollment.

ESRD = end-stage renal disease.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.

**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.

***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

As expected under random assignment, the treatment and control groups had similar characteristics in both the four- and six-month samples. There were statistically significant differences in one baseline characteristics for the four-month sample, the proportion of beneficiaries whose last hospital discharge before intake occurred 366 to 730 days earlier. This difference was significant at the 10 percent level. For the six-month sample, there were two statistically significant differences: the proportion of beneficiaries whose last hospital discharge before intake occurred (1) 0 to 30 days earlier and (2) 366 to 730 days earlier. We would expect this number of false-positive differences to occur by chance, given the number of characteristics examined. Thus, none of the differences in this small, early sample create any cause for concern.

Sensitivity Tests

To assess outcomes, we calculated Medicare-covered service use and cost in the two months after the month of randomization. For example, for an individual who was randomized in the month of September, we tabulated the individual's outcomes in October and November. To examine whether our results were affected by not including costs and services that occurred closer to the randomization date, we conducted a sensitivity analysis examining outcomes for three months—during the month the individual was randomized, as well as the two months after randomization (Table B.7). The results were similar to those for outcomes measured over the two-month period (text Table 5). Thus, it appears the results are not sensitive to how the month of randomization is treated.

TABLE B.7

MEDICARE-COVERED SERVICE USE DURING THE MONTH OF RANDOMIZATION AND THE FOLLOWING TWO MONTHS FOR EARLY ENROLLEES

	Treatment Group	Control Group	Difference[a]	
Inpatient Hospital Services				
Any admission (percent)	33.3	40.0	–6.7	
Mean number of admissions	0.44	0.60	–0.16	
Mean number of hospital days	3.67	4.90	–1.23	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	22.2	20.0	2.2	
Not resulting in admission	0.0	0.0	0.0	
Total	22.2	20.0	2.2	
Mean number of emergency room encounters				
Resulting in admission	0.22	0.20	0.02	
Not resulting in admission	0.00	0.00	0.00	
Total	0.22	0.20	0.02	
Skilled Nursing Facility Services				
Any admission (percent)	11.1	10.0	1.1	
Mean number of admissions	0.11	0.10	0.01	
Mean number of days	4.78	0.80	3.98	
Hospice Services				
Any admission (percent)	0.0	10.0	–10.0	
Mean number of days	0.00	1.30	–1.30	
Home Health Services				
Any use (percent)	33.3	20.0	13.3	
Mean number of visits	12.89	17.70	–4.81	
Outpatient Hospital Services[b]				
Any services (percent)	33.3	40.0	–6.7	
Physician and Other Part B Services[c]				
Any use (percent)	77.8	80.0	–2.2	
Mean number of visits or claims	44.7	31.4	13.3	
Mortality Rate (percent)	0.0	20.0	–20.0	
Total Medicare Reimbursement[d]				
Part A[e]	$5,462	$4,696	$766	
Part B	$15,725	$11,837	$3,888	
Total	$21,187	$16,533	$4,654	***
Reimbursements for Care Coordination[f]	$327	$0	$327	
Number of Beneficiaries	**9**	**10**		

Source: Medicare National Claims History File.

Note: Sample includes those enrolled during the first four months of program operations. Participants were excluded from this table if they had an invalid HIC number on MPR's enrollment file, were identified as a member of the same household as a research sample member, or did not meet Medicare coverage and payer requirements (defined as having Medicare as a secondary payer, being in Medicare managed care plan, or not having Part A and Part B coverage) during the month of randomization. Patient-months were excluded if the participant did not meet the above Medicare coverage and payer requirements that month or had died in a previous month.

"Percents with any medical encounter type" are the percent of treatment or control group members who have at least one encounter of a particular type; "mean numbers of medical encounter types" are the average number of encounters of a particular type per treatment or control group member.

[a]These estimates are based on preliminary data and will be updated in the second site-specific report.

The direction of the treatment-control difference does not by itself signify whether the program is "effective." That is, for some outcomes a statistically significant negative difference (such as lower hospitalization rates for the treatment group than for the controls) suggests that the program is working as intended. However, a positive difference for other outcomes, such as number of physician visits, does not necessarily mean the program is ineffective or having adverse effects, because the program may encourage patients to see their physician more regularly for preventative care or to obtain recommended laboratory tests for their target conditions than they would have in the absence of the demonstration.

Due to rounding, the difference column may differ slightly from the result when the control column is subtracted from the treatment column.

[b]Includes visits to outpatient hospital facilities as well as emergency room visits that do not result in an inpatient admission. Laboratory and radiology services are also included.

[c]Includes diagnostic laboratory and radiology services (including pathologist and radiologist services) from nonhospital providers, suppliers and devices, mammography, ambulance, covered medications, blood, and vaccines.

[d]Does not include reimbursement for care coordination services provided by demonstration programs.

[e]Includes reimbursement for inpatient, skilled nursing facility, hospice, and all home health care (including that paid under Medicare Part B). Excludes reimbursement for care coordination services provided by demonstration programs.

[f]This is the average amount paid to the program as recorded in the Medicare claims data for the month of randomization and the two following months. The difference between the recorded amount and three times the amount the program was allowed to charge per-member-per-month may reflect billing errors, delays, or payment adjustments for patients who disenrolled.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.
**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.
***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

APPENDIX C

SELECTED PROGRAM DOCUMENTS

Quality Oncology print advertisement

Care Management Records Request

Sample request for pathology report and treatment plan cover sheet

Informational brochure for patients

Materials for nurse case manager training on MCCD (schedule and agenda, care management review tool, new care manager record review tool, “cheat sheet”--guidelines for collecting contact data for MCCD evaluation, new MCCD member assessment form

Sample ICM system operational reports