Contract No.: 500-95-0047 (09)
MPR Reference No.: 8756-320

MATHEMATICA
Policy Research, Inc.

The QMed Medicare Coordinated Care Demonstration Program After One Year

Final Report

September 30, 2005

Karen Sautter
Jennifer Schore
Randall Brown
Sherry Aliotta
Deborah Peikes
Sean Orzol

Submitted to:

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Research, Development, and Information
C3-19-07 Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Project Officer:
Carol A. Magee

Submitted by:

Mathematica Policy Research, Inc.
P.O. Box 2393
Princeton, NJ 08543-2393
Telephone: (609) 799-3535
Facsimile: (609) 799-0005

Project Director:
Randall Brown

ACKNOWLEDGEMENTS

Many individuals contributed to the preparation of this report. We would like to thank QMed's program staff including Jane Murray and Teri Kraf for their time in answering our many questions about the operation of their program. We especially thank three CMS staff members—Carol Magee (project officer for the evaluation), Cindy Mason (project officer for the demonstration), and Renee Mentnech (Director, Division of Beneficiary Research) for their overall guidance and ongoing support.

Several other staff members at Mathematica Policy Research made important contributions to this report. Programmers Amy Zambrowski, Nazmul Khan, Stephanie Chin, and Licia Garber skillfully processed Medicare claims data, Medicare enrollment data, and program data. BobSchmitz provided valuable critical comments on an earlier draft of the report. Patricia Ciaccio edited and Jane Nelson produced this report. Any remaining errors or omissions are the responsibility of the authors.

CONTENTS

CONTENTS *(continued)*

Page

TABLES

TABLES *(continued)*

Table **Page**

EXECUTIVE SUMMARY

The Medicare Coordinated Care Demonstration, 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 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 analysis and impact analysis 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 may include:

- 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 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 QMed's Medicare Coordinated Care Demonstration (MCCD) project. After presenting an overview of QMed's MCCD, we address 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? Thereafter follows a discussion of the program's strengths and unique features, as well as potential barriers to program success.

Program Organization and Approaches. QMed, Inc., the host for the demonstration, is a publicly held disease management company located in Laurence Harbor, New Jersey. QMed's

prototype for its demonstration is its ongoing coronary artery disease (CAD) management program, which uses telephone case management and a heart monitoring device that automatically generates prognoses and therapeutic recommendations for CAD patients. QMed reports that its CAD program has reduced the frequency of heart attacks, number and length of hospitalizations, and number of diagnostic and invasive procedures, and it also has increased prescribing of beta blockers.

Although QMed is headquartered in New Jersey, its MCCD program serves patients who live in several California counties. The QMed MCCD patient care staff (which includes case managers and disease management specialists) and administrative staff are located both in California and New Jersey. The case managers conduct assessments, routine monitoring, and patient education by telephone. The disease management specialists conduct in-person cardiac monitoring sessions. The program director, project coordinator, case manager supervisor, and case managers are in QMed's central office in New Jersey. The program's disease management specialists, quality assurance manager, and program manager are in QMed's Stockton, California, office. The project coordinator oversees daily operations by reviewing reports and maintaining contact by telephone with Stockton office staff.

The QMed MCCD has adopted three approaches to improving patient health and reducing health care costs: (1) improving physician practice, (2) improving patient adherence to treatment recommendations, and (3) improving communication and coordination between patients and physicians. The program's primary focus is on improving provider practice, which it hopes to accomplish by providing patients' physicians with evidence-based guidelines and patient-specific reports of clinical information and treatment recommendations based on heart monitoring. The program seeks to improve patient adherence by educating patients about their disease and how to monitor their symptoms. The program aims to improve communication and coordination by teaching patients to communicate more effectively with their doctor and reminding them about doctor appointments and needed tests.

QMed has a close relationship with the physicians in the program's service area because of its reputation for providing cost-saving disease management services to managed care organizations. The program recruits almost all of its patients directly from physicians who agree to participate. After a year of operation, the program had obtained participation agreements with two large physician practices and was negotiating a participation agreement with a third physician group.

Patient Identification. The QMed MCCD began enrolling patients in July 2002. The program requires its participants to have been treated for CAD, to have had CAD-related procedures or tests, or to have had chest symptoms that might be CAD. Patients must live in Stanislaus, San Joaquin, or Sacramento counties in California. As in all the MCCD demonstration programs, beneficiaries must also meet three CMS requirements: (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 identifies patients primarily by reviewing lists of potentially eligible patients of participating physicians. After physician consent is granted for an individual patient to participate, a case manager verifies Medicare eligibility, then mails the patient a letter asking for his or her participation. The letter is signed by the patient's physician or the medical director of the participating physician group. Approximately two weeks later, a

case manager telephones each patient and, using a script, invites the patient to an informational meeting in their area to explain the program. After the meeting, patients are asked to sign the informed consent form if they wish to participate. The names of those who sign the form are then sent to MPR for randomization.

Assessment, Care Planning, and Monitoring. Following enrollment, all treatment group patients receive a telephone assessment conducted by their assigned case manager. The assessment covers demographics, cardiac problem hospitalization and other cardiac medical history, comorbidities common in people with cardiac problems, and current medications. The program also performs a review of the patient's medical chart upon entry into the program and quarterly thereafter, extracting data on office visits, diagnoses, hospitalizations or procedures, and new medications. These data are combined with cardiac monitoring data for the physician's first report from the program.

After the assessment, the case manager makes a cardiac monitoring appointment with the patient. The monitoring device, worn for a 24-hour period, performs an ambulatory electrocardiogram. QMed's monitoring software then generates a report for the physician based on cardiac monitoring readings, assessment data, and chart review describing the patient's risk factors, goals, current medications, and recommendations for treatment changes from QMed's consulting cardiologist. The report also serves as the patient's care plan. Patients undergo cardiac monitoring every six months, at which time the report and care plan are updated.

Case managers monitor patients by telephone every other month. During routine contact, the case manager conducts an assessment of the patient using a scripted questionnaire embedded in QMed's Patient Information and Management System (PIMS). After the assessment, the case manager educates the patient about CAD and the importance of adhering to treatment recommendations and asks about possible service needs (such as transportation). Monitoring frequency increases to at least monthly if a patient's chart review reveals he or she has been hospitalized or if a patient has comorbidities.

Staffing and Program Quality Management. Maintaining and improving quality and making sure that programs attain their goals require that staff have adequate qualifications, training, and supervision and that management has the tools and support to monitor progress toward the program's goals. QMed's case managers must be registered nurses or experienced licensed practical nurses. (All case managers employed during the program's first year were experienced QMed employees.) QMed's disease management specialists must be registered nurses or licensed practical nurses. Upon hire, both types of staff participate in QMed's employee orientation at the New Jersey office. The orientation covers informed consent, enrollment and disenrollment procedures, program interventions, reporting and data entry, and the process for responding to complaints. Staff receive ongoing training each month (for example, diabetes was the topic during diabetes awareness month).

The program's quality assurance manager reviews case manager performance every six months using QMed's employee evaluation tool. In addition, the project coordinator reviews PIMS-generated case manager-specific productivity reports daily and weekly. The program manager reviews the disease management specialists by repeating randomly selected patient medical chart reviews each quarter.

The program evaluates its approach to patient care, as well as operational aspects of the demonstration, during its one-hour bimonthly meetings, which include all program staff. Meeting topics have included physician recruitment and adherence to guidelines, and patient enrollment and adherence to treatment recommendations. The program director also uses an extensive set of reports generated by QMed's data system to monitor enrollment and track changes in patient outcomes and physician practice. The QMed MCCD surveys all patients enrolled in the program annually about their satisfaction with the program. It plans to survey physicians about their satisfaction with the program and how it has affected their clinical practice. The program's quality assurance manager also regularly visits physicians to receive feedback about the program.

WHO ENROLLS IN THE PROGRAM?

The program met its year 1 enrollment target without changing its original approach to identifying patients. After one year of operation, the QMed MCCD had enrolled 645 patients in the demonstration treatment group and 646 in the control group. The program attributes its success primarily to physician support, but also to the face-to-face informed consent meetings, and recruitment letters signed by patients' physicians. Staff believe these interactions dispel some beneficiaries' anxiety about the legitimacy of the program.

To gain another perspective on the proportion of eligible beneficiaries enrolling in the program and to describe their characteristics, the evaluation simulated the QMed MCCD eligibility criteria using Medicare enrollment and claims data. (November 15, 2002, the midpoint of the six-month enrollment period considered, was used as a pseudo-enrollment date for nonparticipants.) The simulation showed that, during the program's first six months of operation, about two percent of an estimated 13,410 eligible beneficiaries enrolled. The simulation did not distinguish between beneficiaries served by physicians participating in the QMed MCCD and those served elsewhere in the program's service area, however, so the number of eligible nonparticipants who might truly have had access to the demonstration is probably much smaller. Nevertheless, eligible nonparticipants who could have been served by the QMed MCCD are likely similar to the larger pool of nonparticipants identified in the claims data.

As noted, QMed identifies patients by reviewing physicians' medical charts for evidence that the patients have CAD. The simulation (which is based on primary and secondary diagnoses for CAD and related procedures recorded on Medicare claims) showed, however, that two-thirds of participants enrolled did not have CAD claims or did have one of the program's exclusion criteria during the year before the program began or during the first six months of enrollment. Half of those who appeared to be ineligible did not have any claims for CAD, CAD-related procedures or tests, or CAD symptoms during this period. This discrepancy may be due to the program using chart reviews to identify eligible patients and not requiring evidence of relatively recent treatment for its target diagnoses. However, only about 12 percent of those not having a claim for the target diagnosis in the 12 months before enrollment had such a claim 13 to 24 months before enrollment. It is unlikely that patients with no claims for a chronic condition over a two-year period are at much risk. An additional quarter of those the simulation classified as ineligible were so classified because they met one of the program's exclusion criteria. Nearly

half of them were under age 65, a group the program had indicated were not eligible but enrolled.

Program participants differed demographically from eligible nonparticipants. Participants were less likely to be very elderly: 5 percent, versus 15 percent of eligible nonparticipants. Participants were slightly more likely to be male (46 versus 42 percent), but much less likely to be poor (12 percent received Medicaid benefits, versus 35 percent of nonparticipants) or nonwhite (11 versus 19 percent).

During the two years before enrolling, participants were less likely to have been treated for a number of diagnoses and thus, were less likely to have been hospitalized and had lower spending, on average. Using the narrower definition of CAD that the evaluation uses across all MCCD programs, roughly 60 percent of participants and 75 percent of eligible nonparticipants had CAD. (Using the broader group of diagnostic and procedure codes that the QMed MCCD actually used increases these rates to 66 percent of participants and 100 percent of all nonparticipants.) Participants were also markedly less likely to have been treated for congestive heart failure, stroke, and peripheral vascular disease. Only 21 percent of participants had been in the hospital in the year before enrolling, compared to 31 percent of nonparticipants. As a result, participants had lower monthly Medicare costs during the year ($641) that were one-third less than monthly costs for eligible nonparticipants ($954).

When developing the cost estimate for its waiver application, MPR estimated that Medicare costs would average $1,116 per month for control group members during the demonstration period. However, those calculations assumed that eligible patients would have an inpatient or outpatient hospital claim in a 12-month period for CAD. The average cost for eligible beneficiaries was about 15 percent below these waiver cost estimates because the program did not require that the services be delivered in a hospital inpatient or outpatient setting. However, the difference between participants and eligible nonparticipants, which is much larger, is due to so few of the participants having a Medicare claim in the preceding two years for CAD, CAD-related procedures or tests, or symptoms of CAD.

Results from the QMed MCCD's first annual patient survey were not available at the time of this writing. However, case managers believed that patients were thankful for the assistance and education the program provided and felt more empowered and in control of their health. Voluntary disenrollment during the first six months was modest, at three percent.

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

A primary goal of the QMed MCCD is to increase physician adherence to evidence-based guidelines. The program has taken three approaches to accomplishing this. First, when physicians agree to participate in the demonstration, they receive practice guidelines, which are updated quarterly. Second, as mentioned earlier, QMed's data system generates reports that compare patient treatment and monitoring results with guidelines. QMed's consulting cardiologist then makes recommendations to make treatment more consistent with guidelines, particularly with respect to prescription medications. Finally, the quality assurance manager meets with each physician to discuss these recommendations and notifies the group's medical director if fewer than 70 percent of a physician's patients are not receiving the recommended

prescriptions. In addition, the program pays physicians $50 for each monitoring report they review.

TABLE 1

CHARACTERISTICS OF QMED 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
65 to 84	87.3	85.4
85 or older	4.5	14.7
Male	45.7	41.9
Nonwhite	11.1	18.6
Medicaid Buy-In for Medicare A or B	12.0	34.6
Medical Conditions Treated in Past Two Years		
CAD[b]	59.4	75.4
Congestive heart failure	23.3	34.2
Stroke	25.0	30.0
Diabetes	29.8	31.5
Cancer	19.2	5.1
Chronic obstructive pulmonary disease	25.3	35.4
Dementia/Alzheimer's disease	0.9	4.1
Peripheral vascular disease	10.4	14.1
Renal disease	5.2	7.2
Total Number of Diagnoses (Number)	2.0	2.4
Hospital Admission in Past Year	21.1	30.7
Hospital Admission in Past Month	1.2	4.3
Total Medicare Reimbursement per Month (Dollars)	$641	$954
Number of Beneficiaries	**666**	**13,148**

Source: Medicare Enrollment Database and National Claims History Files.

Note: For participants, the intake date is their date of enrollment. For eligible nonparticipants, it is November 15, 2002, the midpoint of the six-month enrollment period covered by the participation analysis.

[a] Participants who do not meet CMS's 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. Participants who are members of the same household as a research sample member are included above but are not part of the research sample.

[b] Using the narrower definition of CAD that the evaluation uses across all MCCD programs, roughly 60 percent of participants and 75 percent of eligible nonparticipants had CAD. (Using the broader group of diagnostic and

procedure codes that the QMed MCCD actually used increases these rates to 66 percent of participants and 100 percent of all nonparticipants.)

The program also expects that physicians will approve patients for participation in the program and respond to case managers' concerns about specific patients' conditions and problems. The program has relied primarily on QMed's reputation among area physicians to facilitate these activities.

After a year of operation, staff believed that physicians were highly satisfied with the program. Physicians have cooperated in approving patients for participation, and some have actively encouraged their patients to enroll in the program or directly referred patients to it. Physicians seem to be reviewing the monitoring reports and discussing the results with patients, as well as meeting with the program's quality manager. A few physicians have instead had the quality assurance manager meet with their nurse managers. One physician summarized the program as follows: "It does things that [physicians] don't have time to do like make sure people make appointments, come to appointments, and do their labs. It gives patients more of a feeling that 'somebody cares about me.' Patients look forward to the 'heart study.'"

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

Improving Patient Adherence. The QMed MCCD also plans to improve patient health by improving adherence to treatment recommendations. The program gives patients cardiac-focused written materials about stress management and lifestyle changes (such as increasing exercise, losing weight, and smoking cessation). During patient contacts case managers focus on cardiac-related symptoms and problems, but they will provide education if appropriate. The program also offers educational seminars, maintains an on-site library of pamphlets and videotapes, and sends patients a quarterly educational newsletter. Case managers assess whether teaching has been effective by listening to patients describe their behaviors, asking patients specific questions, and looking at laboratory test results obtained through chart abstraction on a quarterly basis to determine whether the patient has initiated behavior change. If the program finds a patient is not learning, the case manager works with the patient and his or her family/caregiver to identify barriers to learning and behavioral change.

Among the 333 patients enrolled in the QMed MCCD during its first six months, most (79 percent) had received at least one contact for self-care or disease-specific education, and a third had at least one contact during which the disease manager explained medications. Only one patient had a contact during which the disease manager explained tests or procedures.

Improving Communication and Coordination. The QMed MCCD has developed an approach to improving communication and coordination between patients and physicians that seeks to help patients better communicate their health care needs and that provides data directly to physicians to enhance clinical decision making (as well as, ultimately, to improve clinical practice). The program teaches patients when and how to request needed tests and other care from physicians and how to ask questions during physician office visits. The program sends physicians regular reports based on cardiac monitoring that compare the patient's CAD treatment regimen and outcomes with evidence-based guidelines, focusing on medications and medication

problems. The program also contacts physicians by telephone or, if necessary, in person when urgent patient problems arise. The program helps patients resolve apparent conflicts in advice from physicians by having the care managers discuss discrepancies with their patients' primary care physicians. The care managers follow up with the patients to resolve the confusion. However, adverse events and cardiac procedures are identified only through self-report and chart review, rather than through notification by hospital or physicians' offices. Thus, lack of timely information about these events may cause a significant time lapse between hospital discharge and when case managers can follow up with the patients to address new medications or instructions.

Increasing Access to Services. When necessary, QMed's MCCD will arrange for services for its patients and pay for some goods and services; however, increasing access to services is not a major program focus. During routine monitoring, case managers assess patients' needs for support services and identify providers using QMed's county service booklet. The program will also pay for transportation, test strips, and pillboxes if the patient cannot afford them and offers patients a discount on CAD-related prescription drugs through CareMark's mail order prescription drug program. The program will also pay for lipid and Hemoglobin A1C tests through Quest Diagnostics for a small number of patients if their physician feels they need a test more often than Medicare covers. However, the program did not pay for any goods or services (including prescription drugs) during its first six months of operations. Nor did it identify any patients who needed referrals to support service providers. Staff noted that the patients enrolled during this period were relatively active and did not need this type of support. Indeed, the population the program serves is not much sicker than the typical Medicare patient, so it would have little need for such services.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

This report presents preliminary estimates of Medicare service use and costs for the QMed MCCD for those enrolled during the first four months of intake. The follow-up period (the first two full months after random assignment) is too short to draw inferences about the true effects of the MCCD over a longer period. Total Medicare reimbursement for the 211 treatment group members, exclusive of demonstration costs, were $1,153 ($577 per month), on average, during the first two months after enrollment, compared with $1,042 ($521 per month) for the 208 control group members. This difference of 11 percent ($112 over two months, or $56 per month) is not statistically significant. The net treatment-control difference in costs is $303 ($152 per month) when one takes into account the CMS program payment ($191 over two months or $96 per month). It is too soon to tell whether the intervention will ultimately result in lower costs.

CONCLUSION

Program Strengths and Unique Features. QMed's MCCD program, compared with other programs in the demonstration, puts relatively more emphasis on changing physician treatment of CAD and relatively less on changing patient behavior.

- The program had no difficulty meeting its year 1 enrollment target by first recruiting physician groups to participate in the demonstration and reviewing practice rosters for potentially eligible patients. QMed's preexisting strong reputation with area physicians enabled the program to do this.

- The program assesses all patients with a tool that focuses on cardiac problems and comorbidities common to people with CAD. Disease management specialists perform quarterly reviews of patients' medical charts, extracting data on diagnoses, hospitalizations, and medications. These data are combined with cardiac monitoring data for the physician's first report from the program.

- The program performs an electrocardiogram on each patient when the patient enrolls and every six months thereafter. Based on the initial monitoring, the program's software generates treatment recommendations and clinical goals, which serve as the patient's care plan. Case managers follow up with patients by telephone at least every two months.

- During routine monitoring, case managers review a checklist of cardiac-focused educational topics with patients. The program also offers educational seminars, maintains an on-site library, and produces a quarterly educational newsletter.

- The program teaches patients to communicate more effectively with their physicians by providing them with wallet cards documenting their medications and vital statistics. It also teaches them to coordinate their own care by providing reminders of needed tests and follow-up physician visits.

- The program will pay for diabetic test strips, pillboxes, and health care-related transportation (if patients cannot afford them) and will help patients pay for CAD-related prescription and over-the-counter drugs and laboratory tests (if the patient requires more frequent testing than Medicare covers). During the first year of operation, however, no such services had been delivered.

- All the case managers working for the program during its first year were seasoned QMed employees and licensed practical nurses and registered nurses.

- Following each cardiac monitoring session, the program generates reports for physicians that compare their treatment recommendations with evidence-based guidelines. The reports highlight deviations from optimal prescribing and problems with polypharmacy and medication interactions.

- The program's quality assurance manager meets with physicians regularly to discuss cardiac monitoring reports and patient adherence, as well as to solicit feedback about the program. Staff report that physicians are reviewing the reports and respond to case manager requests about specific patients.

- Finally, while the program does not provide financial incentives to staff to achieve particular patient outcomes or program goals, it does pay physicians $25 per session for providing the program with patient medical charts and $50 for reviewing each cardiac monitoring report.

Potential Barriers to Program Success. The QMed MCCD faces a serious barrier to effectiveness because of poor targeting. Preliminary Medicare data analysis raises potential concerns that the program is not enrolling patients who are at much risk of incurring high health care costs in the short run and, therefore, are not likely to show improvements on most of the utilization, cost, and well-being measures over the period that the evaluation examines. Among those patients enrolled during the program's first six months, program participants were no more likely than the average Medicare beneficiary to be hospitalized in a given year (20 percent chance). More than one-third of enrollees had no Medicare claim of any type for CAD in the year before enrollment, and most of these patients had no claims for CAD 13 to 24 months before enrollment. Thus, it is difficult to see how an intervention that focuses on patients with CAD will be of much value to these patients during the period covered by the evaluation. (QMed MCCD staff note, however, that outcomes for CAD patients may be more likely in the longer term.) Enrolled participants also had lower Medicare costs than expected: $641 per month in the preenrollment year, compared to $1,116 estimated for the target population in its waiver application and $954 for eligible nonparticipants in the area. If postenrollment Medicare costs remain as low as preenrollment ones, it may be difficult for the program to save enough through reductions in services normally covered by Medicare to cover program fees of $110 per month, even though this fee is relatively low compared to those of other MCCD programs. However, if the program is able to slow the progression of its patients' CAD, it may be able to cover the costs of its program fees.

INTRODUCTION

The Medicare Coordinated Care Demonstration, mandated by the Balanced Budget Act of 1997, is testing models aimed at improving the care of chronically ill beneficiaries with Medicare fee-for-service 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 16 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 will describe each program during its first year of implementation and provide 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 QMed's Medicare Coordinated Care Demonstration Project, called the QMed MCCD Heart Study. QMed, Inc., a publicly held disease management company located in Eatontown, New Jersey, provides cardiovascular disease management services to managed

[1] Lovelace Health System's CMS Medicare Case Management Demonstration for Congestive Heart Failure and Diabetes Mellitus is also part of the MPR evaluation. Appendix Table A.1 lists the host for each demonstration program in the evaluation, as well as each program's service area and target diagnoses.

care organizations (MCOs) and employer groups. QMed's MCCD, which began enrollment in July 2002, enrolls Medicare beneficiaries with coronary artery disease (CAD).

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. In addition, the structure of the protocols 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 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 QMed MCCD's service area who were eligible for

the program and the percentage who actually enrolled during the program's first six months of operation. Beneficiaries are identified as eligible if, for any month between July 2002 and January 2003, they (1) lived in the program's service area, (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 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. Participants and eligible nonparticipants were then compared 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 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.

Despite these shortcomings, the treatment-control differences are presented 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. These analyses also will examine patient outcomes based on telephone interviews with treatment and control group members. Interview-based outcomes include the receipt of preventive health services, general health behaviors, self-management,

functioning, health status, and satisfaction with care, as well as disease-specific behaviors and health care.

OVERVIEW OF THE QMED MCCD HEART STUDY

Program Organization and Relationship to Physicians. QMed, Inc., the host for the MCCD Heart Study, is a publicly held disease management company located in Laurence Harbor, New Jersey, with satellite offices throughout the country. QMed has worked with Medicare managed care plans in California for roughly six years. QMed, founded in 1983 to develop diagnostic and prognostic medical devices for chronic diseases, developed technology for managing CAD called the On-line Health Management System for Coronary Artery Disease (ohms|cad®). Ohms|cad is a real-time, digital monitoring device that performs an electrocardiogram on patients with, or at-risk for, CAD and automatically generates prognoses and therapeutic recommendations for each patient based on individual risk factors. When combined with patient-customized education, QMed has reported that ohms|cad reduces the frequency of heart attacks, the number and length of hospitalizations, and the number of diagnostic and invasive procedures, and it increases the prescribing of beta blockers compared to other Medicare beneficiaries.

The MCCD Heart Study uses two types of patient care staff. Case managers conduct patient assessments, routine monitoring, and education by telephone. Disease management specialists interact with patients in person by connecting them to QMed's ohms|cad monitoring device, as well as by checking the eligibility of interested beneficiaries before enrollment and conducting medical chart reviews.

The case managers are located in QMed's New Jersey office, as are QMed's other key MCCD staff, including the program director, program coordinator, and case manager supervisor. The program's disease management specialists, quality assurance manager, program manager,

and administrative assistant are located in the QMed's Stockton, California, satellite office. The program director has overall responsibility for the demonstration, as well as for other QMed contracts. The program coordinator works full-time on the MCCD and oversees day-to-day operations by reviewing reports and maintaining contact by telephone with Stockton office staff. The case manager supervisor has oversight of case management activities, helps with patients who have particularly acute problems (for example, shortness of breath), and assesses patients with special needs (for example, people with disabilities). The quality assurance manager monitors physician adherence to practice guidelines, conducts educational seminars for patients, and assists in enrollment by giving presentations to eligible patients. The program manager supervises the disease management specialists and also assists in enrollment by giving presentations to eligible patients. The administrative assistant arranges transportation for patients, maintains the on-site library, mails educational materials, and helps with enrollment paperwork. After a year of operation, the program had three case managers and two disease management specialists. The program anticipates case manager caseloads of 100 patients each when the program reaches full enrollment.

QMed is well known to physicians in the Stockton area, and this has facilitated physician participation in the MCCD. QMed staff noted that the company has a good reputation among physicians based on its provision of disease management services to MCOs in the area. To enlist physician support for the MCCD, the program director and program coordinator made presentations to several large practices and distributed packets containing information about the program, as discussed in more detail below.

Primary Approaches. The QMed MCCD has adopted three main approaches to improving patient health and reducing health care costs: (1) improving physician practice, (2) improving patient adherence to treatment recommendations, and (3) improving communication and

coordination between patients and physicians. The program seeks to improve physician practice by providing patients' primary care physicians with evidence-based guidelines and patient-specific reports of clinical information and treatment recommendations based on program heart monitoring. The program seeks to improve patient adherence by educating patients about their disease and how to monitor symptoms on their own. The program aims to improve communication and coordination by reminding patients about doctor appointments and tests and teaching them to communicate more effectively with their doctors.

Target Criteria and Patient Identification. The QMed MCCD requires its participants have been treated for CAD or to have a history of medical events or symptoms typically associated with CAD.[2] Patients' primary care physicians must consent to their participation. Patients must live in one of three northern Californian counties: Stanislaus, San Joaquin, or Sacramento.[3] As in all MCCD 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 those patients who (1) have end-stage renal disease, (2) are transplant recipients or on a transplant list, (3) are immune suppressed, (4) have a terminal illness or receive the Medicare hospice benefit, (5) have heartbeats continuously triggered by a pacemaker (sometimes referred to as having "a permanently paced heart rhythm"), or (6) participate in another research study.[4]

[2] Specifically, the program targets beneficiaries who have had myocardial infarction, percutaneous transluminal coronary angioplasty, coronary artery bypass grafting surgery (CABG), angina, symptoms involving the respiratory system, or other chest symptoms.

[3] After a year of operation, QMed had not begun recruiting in Sacramento County, and no patients from this area are included in the analyses.

[4] QMed had also proposed to exclude beneficiaries under age 65, but one-third of participants enrolling during the first six months of operations were that young.

The QMed MCCD identified patients during its first year of operation primarily by having its staff manually review medical charts of participating physician groups. (Later in the year, in early 2003, the program changed from this manual review to an automated review of the physician groups' electronic billing records that searched for a CAD diagnosis.) To recruit physician groups, the program director or program coordinator initially approach the medical director of each group, explain the program, and obtain his or her consent to present the program to individual physicians in the practice. Staff then describe the program to physicians at a practice group meeting and provide each physician with an introductory packet, which includes a signed letter of endorsement from the practice's medical director, CAD and diabetes treatment guidelines, the patient informed consent form, a PowerPoint presentation describing the MCCD, and a sample ohms|cad report. Physicians who participate agree to review lists of their patients for program appropriateness, review ohms|cad reports, and respond to questions from case managers about specific patients. After a year of operation, the QMed MCCD had obtained participation agreements with two large physician practices in the Stockton area and was negotiating a participation agreement with a third physician group. Sixty-five physicians had agreed to participate in the program. (See Appendix C for the practice medical director's endorsement letter and physician participation agreement form.)

Next, the program gives the participating practice an Excel spreadsheet to help it generate a list of patients with CAD. The disease management specialists then go to the practice offices and pull medical charts of listed patients to do a preliminary check of CMS's insurance and the program's eligibility criteria. (The MCCD pays physicians or the participating practice $25 per session for providing access to patient medical charts.) The MCCD program managers then visit physicians in person to review each of their potentially eligible patients for program appropriateness. Physicians sign a form authorizing the program to enroll those patients they

deem appropriate. A case manager then confirms Medicare eligibility for each patient by checking the Common Working File. After eligibility has been confirmed, a case manager sends the patient a letter, signed by the patient's physician or by the medical director of the participating physician group, inviting him or her to participate. Approximately two weeks after sending the letter, a case manager follows up by telephone. Using a script, the case manager invites the patient to an informational meeting (called the "informed consent" meeting) in their area to explain the program and obtain informed consent. Up to 10 interested patients and their family members/caregivers attend each meeting, during which a program representative describes the benefits of the program, patient participation requirements, and randomization. (The program representative may be a disease management specialist, the program manager, or the quality assurance manager.) After the meeting, interested patients are asked to sign the informed consent form and fill out an evaluation of the presentation. Patients can take the informed consent form home and mail it to the program. If the program does not receive the informed consent form within two weeks, a case manager follows up with the patient by telephone until the patient decides whether to participate. The program then forwards enrollment data for consenting patients to the evaluator for random assignment.[5] (Appendix C contains the invitation letter and informed consent meeting script.)

Although the program identified most of its patients (more than 90 percent) during its first year by reviewing lists generated by physician practices, it has received a small number of direct referrals from physicians and individuals. Staff reported that physicians often think of additional MCCD candidates when they review the lists of eligible patients. The program has also

[5] Program staff stated that, during the first five months of operation, they checked a patient's exclusion criteria *following random assignment*. During that period, however, the program did not disenroll any patients due to ineligibility.

advertised in a local Stockton newspaper, senior centers, and physicians' offices. However, these efforts have generated only a handful of self-referrals; most self-referrals have been spouses or family members of program participants.

Assessment, Care Planning, and Monitoring. Following random assignment to the treatment group, each patient is assigned a case manager. Within seven days of random assignment, the case manager sends the patient a welcome package (available in both English and Spanish), which includes materials explaining the program, information about the QMed MCCD discount prescription drug program through CareMark, a wallet card for tracking medications and vital statistics, and an educational pamphlet about CAD. During this time, the case manager contacts the patient to welcome him or her to the program. During the welcome call, the case manager verifies the patient's contact information and the primary care physician's and/or cardiologist's contact information. The case manager also determines whether the patient needs additional assistance to fully participate in the program (for example, translation services; help with a hearing, visual, or speech impairment, or transportation to monitoring appointments at the program office). The case manager schedules a follow-up call with the patient to perform the initial assessment within the following week, although they will conduct the assessment during the welcome call if the patient is willing. (See Appendix C for the "welcome call" script.)

During the initial assessment, the case manager uses the program's "Healthy Heart Profile" to ask the patient questions. The assessment is narrowly focused on cardiac problems, covering history of heart problems, cardiac-related hospitalizations and procedures, comorbidities, and current medications. (See Appendix C for the "Healthy Heart Profile" form.) Results of the

assessment are documented in QMed's Patient and Information Management System (PIMS).[6] The program's disease management specialists also perform an initial review of the patient's medical chart in his or her physician's office, extracting data on office visits, diagnoses, hospitalizations or procedures, and new medications. These data are input to PIMS and are combined with cardiac monitoring data for the physician's first report from the program. (These chart extractions are performed quarterly as part of routine monitoring.)

Between July 2002 and January 2003, the first six months of program operation, 333 patients enrolled and were randomly assigned to the QMed MCCD's treatment group (Table 1). Among those patients, 89 percent (296 patients) had at least one contact for assessment. Among those patients contacted for an assessment, only 28 percent had their first assessment contact within two weeks of random assignment. The program's goal had been to complete all assessments within two weeks of random assignment. Program staff reported that the delays were due primarily to patients' difficulty finding time in their busy schedules for the assessments and delays in obtaining Notification of Election (NOE) from CMS early in the first year of operation.

Approximately 45 to 90 days after the patient enrolls in the program, patients are monitored using QMed's ambulatory electrocardiogram device. The device can be attached to a patient's belt loop or worn over the shoulder. The patient meets with a disease management specialist at QMed's Stockton office who attaches five electrodes to the patient and connects them to the monitor. The patient wears the device for 24 hours and returns the next day to have the monitor removed. During each cardiac monitoring appointment, disease management specialists repeat the "Healthy Heart Profile" assessment in person.

[6] PIMS is a stand-alone computer system that prompts case managers to contact patients and record their interactions with patients. It is a sophisticated system that uses branching logic to guide case managers through the case management process. Appendix C includes examples of screens from PIMS.

TABLE 1

STAFF CONTACTS WITH PATIENTS DURING FIRST SIX MONTHS

Number of Patients Enrolled[a]	333
Number of Patients with at Least One Staff Contact (Percent)	305 (91.6)
Total Number of Contacts for All Patients	1,430
Average Number of Contacts per Patient, Among Those Contacted	4.7
Number of Staff Contacting Patients	8
Among Those Patients with at Least One Contact:	
Percentage of contacts staff initiated	80.3
Percentage of contacts in person at patient's residence	0.0
Percentage of contacts by telephone	81.7
Percentage of contacts in person elsewhere	18.3
Of All Patients Enrolled, Percentage with Assessment Contact	88.9
Among Those Patients with an Assessment, Percentage of Patients Whose First Assessment Contact Is:	
Within a week of random assignment	2.4
Between one and two weeks after random assignment	25.7
More than two weeks after random assignment	72.5
Of All Patients Enrolled, Percentage of Patients with Contacts for:	
Routine patient monitoring	88.6
Providing emotional support	0.3
Providing disease-specific or self-care education	79.3
Explaining tests or procedures	0.3
Explaining medications	33.3
Monitoring abnormal results	0.9
Identifying need for non-Medicare service[b]	0.0
Identifying need for Medicare service	0.6
Monitoring services	0.0
Average Number of Patients Contacted per Staff Member	38.1
Average Number of Patient Contacts per Staff Member	178.8

Source: QMed program data received April 2003 and updated July 2003. Covers six-month period beginning July 12, 2002, and ending January 7, 2003.

Note: Contacts described in this table include those made by disease management specialists, nurse case managers, and their clinical supervisors.

[a]Number of patients enrolled in the treatment group as of January 7, 2003.

[b]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.

The monitoring data are then transferred by telephone modem to QMed's New Jersey office, where they are combined with data from the patient assessment and chart review. QMed's data system generates a report describing the patient's risk factors, laboratory results, clinical and behavioral goals based on evidence-based guidelines, and current medications. Then, QMed's consulting cardiologist adds recommendations for treatment changes to the report, and the report is shared with the patient's physician. The report also serves as the patient's program care plan. Case managers can consult the report during routine contacts to determine if patients are meeting clinical and behavioral goals and taking recommended medications, as well as to assess patients' understanding and to educate them where appropriate.

Patients receive ambulatory electrocardiograms with the QMed device every six months, at which point the monitoring report for the physician is updated. Following device monitoring, patients also receive a short report, which describes the educational materials the program has mailed to them, their clinical readings (lipids and blood pressure), and their goals. (See Appendix C for examples of physician and patient ohms|cad reports.)

After the first electrocardiogram monitoring session, the case manager contacts the patient by telephone every other month after the first electrocardiogram monitoring session. Each day, PIMS prompts case managers about scheduled calls. During those calls, the case manager uses questions scripted in PIMS to ask the patient about changes in their health status or functional status, changes in their medication regimen, adherence to medications, changes in diet, and whether they are experiencing stress or emotional upset. The case manager then asks the patient if they have any questions, educates the patient about CAD and the importance of medication and other treatment adherence, and inquires about service needs (such as transportation). The case manager may also review areas for improvement with the patient (such as increased exercise), as well as any issues identified during the last contact. Monitoring frequency increases

to at least monthly (or more frequently at the discretion of the case manager) if chart review reveals the patient has been hospitalized or if the patient has comorbidities. If the case manager cannot contact a patient by telephone, they mail the patient a letter with a written assessment to complete and mail to the program. If a patient calls his or her case manager between routine monitoring calls, the case manager uses a shortened questionnaire, also scripted in PIMS, to check on the patient's status. Case managers document routine monitoring results in PIMS. (See Appendix C for the "full assessment" script and mailed written assessment.)

The QMed MCCD has only a few patients (known as "snowbirds") who may temporarily move away from the service area; the program's policy is to maintain contact with these patients. Most patients give case managers a telephone number where they can be reached; however, some patients prefer to be contacted by mail. In these cases, case managers send patients written questions about their health status, as well as appropriate educational materials. The program continues to perform chart reviews while the patient is away, but regular ambulatory monitoring is postponed until the patient returns.

Of the 333 patients enrolled during the first six months of operation, 305 patients (92 percent) had at least one contact with a case manager (Table 1). Patients had four contacts during this period, on average. Case managers initiated almost all contacts (80 percent), and most (82 percent) were by telephone. The rest of the contacts were in person, for ambulatory monitoring, at QMed's Stockton office. Although these contacts include those for assessment, most enrollees (89 percent) also had a contact for routine monitoring.

Staffing and Program Quality Management. Maintaining and improving quality and ensuring that programs attain their goals require that staff have adequate qualifications, training, and supervision and that management has the tools and support to monitor progress toward the program's goals. QMed's case managers must be registered nurses or experienced licensed

practical nurses. QMed's disease management specialists must be registered nurses or licensed practical nurses. Upon hire, case managers and disease management specialists participate in QMed's employee orientation at the New Jersey office. The orientation covers informed consent, enrollment and disenrollment procedures, assessment procedures, reporting and data entry, and the process for responding to complaints. All case managers and disease management specialists are on probation for their first 90 days. At the end of the probationary period, staff undergo an evaluation using QMed's case manager assessment tool. During the probation period, newly hired case managers may only make welcome calls and perform initial assessments. However, all the case managers on staff during the first year of the demonstration had been QMed employees before the demonstration and assumed full responsibility for their caseload when they started working on the MCCD.

QMed's quality assurance director, who is not on the MCCD staff, evaluates all QMed's case managers, including those working on the MCCD, every six months. The evaluation is conducted with the same tool administered to staff after the probation period. In addition, the New Jersey-based program coordinator reviews PIMS-generated reports, daily and weekly, of scheduled work and the number of contacts completed by case managers. The Stockton-based program manager reviews the disease management specialists by going back to physicians' offices, randomly repeating chart extractions, and comparing her findings to those of the disease management specialists. These chart audits are performed quarterly.

Overall program oversight and quality improvement for patient care, as well as operational aspects of the demonstration, occur during one-hour bimonthly telephone meetings, which include all program staff. During those meetings, staff discuss topics specific to current demonstration operational issues (for example, enrollment outreach). Staff may propose and discuss changes to program processes or report ongoing activities. For example, during one

meeting, a staff member reported the physician adherence report was too difficult to work with. Other staff members agreed that a new format was needed (see Appendix C for an example of staff meeting minutes).

The program director uses an extensive set of reports generated using PIMS and the ohms|cad system to monitor enrollment and track changes in patient outcomes and physician practice. Reports are generated on an individual level (by patient and physician) or an aggregate level (by physician practice and the entire MCCD). Individual-level reports include the ohms|cad monitoring report, by patient, and reports describing adherence to guidelines, by physician. The QMed MCCD also generates aggregated adherence reports for an entire physician practice, as well as reports of demographic and clinical characteristics (such as blood pressure and lipid profile) and outcome data (such as use of beta blockers or ACE inhibitors) for all enrolled patients. In addition, the program produces reports to monitor enrollment, disenrollment, and the use of the ambulatory cardiac monitoring devices. Except for the monitoring device report, which is generated every six months, reports are generated and reviewed monthly. (See Appendix C for examples of the overall patient clinical characteristics report and the enrollment report.)

The QMed MCCD surveys all patients annually about their satisfaction with the program. The MCCD plans to survey physicians about their satisfaction with the program and how it has affected their clinical practice, but has not yet done so. The quality assurance manager regularly communicates with physicians to receive feedback about the program. QMed's quality department administers both the patient and physician satisfaction surveys and do not involve demonstration staff. (See Appendix C for the patient and physician satisfaction surveys.)

When the program receives a complaint, the case manager reports it to QMed's quality department, which is separate from the MCCD. The quality department reviews the complaint

and program staff address it. The program has received a few complaints from both patients and physicians. The main complaint from patients was that the contact they have with case managers is too frequent. In response, the program reduced the frequency of monitoring from monthly to every other month. The most common complaint from physicians has been that they do not have enough time to review the cardiac monitoring report before the program prompts patients to call the physician about it and ask whether an appointment with the physician is necessary. The program now delays such reminders to patients about contacting their physician.

WHO ENROLLS IN THE PROGRAM?

The program exceeded its year 1 enrollment target without substantially modifying its planned approach to identifying patients, and staff report that patients are highly satisfied with program services. However, the program appears to have enrolled patients who have lower-than-expected Medicare costs.

Enrollment After One Year. After one year of operation, the QMed MCCD had enrolled 645 patients in the demonstration treatment group and 646 in the control group (MPR weekly enrollment report, week ending July 13, 2003). The program's target enrollment was 571 treatment group members over the entire demonstration. Staff attribute this success to physician support for the program based on their previous experience working with QMed, as well as to the face-to-face informed consent meetings with beneficiaries and recruitment letters signed by patients' physicians. Staff believe these interactions dispel some beneficiaries' anxiety about the legitimacy of the program.

Roughly a third of all patients identified as potentially eligible for the program ultimately agreed to participate. The program identified 4,600 potentially eligible fee-for-service Medicare beneficiaries living in Stanislaus and San Joaquin counties through May 2004. Of those, roughly 900 were found to have a condition that made them ineligible for the program or to have a

physician not participating in the program. Staff invited the remaining 3,700 beneficiaries to informed consent meetings; about 2,600 (70 percent of those invited) attended. As of the end of May 2004, the program had enrolled 1,448 participants (or more than half of those attending the meetings). Staff reported that the main reasons patients declined to participate were that they (1) were caring for an ill spouse, (2) did not want the frequent contact with staff the program requires, or (3) did not understand what the program was about.

Percent of Eligible Beneficiaries Participating. To gain another perspective on program participants, the evaluation simulated the program's eligibility criteria using Medicare enrollment and claims data to estimate the percent of eligible beneficiaries who chose to participate in the QMed MCCD. (Appendix B contains a detailed description of the simulation.) This simulation identified 13,410 beneficiaries eligible for the program between July and December 2002, the program's first six months of operation. 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.[7] During the same six months, 714 beneficiaries enrolled in the program, of whom only 262 were "eligible" according to the evaluation's simulation. To use a consistent definition of the beneficiary groups for the numerator and denominator of the ratio, only "eligible" beneficiaries are included in the calculation of the participation rate. Thus, about two percent of the 13,410 eligible beneficiaries enrolled. (See Tables B.2 and B.3.) The simulation did not distinguish between beneficiaries served by physicians participating in the QMed MCCD

[7] From July 2002 through December 2002, 132,139 beneficiaries were living in the program's service area. Of those, 52,197 *(*40 percent) would have been ineligible for the program because they did not meet one of CMS's demonstration-wide criteria. Of the remaining 79,942 beneficiaries who met these criteria, 13,410 *(*17 percent) also had a claim for one of the program's diagnostic criteria at some point during the six-month intake window or the previous year, and they had none of its exclusion criteria (to the extent they could be simulated with the Medicare data). (See Table B.2.)

and those served elsewhere in the program's service area, however, so the number of eligible nonparticipants who might truly have had access to the demonstration is probably much smaller.

The large proportion of beneficiaries enrolled in the program who do not meet the eligibility criteria used in the simulation can be explained as follows. The simulation treats as ineligible 12 enrollees with incorrect Health Insurance Claim (HIC) numbers on MPR's enrollment file, 46 whose records indicated they lived outside of the program's service area, and 33 who did not meet the CMS's demonstration-wide criteria.[8] However, 241 enrollees (half of the ineligible enrollees) were classified as ineligible because they did not have any claims for CAD or symptoms suggestive of CAD during the year before the program began or even during the first six months after enrollment. (Furthermore, only 28 of the 241 enrollees had any encounter for the disease in the period 13 to 24 months before enrollment. The 18-month period used in the simulation was chosen because evaluation staff believed the program would focus recruitment on beneficiaries who had received at least some recent treatment for the target condition, but the program did not explicitly require this.) An additional quarter of the enrollees classified as ineligible (120 beneficiaries) was comprised of enrollees having one of the program's exclusion criteria according to the claims data. Half of these beneficiaries were younger than age 65, and the rest had end-stage renal disease, were transplant recipients, were immune-suppressed, had a terminal illness, or received a hospice medical benefit. (The program also planned to exclude beneficiaries who are on a transplant list, have a heartbeat continuously triggered by a pacemaker, or participate in another research study, but these criteria could not be simulated using claims data.)

[8] Beneficiaries with invalid HIC numbers may well be eligible, but the beneficiaries' Medicare data could not be obtained to assess that, so they were excluded. The HIC numbers have since been corrected.

QMed staff believe the large number of enrollees who appear to be ineligible for the program according to the evaluation's simulation reflects the program's early practice of using chart reviews and physician confirmation of a CAD diagnosis to determine eligibility. As noted, staff stated that they checked the exclusion criteria after randomization and disenrolled beneficiaries they believed would not benefit from the intervention. However, data the program provided for the evaluation showed that no patients were disenrolled for this reason during the program's first six months.[9] In January 2003 (about seven months after enrollment began), the program switched to using medical billing records to identify eligible beneficiaries. Staff believe, as a result, all beneficiaries who enrolled following the change would meet the program's eligibility criteria.[10]

Comparison of Participants and Eligible Nonparticipants. An analysis of Medicare enrollment and claims data showed that program participants and eligible nonparticipants differed on a range of demographic characteristics (Table 2). Some of these differences likely reflect differences between the physician groups participating in the program and other area physicians in the types of patients served. Some of the demographic differences are probably due in part to the fact that a sizeable proportion of enrollees do not meet the diagnostic criteria used to identify eligible nonparticipants.[11] Participants were younger, on average, than eligible

[9] In fall 2004, the program also reviewed its records for patients the simulation suggested did not have its target conditions and planned to disenroll any patients who were not eligible.

[10] In late 2004, QMed altered its MCCD program eligibility criteria to include patients under age 65 and those with permanently paced cardiac rhythms. It also began to exclude patients with a history of angina but without a history of a definitive event such as a myocardial infarction, PTCA, or CABG. In addition, the program began to identify all of its potential patients by reviewing electronic billing information.

[11] The comparison of participants to eligible nonparticipants in Table 2 excludes only participants with invalid HIC numbers and those who did not meet Medicare demonstration-wide requirements, leaving 666 participants. Thus, the comparison more closely reflects the differences between all actual participants and those who were eligible to participate but did not.

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[b]	
Age at Intake			
Average age (in years)	72.8	76.4	***
Younger than 65	8.3	0.0	***
65 to 74	50.2	43.8	***
75 to 84	37.1	41.6	**
85 or older	4.5	14.7	***
Male	45.7	41.9	*
Nonwhite	11.1	18.6	***
Original Reason for Medicare: Disabled or ESRD	18.3	13.9	***
State Buy-In for Medicare Part A or B	12.0	34.6	***
Newly Eligible for Medicare (Eligible Less than Six Months)	0.30	0.20	
Enrolled in Fee-for-Service Medicare 6 or More Months During Two Years Before Intake	98.4	98.8	
Medical Conditions Treated During Two Years Before Month of Intake[c]			
Coronary artery disease	59.4	75.4	***
Congestive heart failure	23.2	34.2	***
Stroke	25.0	30.0	***
Diabetes	29.8	31.5	
Cancer	19.2	5.1	***
Chronic obstructive pulmonary disease	25.3	35.4	***
Dementia (including Alzheimer's disease)	0.9	4.1	***
Peripheral vascular disease	10.4	14.1	***
Renal disease	5.2	7.2	*
Total number of diagnoses (number)	2.0	2.4	***
Days Between Last Hospital Admission and Intake Date[c]			
No hospitalization in past two years	67.0	57.2	***
0 to 30	1.2	4.3	***
31 to 60	2.3	3.6	*
61 to 180	9.8	10.5	
181 to 365	7.8	12.3	***
366 to 730	11.9	12.1	
Annualized Number of Hospitalizations During Two Years Before Month of Intake[c,d]			
0	67.2	57.9	***
0.1 to 1.0	23.2	28.7	***
1.1 to 2.0	6.4	9.7	***
2.1 to 3.0	2.1	2.4	
3.1 or more	1.1	1.3	

TABLE 2 *(continued)*

	Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants[b]	
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[c]			
Part A	$345	$646	***
Part B	$296	$308	
Total	$641	$954	***
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[c]			
$0	1.5	0.9	
$1 to 500	74.4	67.5	***
$501 to 1,000	8.4	10.9	**
$1,001 to 2,000	7.7	8.3	
More than $2,000	8.0	12.4	***
Number of Beneficiaries	**666**	**13,148**	

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 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]The simulation did not distinguish between beneficiaries served by physicians participating in the QMed MCCD and those served elsewhere in the program's service area, however, so the number of eligible nonparticipants who might truly have had access to the demonstration is probably much smaller.

[c]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.)

[d]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.

*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.

nonparticipants. Among the MCCD participants, 5 percent were age 85 or older, compared to 15 percent of eligible nonparticipants. Because of this age differential and the greater longevity of females, a slightly higher proportion of participants were male (46 percent, compared to 42 percent of nonparticipants). Participants also were less likely to be poor, as reflected by their eligibility for Medicaid: 12 percent, compared to 35 percent of nonparticipants. The two groups had different racial compositions: 11 percent of participants were nonwhite, versus 19 percent of nonparticipants. A higher proportion of participants were eligible for Medicare because of disability: 18 percent of participants versus 14 percent of nonparticipants were originally eligible due to disability or to having end-stage renal disease.

Participants were less likely than eligible nonparticipants to have a series of chronic conditions. Using the evaluation's standard definition for CAD (which was narrower than the program's target criteria), during the two years before enrolling, only 59 percent of participants had been treated for that condition—the primary target diagnosis for the QMed MCCD—compared to 75 percent of nonparticipants.[12] Nonparticipants also had higher rates of congestive heart failure, stroke, chronic obstructive pulmonary disease, dementia, peripheral vascular disease, and renal disease, which were not target conditions. Participants were, however, more likely to have been treated for cancer.

Because their health was better, participants had lower hospitalization rates and total Medicare spending than eligible nonparticipants. About 21 percent of participants had a hospitalization in the year before enrollment and had monthly Medicare reimbursements of $641, on average, over that year, compared to a 31 percent hospitalization rate and $954 in monthly

[12] Not all participants and nonparticipants have CAD, because, in addition to targeting beneficiaries with CAD, QMed targets beneficiaries who have had diagnostic tests or procedures that indicate the possibility of CAD. Using QMed's own, more expansive list of target diagnoses and procedure codes for the MCCD, 65 percent of participants and 100 percent of eligible nonparticipants meet the target criteria.

Medicare reimbursements for eligible nonparticipants. Nonparticipants were also more likely than participants to have had a hospitalization in the month before intake (4.3 versus 1.2 percent).[13]

When developing the cost estimate for the QMed MCCD waiver application, MPR estimated that, without the program, Medicare reimbursements would average $1,116 per month for eligible beneficiaries. However, these calculations assumed that eligible beneficiaries would have an inpatient or outpatient hospital claim for CAD or a CAD-related procedure or test in a 12-month period. The average cost for eligible (nonparticipating) beneficiaries was about 15 percent below these waiver cost estimates because the QMed MCCD did not require that the services be delivered in a hospital inpatient or outpatient setting. However, the difference between participants and eligible nonparticipants, which is much larger, is due to so few of the participants having a Medicare claim in the preceding two years for CAD, CAD-related procedures or tests, or CAD symptoms. (The participation analysis did not require that services be delivered in a hospital inpatient or outpatient setting.)

Satisfaction and Voluntary Disenrollment. Preliminary results from the program's first annual patient survey were not available for this report. Anecdotally, however, case managers report that patients are thankful for the assistance and education the program provides and feel more empowered and in control of their health. Staff believe the program works best for motivated patients who need guidance on how to take care of themselves.

Patients may stay in the QMed MCCD for the duration of the demonstration (that is, until July 2006). Among the 333 treatment group patients who enrolled during the first six months of operation, 44 percent were enrolled 10 weeks or less, 32 percent were enrolled between 11 and

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

20 weeks, and 24 percent were enrolled 21 weeks or more (Table 3). Voluntary disenrollment during the first six months was modest. Only 10 of 333 patients disenrolled voluntarily. Reasons for disenrolling included (1) the program taking too much of their time, (2) feeling "too sick" to participate, and (3) planning to move. In addition, 19 patients disenrolled when their physician decided to discontinue participation.

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

The importance to program success of engaging eligible beneficiaries is self-evident, but the importance of engaging physicians may be less so. Case managers must develop trusting, collaborative relationships with primary care physicians for physicians to feel comfortable communicating important information to them about their patients (for example, medication changes, new problems identified during office visits, or areas for additional patient education). Such relationships also are important in making physicians feel that information the case managers give them is credible and warrants their attention (for example, regarding problems in the home environment that affect patients' health, functional deficits that patients do not tell physicians about, or reminders about providing preventive care). A trusting, respectful relationship also will make it easier for case managers to reach physicians when urgent problems arise, and it will facilitate communication and coordination across medical care providers (Chen et al. 2000). Moreover, to increase acceptance of care management among physicians in general, case mangers need to engage physicians.

The QMed MCCD seeks to improve physician practice by supporting consistent use of evidence-based practice guidelines. The program also would like primary care physicians to view case managers as supporting the clinical decision-making process; they do not, however, expect physicians to collaborate with case managers. The program seeks to supplement physicians' knowledge about their patients primarily through written reports, with more

TABLE 3

DISENROLLMENT FOR PATIENTS ENROLLED DURING FIRST SIX MONTHS

Number of Patients Enrolled[a]	333
Length of Enrollment as of January 7, 2003 (Percentage of Patients)	
10 weeks or less	44.1
11 to 20 weeks	31.8
21 or more weeks	24.0
Mean Length of Enrollment (Weeks)	13.4
Number of Patients Who Disenrolled	36
Number Who Disenrolled Because:	
Patient died	1
Patient lost program eligibility[b]	0
Patient initiated disenrollment	9
Patient's physician stopped participating	25
Other	1
Number Disenrolling:	
Within a week after random assignment	0
Between 1 and 4 weeks	19
Between 5 and 12 weeks	9
After 12 weeks	8

Source: QMed program data received April 2003 and updated July 2003. Covers six-month period beginning July 12, 2002, and ending January 7, 2003.

[a]Number of patients ever enrolled in the treatment group through January 7, 2003.

[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.

immediate alerts when a patient has an urgent problem; it encourages physicians to cooperate with case managers when such problems arise.

Improving Practice. A primary goal of the QMed MCCD is to improve physician practice by increasing their use of evidence-based practice guidelines. The program has taken three main approaches to achieving this goal. First, physicians receive a copy of treatment guidelines for CAD (including recommendations for diabetes control and management of hyperlipidemia) as part of the packet they receive when approached for participation (see Appendix C for the practice guidelines). Physicians also receive quarterly updates to guidelines by mail, or by fax if immediate notification is required (for example, when new information about medication side effects emerges). Second, QMed's monitoring system generates patient-specific reports for physicians based on ohms|cad monitoring within two days of each patient's monitoring session. The reports, which are sent twice a year, describe each patient's cardiovascular history, indicate whether monitoring detected ambulant myocardial ischemia, provide detailed information abstracted from the patient's chart (including medications and lab test results), and recommend modification or initiation of treatment consistent with guidelines. QMed's consulting cardiologist reviews the report and sometimes makes additional recommendations about treatment, usually concerning polypharmacy or adverse drug interactions. When the cardiologist makes such recommendations (which has happened for less than one percent of all patients during the program's first year), the program gives the physician a toll-free number to call the cardiologist to discuss the recommendations. Although such a response is voluntary, staff report that all physicians who have received these recommendations have contacted the cardiologist. Finally, the quality assurance manager meets with physicians to discuss their use of the guidelines as monitored by ohms|cad. As mentioned, the program generates monthly reports on physician adherence, both on an individual physician and practice group level. The quality

assurance manager notifies the practice group's medical director if a physician is consistently below 70 percent adherence.

After a year of operation, staff believed that most physicians were highly satisfied with the program. Although the program has not yet formally surveyed physicians about their satisfaction with the program, anecdotally, staff report that physicians are happy with the program and its potential to improve patient care. The quality assurance manager reported that participating physicians practicing in rural areas are pleased that their patients can participate, because special programs often are not implemented in rural areas. One physician the program selected for the evaluation team to interview summarized his view of the program as follows: "The program does things that [physicians] don't have time to do like make sure people make appointments, come to appointments, and do their labs. It gives patients more of a feeling that 'somebody cares about me.' Patients look forward to the heart study."

Relationship Between Physicians and Case Managers. Most contact between the program and patient physicians is through its written patient monitoring reports, with in-person followup by the program's quality assurance manager. Direct contact between physicians and case managers is limited to urgent patient problems, which are relatively rare. The program, thus, has limited expectations of physicians: (1) to review patient appropriateness for program participation, (2) to review patient monitoring reports, and (3) to respond to case managers' concerns about specific patients.

The QMed MCCD has adopted three primary strategies to engage physicians: (1) relying on physicians' previous positive managed care experience with QMed, (2) paying physicians for reviewing reports, and (3) sending the quality assurance manager to regularly meet with physicians in person. During these meetings, the quality assurance manager reviews each patient's treatment adherence with the physician. Physicians receive a quality certificate if their

patients are adhering to treatment. The manager also reviews the physician's adherence to evidence-based guidelines. Meetings occur every six to eight weeks, unless the physician is almost fully adhering to the guidelines. The quality assurance manager also asks physicians for feedback on how the program is working for them so that staff can make changes if necessary. For example, a group of Modesto physicians had recommendations to streamline the program's paperwork. Program staff discussed these recommendations and implemented changes within two weeks. Also at the request of physicians, the program delays notifying patients about the availability of the reports so that physicians have time to review the report and determine if followup is necessary. The quality manager reports that the quick turnaround "reinforces the concept that feedback is welcome" and that the program is not a watchdog for physicians' practice patterns.

Efforts to engage physicians appear to have succeeded within the program's expectations. Physicians have cooperated in approving patients for participation, and some have actively encouraged their patients to enroll in the program or directly referred patients to it. Staff also report that physicians are receptive to case managers' telephone calls and have been reviewing the monitoring reports and discussing the results with their patients. Most physicians have been receptive to meeting with the quality assurance manager, although some have been too busy to do so, having their nurse managers attend the meetings instead.

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

Improving patient adherence to treatment recommendations is another approach the QMed MCCD takes to improve patient health. It supports this approach by teaching patients to be better self-managers. Improving communication and coordination between patients and physicians is an important related goal. The program supports this by teaching patients to

communicate more effectively with their physicians and to become more proactive in arranging their care.

Improving Patient Adherence. To help patients adhere more closely to their treatment regimens, case managers and other program staff educate patients to better understand CAD and how to manage its symptoms. Education begins when the program sends newly enrolled patients the America Heart Association's (AHA's) "Fact Sheet on Heart Attack, Stroke, and Risk Factors" pamphlet as part of the welcome package. The welcome package also includes a wallet card, which allows patients to keep track of medication dosages and frequency of administration, as well as goals and current readings for blood pressure, weight, cholesterol, triglycerides, and Hemoglobin A1C (see Appendix C for the wallet card and AHA Fact Sheet).

The education intervention, based on a CAD curriculum developed by QMed, has two parts: (1) understanding heart disease, and (2) managing heart disease. In the first part of the curriculum, all patients learn how their heart works and what CAD and heart disease are. The second part of the curriculum addresses self-care of heart disease, including the following topics: hypertension, cholesterol, nutrition and weight control, smoking, medication adherence, psychosocial and sociological issues (such as stress), fitness and exercise, and surgical procedures and testing. During routine contacts with patients, case managers follow a script in PIMS to determine patients' educational needs (see Appendix C for the educational script).

During routine contacts, case managers review educational concepts in the key areas identified above with patients and ask if they have any questions. PIMS asks case managers to fill out a checklist indicating (1) which areas in the curriculum a patient has understood; (2) what further education is needed (such as written materials, additional telephone contact, or referral to community resources); and (3) any barriers to learning. Patients are also asked if they would like educational materials when they come to cardiac monitoring sessions, as well as during routine

contacts. All educational materials are written at both the third- and fifth-grade reading levels. The program's administrative assistant mails materials to patients. The program also maintains a library in its Stockton office with pamphlets and videotapes that patients can borrow. (See Appendix C for the educational checklist.)

The program supplements the cardiac-focused education that case managers provide during routine contacts with educational seminars and quarterly newsletters. The program offers seminars in the Stockton office and at other sites, such as local hospitals and participating physicians' offices. The program's quality assurance manager conducts these seminars, which cover such topics as diabetes, healthy cooking, maintaining a healthy diet when dining out, hypertension, cholesterol, and polypharmacy. Approximately 25 percent of patients have attended at least one seminar. The quality assurance manager sometimes brings to the seminars examples of healthy foods patients might make themselves. The program also sends patients a quarterly newsletter covering such topics as descriptions of program activities, lists of educational materials available at the QMed library or online, healthy recipes, and lists of upcoming educational classes being offered by QMed (see Appendix C for an example of a quarterly educational newsletter).

The program tailors its educational intervention for learning differences. During the initial assessment, the case manager determines whether the patient has a visual or hearing impairment, low literacy, or a language barrier that would affect how the program provides education. The QMed MCCD uses a special telephone service for patients with visual and hearing impairment. For patients with cognitive deficits (such as dementia), the case manager works with the patient's caregiver to facilitate education.

The program serves a small number of non-English-speaking patients (less than five percent) and uses a telephone translation service to communicate with them. The program's educational

materials are also available in Spanish. Although the program's educational seminars are presented in English, the quality assurance manager speaks Spanish and works with Spanish-speaking patients after the classes to ensure they understand the material. For example, a Spanish-speaking couple attended a seminar on cholesterol management. After the seminar, the quality assurance manager met with the couple and highlighted the most important concepts discussed during the seminar. She also gave the couple educational materials in Spanish, as well as a log for tracking their lipids. The couple remarked that, because they had never learned English, they had not understood how their lifestyle might be contributing to their risk for CAD. The quality assurance manager added that, after the couple left the seminar, "They left feeling empowered and much more in control of issues which could definitely impact their health and well being."

All case managers have several years of experience providing education to patients in clinical settings, although the QMed MCCD does not offer staff additional training in patient education. The program's quality assurance manager, who teaches the on-site educational seminars, has a master's of public health in health education.

Case managers assess whether teaching has been effective by listening to patients describe their activities and behaviors or by asking patients specific questions. For example, the case manager might ask patients whose goal is lipid control to name low-cholesterol foods they have incorporated in their diet. The case manager looks at laboratory test results obtained through chart abstraction to indicate whether the patient has initiated behavior change. For example, for patients whose goal is lipid control, the case manager compares the patients' lipoprotein test results to prior results and assesses whether they are making progress toward lowering their lipoprotein levels to within normal range. As mentioned, PIMS contains an educational checklist that the case managers uses to track education areas patients have mastered.

If the program finds a patient is not learning, the case manager works with the patient and his or her family or caregiver to identify barriers to learning and behavioral change. PIMS tracks these barriers. For example, a male patient in his 70s stopped his routine of exercising with his wife every morning at a local senior center. The case manager learned from the patient's wife that her husband had not been feeling well and had been complaining more of fatigue and lack of energy. The case manager encouraged the patient to make an appointment to see his physician, who determined the patient had anemia. After treatment, the patient resumed his daily exercise routine.

Among the 333 patients enrolled in the QMed MCCD during its first six months, most (79 percent) had received at least one contact for self-care or disease-specific education, and a third had at least one contact during which the disease manager explained medications. Only one patient had a contact during which the disease manager explained tests or procedures (Table 1).

The QMed MCCD appears to have implemented a patient education strategy that may result in improved patient adherence to treatment recommendations. In their one-on-one interactions, the case managers use QMed's CAD curriculum to educate patients about cardiac disease and self-care. However, contact between patients and case managers occurs every two months, which may be too infrequent to help patients change their behavior. The program supplements one-on-one teaching with educational seminars and newsletters that also address comorbid conditions and lifestyle change. The case managers have experience in providing patient education, but the program does not provide opportunities for in-service training. The program addresses the needs of patients with impairments or who are not English speakers. Finally, the case managers determine whether patient teaching has been effective by listening and work to overcome barriers to learning and behavior change. Whether patients are actually taking in

educational messages and changing their behavior will be more evident from the evaluation's analyses of patient and physician surveys and of Medicare claims data.

Improving Communication and Coordination. Another one of the program's approaches to improving patient health is to teach patients to communicate more effectively with their physicians and arrange for their own care. The program also aims to improve coordination by regularly communicating patient-specific information to physicians, ensuring patients receive the recommended care for their conditions, following up with patients after they experience adverse events, and resolving polypharmacy issues.

Case managers seek to improve communication between patients and physicians by teaching patients how to communicate better with their physicians. Case managers remind patients of issues they need to discuss with their physician during office visits. As mentioned, the program provides patients with a wallet card when they first enroll. The card allows patients to track their medications and laboratory values, and it also prompts them to ask their physician about certain issues during visits. These issues include emotional well-being, lifestyle changes needed (smoking cessation, healthy eating, and exercise), the importance of taking medication as directed, and preventive care (flu shots and the pneumonia vaccine). Case managers encourage patients to take the wallet card to office visits to help them begin a conversation with their physician. Case managers also encourage patients to write down questions they have for their physician and take the questions to appointments so they will not become intimidated or overwhelmed during the visit.

Because one of the program's goals is to empower patients to communicate their concerns to their physicians, case managers rarely intervene on behalf of patients. However, case managers will schedule doctor appointments when patients are reluctant to do so. For example, during a routine assessment, a 67-year-old female patient told her case manager that she had experienced

chest pain, shortness of breath, and a sharp pain in her shoulder in the past week. The patient had not called or seen her physician in more than a year. The case manager determined that the patient was experiencing angina and called the patient's physician to make an appointment. In addition, the case manager explained to the patient that it was important for her to call her physician if she had these symptoms again.

Case managers seek to better coordinate patient care through regular communication of patient-specific information to physicians. As mentioned, the program sends physicians patient monitoring reports every six months. The report also reminds physicians when patients are due for laboratory tests, such as a lipid profile or Hemoglobin A1C. The program also contacts physicians to alert them to acute problems that need their immediate attention, such as unusually poor results from a patient's cardiac monitoring. In one such instance, the case manager was having difficulty contacting the physician by telephone, so the quality assurance manager hand-carried the report to the physician's office, and the physician saw the patient that day.

Case managers also try to make coordination easier by sending patients reminder cards about scheduling recommended care. PIMS prompts case managers to mail the reminders, which encourage patients to contact their physician to get the results of their cardiac monitoring session or schedule a lipid or Hemoglobin A1C test (see Appendix C for the monitoring report and laboratory reminder cards).

The program also aims to improve coordination by tracking events such as hospitalizations, emergency room visits, and cardiac procedures. Case managers usually learn about these events from the patient or his or her caregiver during routine telephone monitoring or through reviews of physicians' medical charts. The case manager follows up with the patient to make sure the treatment is improving the patient's condition, sometimes increasing the frequency of monitoring. For example, a patient who recently underwent CABG might be called weekly,

rather than monthly. Case managers also follow up with physicians after adverse events, making sure they know of any new medications prescribed in the hospital. All unexpected events or procedures are documented in PIMS and tracked using a spreadsheet.

To further ensure coordination, the program assesses polypharmacy and adverse drug interaction issues. Patients are told to bring all their medications to their first cardiac monitoring appointment. During this appointment, the disease management specialists review patients' medications. As mentioned earlier, each time a cardiac monitoring report is generated, medications are reviewed and compared to evidence-based guidelines. At this time, QMed's consulting cardiologist also will review medication regimens. For example, one patient was taking three oral hypoglycemic agents but had not shown improvement. The cardiologist recommended that the patient take insulin instead, and the patient's physician agreed to the change. Case managers also sometimes identify potential adverse drug interactions or side effects during routine monitoring. For example, a patient started taking a new medication prescribed by her physician but did not like the way it made her feel, so she stopped taking it. The patient then began taking a medication her cousin bought for her in Mexico. The patient told her case manager that she had not mentioned this to her physician. When the case manager explained to the patient that medicating herself could have serious consequences, the patient said she would telephone her physician.

The QMed MCCD has developed an approach to improving communication and coordination between patients and physicians that seeks to help patients better communicate their health care needs and that provides data directly to physicians to enhance clinical decision making (as well as, ultimately, to improve clinical practice). The program teaches patients when and how to request needed tests and other care from physicians and how to ask questions during physician office visits. The program sends physicians regular reports based on cardiac

monitoring that compare the patient's CAD treatment regimen and outcomes with evidence-based guidelines, focusing on medications and medication problems. The program also contacts physicians by telephone or, if necessary, in person when urgent patient problems arise. The program helps patients resolve apparent conflicts in advice from physicians by having the care manager discuss the discrepancy with the patients' primary care physicians. The care managers then follow up with the patients to resolve the confusion. However, since adverse events and cardiac procedures are identified through self-report and chart review, lack of timely information about these events may cause a significant time lapse between hospital discharge and when case managers can follow up with the patients to address new medications or instructions.

Increasing Access to Services. Although, when necessary, QMed's MCCD will arrange for services for its patients or purchase some goods and services, increasing access to services is not a program focus. During routine monitoring, case managers assess patients' needs for support services. For example, case managers routinely ask patients if there have been any changes in the way they are able to care for their daily personal needs. If a patient reports difficulty performing activities of daily living (such as personal care, grocery shopping, transportation, cleaning, or preparing meals), the case manager, with approval from the physician, will arrange for meal delivery, home care, or the provision of durable medical equipment through organizations listed in QMed's county service booklet. The program's administrative assistant arranges for transportation to and from patients' medical appointments, the pharmacy, and the program office for cardiac monitoring sessions. The administrative assistant also identifies transportation needs when patients cancel or miss their monitoring sessions.

The QMed MCCD will pay for some goods and services (for example, medical transportation, diabetic test strips, and pillboxes) if the patient cannot afford them. The program also offers patients a discount on CAD-related maintenance or long-term prescription drugs

through CareMark's mail order prescription drug program (see Appendix C for the CareMark pamphlet). The program will also pay for over-the-counter and short-term medications recommended by its clinical software (such as aspirin). The QMed MCCD also will pay for lipid and hemoglobin A1C tests through Quest Diagnostics for a small number of patients if their physicians feel they need a test more often than Medicare covers.

During the first six months of program operation, however, the QMed MCCD did not pay for any goods or services. In particular, staff found that all patients enrolled during the program's first six months could afford to purchase their heart medications. In addition, case managers did not identify any patients who needed non-Medicare support services. Only 2 of the 333 patients enrolled during the program's first six months needed Medicare services (Table 1). As noted earlier, the patients who enrolled in the QMed MCCD during this period were relatively healthy and probably did not require such support.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

This report provides preliminary estimates of the effect of the QMed MCCD 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. Thus, the estimates include patients' experiences during the program's first six months of operation only, when staff may have been fine-tuning the intervention. Moreover, over time, the program may enroll patients with quite different characteristics.

Total Medicare Part A and B reimbursements for the treatment group, exclusive of demonstration payment, were $1,153 ($577 per month), on average, during the first two months

after enrollment, compared to $1,042 ($521 per month) for the control group (Table 4). This small treatment-control difference of $112 ($56 per month), or 11 percent, is not statistically significant.[14] Treatment and control group service use was comparable, with one exception: the treatment group had a statistically significantly greater use of physician and other Part B services. This may reflect an increase in receipt of preventive care, such as lipid and hemoglobin A1C laboratory tests.

Medicare reimbursements for treatment group members increase by $191 when one takes into account the per-member per-month program payment to the MCCD over the first two months (or $96 per month). Thus, total treatment group costs per beneficiary are $303 ($152 per month) more than control group cost over the two-month follow-up period.

We also examined monthly trends in treatment-control differences from July through December 2002, the first six months of program operation (Table 5). The sample enrolled is too small (below 50 patients in each group) in the first month to draw any inferences. In the remaining five months, the treatment and control groups had statistically comparable rates of hospitalization and incurred statistically comparable Medicare expenditures.

The early cohort and short follow-up period prevent the analysis from indicating whether the program will generate long-term savings. Program-induced reductions in hospital use may well occur only after a patient has been enrolled for several months and the program has had time to affect the patient's behavior and health.

[14]As would be expected with random assignment, the treatment and control groups were statistically similar. Thus, these postenrollment differences in Medicare service use and costs do not appear to be due to preexisting differences in the two groups. (See Appendix Table B.6.)

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)	6.2	3.4	2.8	
Mean number of admissions	0.07	0.04	0.03	
Mean number of hospital days	0.38	0.17	0.21	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	2.8	1.4	1.4	
Not resulting in admission	2.8	4.3	–1.5	
Total	5.2	5.8	–0.6	
Mean number of emergency room encounters				
Resulting in admission	0.03	0.01	0.02	
Not resulting in admission	0.03	0.04	–0.01	
Total	0.07	0.06	0.01	
Skilled Nursing Facility Services				
Any admission (percent)	1.4	0.0	1.4	*
Mean number of admissions	0.01	0.00	0.01	*
Mean number of days	0.14	0.00	0.14	*
Hospice Services				
Any admission (percent)	0.5	0.0	0.5	
Mean number of days	0.03	0.00	0.03	
Home Health Services				
Any use (percent)	0.5	0.5	0.0	
Mean number of visits	0.02	0.06	–0.04	
Outpatient Hospital Services[b]				
Any use (percent)	46.9	49.5	–2.6	
Physician and Other Part B Services[c]				
Any use (percent)	97.6	84.6	13.0	***
Mean number of visits or claims	6.0	4.1	1.9	***
Mortality Rate (Percent)	0.0	0.0	0.0	
Total Medicare Reimbursement[d]				
Part A[e]	$623	$490	$133	
Part B	$530	$551	–$21	
Total	$1,153	$1,042	$112	
				***
Reimbursement for Care Coordination[f]	$191	$0	$191	
Number of Beneficiaries	**211**	**208**		

Source: Medicare National Claims History File.

TABLE 4 *(continued)*

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 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.

TABLE 5

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

	Group	Jul 02	Aug 02	Sep 02	Oct 02	Nov 02	Dec 02
Cumulative Enrollment Through Month End	Treatment	40	104	129	183	309	325
	Control	40	106	130	182	308	322
Mean Number of Beneficiaries Enrolled Who Meet Medicare Coverage and Payer Requirements and Are Alive That Month	Treatment	40	103	127	177	297	309
	Control	38	99	122	172	291	304
Average Medicare Reimbursement During the Month[a]	Treatment	$260	$637	$447	$786	$482	$552
	Control	$274	$644	$419	$502	$427	$633
Average Reimbursement for Care Coordination During the Month[a,b]	Treatment	$39	$84	$88	$88	$80	$80
Whether Admitted to Hospital This Month[a] (Percentage)	Treatment	0.0	5.8	3.1	3.4	2.4	1.6
	Control	0.0	2.0	0.8	1.7	2.1	2.6
Treatment – Control Difference[c]							
Average Medicare Reimbursement[a]		–$14	–$7	$28	$284	$55	–$81
Average Reimbursement for Medicare plus Care Coordination[a]		$25	$77	$116	$372	$136	–$1
Percentage Hospitalized[a]		0.0	3.8	2.3	1.6	0.3	–1.0

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 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.

*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.

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 may be people with recognized high-cost diagnoses such as heart failure, but they also may include people 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. A 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- and short-term goals and that is updated and revised as the patient's condition changes; another key feature is a process for providing aggregate- and patient-level feedback to care coordinators, 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, as well as addressing 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 having actively involved providers. Strong programs typically have care coordinators 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 coordinators and allow the program to modify or intensify the intervention if it appears that the intervention is not having the expected effect on intermediate or ultimate outcome indicators. Financial incentives can encourage physicians and program staff to look for creative ways to meet patient goals and reduce total health care costs (Schore et al. 1999).

Program Strengths and Unique Features. Unlike most other programs in the demonstration, QMed's MCCD emphasizes changing physician treatment for CAD, rather than changing patient behavior. Its relatively narrow focus, however, may diminish the importance of issues that would be considered potential barriers in a more patient-centered intervention. For example, because the program emphasizes improving physician practice as its primary means to improving patient health, its patient education intervention is less comprehensive than those of other MCCD programs, and its case managers have less training in patient education than those of some other programs.

- The program had no difficulty meeting its year 1 enrollment target by first recruiting physician groups to participate in the demonstration and reviewing practice rosters for potentially eligible patients. QMed was able to do this because of its strong reputation with area physicians as a result of contracts it held to provide disease management services for MCOs.
- The program assesses all patients with a tool that focuses on cardiac problems and comorbidities common to people with CAD. The program's disease management specialists also perform quarterly reviews of patients' medical charts, extracting data on office visits, diagnoses, hospitalizations or procedures, and new medications.

These data are combined with cardiac monitoring data for the physician's first report from the program.

- The program performs an electrocardiogram on each patient when the patient enrolls and every six months thereafter. Based on the initial monitoring, the program's software generates treatment recommendations and clinical goals, which serve as the patient's care plan. Case managers follow up with patients by telephone at least every two months, during which they review patient health and make needed changes to the care plan.

- During each telephone monitoring session, case managers also provide patients with education to better manage CAD. Case managers follow a checklist of cardiac-focused educational topics to review with patients. The program also offers educational seminars, maintains an on-site library, and produces a quarterly educational newsletter.

- The program teaches patients to communicate more effectively with their physicians by providing them with wallet cards documenting their medications and vital statistics. It also teaches them to coordinate their own care by providing reminders of needed tests and follow-up physician visits. Case managers will contact physicians directly on behalf of a patient, however, when urgent problems arise that the patient will not or cannot address with the physician.

- The program planned to pay for diabetic test strips, pillboxes, and health care-related transportation, as well as to help patients pay for CAD-related prescription and over-the-counter drugs and laboratory tests (if the patient requires more frequent testing than is covered by Medicare). However, none of the patients who enrolled during the program's first six months required these services during that period.

- All the case managers working for the program during its first year were seasoned QMed employees and licensed practical nurses and registered nurses.

- Providing feedback to physicians is the cornerstone of the QMed MCCD intervention. The program generates reports for physicians following each cardiac monitoring session that compare their treatment recommendations with evidence-based guidelines. Among other things, the reports highlight deviations from optimal prescribing and problems with polypharmacy and medication interactions.

- The QMed MCCD's primary approach to improving patient health is to improve physician practice by providing them with decision support tools, as just described. The program's quality assurance manager also meets with physicians regularly to discuss the reports and patient adherence, as well as to solicit feedback about the program. Staff report, based on anecdotal evidence, that physicians are reviewing the reports and responding to case manager requests about specific patients and that they seem satisfied with the program's ability to help them improve patient care.

- Finally, while the program does not provide financial incentives to staff to achieve particular patient outcomes or program goals, it does pay physicians $25 per session for providing the program with patient medical charts and $50 for reviewing each cardiac monitoring report.

Potential Barriers to Program Success. The QMed MCCD faces a serious barrier to effectiveness because of poor targeting. Preliminary Medicare data analysis raises potential concerns that the program is not enrolling patients who are at much risk of incurring high health care costs in the short term and, therefore, are not likely to show improvements on most of the utilization, cost, and well-being measures over the period the evaluation examines. Among those patients enrolled during the program's first six months, program participants were no more likely than the average Medicare beneficiary to be hospitalized in a given year (20 percent chance). More than one-third of enrollees had no Medicare claim of any type for CAD in the year before enrollment, and most of these also had no claims for CAD in the 13 to 24 months before enrollment. Thus, it is difficult to see how an intervention that focuses on patients with CAD is likely to be of much value to them during the period covered by the evaluation. (QMed MCCD staff note, however, that outcomes for CAD patients may be more likely in the longer term.) Enrolled participants also had lower Medicare costs than expected: $641 per month in the preenrollment year, compared to $1,116 estimated for the target population in its waiver application and $954 for eligible nonparticipants in the area. If postenrollment Medicare costs remain as low as preenrollment ones, it may be difficult for the program to save enough through reductions in services normally covered by Medicare to cover program fees of $110 per month, even though this fee is relatively low compared to the fees of other programs. However, if the program is able to slow the progression of patients' CAD, it may be able to cover the costs of its program fees.

Plans for the Second Site-Specific Report. Over the first two years of operation, a second report on MCCD activities will be prepared, which will focus more heavily on program impacts, estimated from both survey and Medicare claims data. This report, due in mid-2005, will

describe changes made to the program and the reasons for those changes, as well as staff impressions of the program's successes.

REFERENCES

Aubry, Barbara. "Bolstering Disease Management Programs." *Healthplan*, July-August 2000, pp. 11-12.

Bodenheimer, Thomas. "Disease Management—Promises and Pitfalls." *New England Journal of Medicine*, vol. 340, no. 15, April 15, 1999, pp. 1202-1205.

Brown, Randall, Deborah Peikes, Eric Schone, Nazmul Khan, Arnie Aldridge, and Lucy Lu. "Waiver Cost Estimates for the Medicare Coordinated Care Demonstration." Princeton, NJ: Mathematica Policy Research, Inc., August 31, 2001.

Chen, Arnold. "The Early Experiences of the Carle Medicare Coordinated Care Demonstration Program." (draft) Princeton, NJ: Mathematica Policy Research, Inc., July, 2003.

Chen, Arnold, Randall Brown, Nancy Archibald, Sherry Aliotta, and Peter Fox. "Best Practices in Coordinated Care." Princeton, NJ: Mathematica Policy Research, Inc., February 29, 2000.

Fox, Peter. "Screening: The Key to Early Intervention for High-Risk Seniors." *Healthplan*, November-December 2000, pp. 56-61.

Hagland, Mark. "Integrating Disease Management." *Healthplan*, January-February 2000, pp. 43-46.

Lorig, Kate, David Sobel, Anita Stewart, et al. "Evidence Suggesting that a Chronic Disease Self-Management Program Can Improve Health Status While Reducing Hospitalization." *Medical Care*, vol. 37, no. 1, 1999, pp. 5-14.

Rector, Thomas, and Patricia Venus. "Judging the Value of Population-Based Disease Management." *Inquiry*, vol. 36, summer 1999, pp. 122-126.

Roter, Debra, Judith Hall, Rolande Merisca, et al. "Effectiveness of Interventions to Improve Patient Compliance." *Medical Care*, vol. 36, no. 8, 1998, pp. 1138-1161.

Schore, Jennifer, Randall Brown, and Valerie Cheh. "Case Management for High-Cost Medicare Beneficiaries." *Health Care Financing Review*, vol. 20, no. 4, summer 1999, pp. 87-102.

Vernarec, Emil. "Health Care Power Shifts to the People." *Business and Health: The State of Health Care in America 1999*, pp. 8-13.

Williams, Mark. "Chronic Care Clinics: Why Don't They Work?" *Journal of the American Geriatric Society*, vol. 47, no. 7, July 1999, pp. 908-909.

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	Dade and Broward counties, 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

QMed, Inc. Medicare Coordinated Care Demonstration: the On-Line Health Management System for Coronary Artery Disease Trial (proposal submitted to the Health Care Financing Administration, October 2000)

Disease Management Specialist Manual 2002

Medicare Coordinated Care Demonstration Educational Materials Binder (undated)

"Physician Recruitment and Continued Engagement" PowerPoint presentation slides, MCCD Conference (March 23, 2004)

Program Staff Anecdotes (by Email, September 2003)

Physician's Participation Introductory Packet

Enrollment Materials:
- Informed consent form
- Invitational letter and script*
- Letter to treatment group member
- Informed consent meeting evaluation form

Assessment Forms
- Healthy Heart Profile*
- Full assessment form*
- Partial assessment form
- Written assessment form and cover letter*

Welcome Package:
- Wallet card*
- Ohms|cad monitoring patient pamphlet
- American Heart Association Fact Sheet on Heart Attack, Stroke, and Risk Factors

Examples of Screens from the Patient Information and Management System (PIMS)

Examples of Reports Generated by the Ohms|Cad System and PIMS

Patient and Physician Satisfaction Surveys and Cover Letters*

Community Resources Guide

*Included in Appendix C of this Report

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.

A. 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 July 12, 2002, through January 7, 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.

1. 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 QMed Inc.'s (QMed) 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, QMed 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 have coronary artery disease, have undergone CAD-related procedures or tests, or have symptoms that suggest a possibility of CAD along with one of its

TABLE B.1

ELIGIBILITY CRITERIA

Inclusion Criteria	<u>Original (used for waiver estimates):</u> An inpatient or outpatient hospital claim in the previous year for Coronary Artery Disease, for procedures or tests for CAD, or for symptoms that suggest a possibility of CAD and its major comorbidities. <u>Current</u> Management of patients with Coronary Artery Disease, CAD-related procedures or tests, or symptoms that suggest a possibility of CAD. QMed did not apply any utilization requirement or timeframe for inclusion. Use any of the following ICD-9 codes, CPT codes, ICD PX codes, Revenue codes or DRGs: 1) Has a claim showing any of these ICD-9 codes (CAD-related diagnosis codes): [401, 402, 402.0, 402.00, 402.1, 402.10, 402.9, 402.90, 405, 427] AND has a claim showing any of these: (410, 411.1, 411.81, 411.89, 413) 2) Has a claim showing any of these ICD-9 codes (symptoms involving cardiovascular system): (785–785.1) AND has a claim showing any of these: (410–414) 3) ICD-9 (CAD-related diagnosis codes): (410–414) 4) ICD-9 (symptoms involving respiratory system and other chest symptoms): (786.5–786.59) 5) CPT codes: (Cardiography: 93015–93018), (Cardiovascular System Tests: 78459–78496), (Cardiac Catheterization: 93501, 93510, 93511, 93514, 93524-93529, 93542, 93543, 93545–93556) 6) ICD PX codes: (Cardiovascular Tests: 89.41–89.43, 89.44, 92.05), (Cardiac Catheterization: 37.21–37.23, 38.91) 7) Revenue Codes (Cardiovascular Tests and Cardiac Catheterization): 340, 482, 481 8) DRGs of (Coronary Bypass: 106, 107), (Major Cardiovascular Procedures: 110, 111), (Circulatory Disorders: 121–125), (Atherosclerosis: 132, 133), (Chest Pain: 140, or 143) and an ICD9 of (CAD-related diagnosis codes: 410–414.99)

TABLE B.1 *(continued)*

Exclusion Criteria	Patients with any of the following characteristics will be excluded from the program 1. Under 65 (QMed ended up enrolling patients under the age of 65) 2. ESRD (measured by ESRD entitlement to Medicare or any of the following CPT Codes: 90918–90925, 90935, 90937, 90945, 90947, 90989, 90993, 90999) 3. Transplant recipients or presently on any transplant list (ICD9 Codes: [V42.x, V43.2] or CPT Codes: [33930–33945, 47133–47136,48550–48556, 38240–38241, 50300–50380]) 4. Immune-suppressed (ICD9 Codes: [042, 176, 136.3] or CPT Codes: [87390–87391]) 5. Terminal illness or hospice medical benefit (ICD9 Codes: [140–208, 230–239] and CPT Codes: [17304–17310, 36640, 96400–96450, 96542–96549, 77300–77499, 51720]) 6. Major Trauma (ICD9 Codes: 800–999) 7. Permanently paced heart rhythm* 8. Research study participants*
Providers/Referral Sources	Sutter Gould Medical Group, Lodi Primary Medical Associates IPA, Stockton Medical Associates IPA, and Manteca Medical Associates IPA coming soon: Catholic Healthcare West Note: Lodi, Stockton, and Manteca IPA's were formerly known as St. Joseph's Medical Associates.
Geographic location	San Joaquin and Stanislaus counties, CA. QMed was cleared by CMS to enroll in Sacramento county but chose not to enroll from sources there, so this analysis does not include Sacramento county.

*Unable to measure using claims data.

major comorbidities. QMed did not apply a utilization requirement for inclusion into the program. Along with meeting the diagnosis criteria, at the time of enrollment beneficiaries could not: (1) be under the age of 65,[1] (2) have ESRD, (3) be a transplant recipient or presently be on a transplant list, (4) be immunesuppressed, (5) have a terminal illness or be in a hospice, (6) have a permanently paced heart rhythm, or (7) be a research study participant.

We could approximate most of QMed's criteria using Medicare data with some exceptions. We implemented QMed's requirement that a patient must have ever had the target condition, CAD, by examining whether a beneficiary had any medical encounter for the codes that QMed provided at any point during an 18-month period starting August 1, 2001 and ending January 31, 2003. We used the same period to approximate whether beneficiaries met the program's medical exclusion criteria at the time of enrollment. We were unable to observe the complete diagnostic history for beneficiaries who had not been in FFS Medicare during the full year before the 6-month enrollment window.[2] In addition, we did not limit eligible beneficiaries to people who had used specific hospitals or doctors who refer patients to the program, making our estimates potentially overstate the true number of people QMed would have approached about participating. Finally, we could not approximate three of QMed's exclusion criteria using Medicare data: (1) patients who are presently on a list for an organ transplant, (2) patients with a permanently paced heart rhythm, or (3) participation in other research studies.

[1] Despite stating that it excludes beneficiaries under age 65, QMed enrolled patients under the age of 65. For the analysis, we used our understanding of the target criteria, which indicated that they excluded patients under the age of 65.

[2] Among the 666 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, 17 percent were enrolled in Medicare FFS less than a year before they enrolled in the demonstration; 1.7 percent of participants were in FFS fewer than 6 of the 12 months before enrolling.

2. 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.

3. 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).[3] All claims files were accessed through CMS's Data

[3] Occasionally, the HIC number in the cross-reference file was not in the EDB file that we used. Because data from the EDB were needed for the analyses, such beneficiaries were dropped from the sample. One reason for

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 allowed a minimum of a two-month lag between a patient's receipt of a Medicare-covered service in the last month we examined—January 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 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 August 2000 through January 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

(continued)
differences between the HIC numbers in the EDB and cross-reference files was that the two files were updated at different times. CMS created the cross-reference file using the unloaded version of the EDB, which was updated quarterly. We extracted data using the production version of the EDB, which was updated every night.

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, or roughly the midpoint of the six-month enrollment window.

4. 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 132,139 beneficiaries who lived in QMed's catchment area at some point during the first six months of enrollment (Table B.2). We then excluded 52,197 people (39.5

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	132,139
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	–52,197
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	–58,150
Met at least one of the exclusion criteria during the 18 months from August 2001 through January 2003	–8,382
Eligible Sample	**13,410**

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 58,150 of the remaining people (44.4 percent of all area beneficiaries) were dropped from the sample, as they were not treated for any claims for the target diagnoses that the program identified as necessary for inclusion during the year before the program began or the first six months of enrollment. Finally, 8,382 people were identified as having at least one of QMed's exclusion criteria during the 18-months from August 2001 through January 2003, leaving us with a sample of 13,410 beneficiaries we estimated would have been eligible to participate in QMed's program.

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	358	356	714
Minus Those Who:			
Had an invalid HIC number on MPR's enrollment file	–6	–6	–12
Not in geographic catchment area during the month of intake	–24	–22	–46
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	–15	–18	–33
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	–113	–128	–241
Met at least one of the exclusion criteria during the 18 months from August 2001 through January 2003	–65	–55	–120
Eligible Sample	**135**	**127**	**262**

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.

QMed randomized 714 beneficiaries who enrolled in the demonstration program during the first six months of operation (Table B.3). Of these, 12 people could not be matched to their Medicare claims data due to problems with their reported HIC numbers and were therefore excluded from the participation sample.[4] QMed randomized 46 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. We also excluded 33 participants who did not meet CMS's insurance requirements for participation in the program during the month of intake. We also dropped 241 beneficiaries from the participation analyses for not having one or more of the target diagnoses on any claim and 120 beneficiaries because they met one of the program's medical exclusion criteria during the 18-month period, August 1, 2001 through January 2003. (Only 28 of the 241 beneficiaries had a claim for a target diagnosis during the year before the 18-month period.) Thus, among the 714 participants randomized by QMed into the program, after exclusions, 262 people are included in the participation analyses as eligible participants.

QMed's participation rate for the first six months of enrollment is therefore calculated as the number of participants who met the eligibility requirements (262), divided by the number of eligibles who live in the catchment area (13,410), or 1.95 percent.

Table B.4 describes the characteristics of the 262 participants who were enrolled by QMed during the first six months and who appear to meet QMed's eligibility requirements, as measured in Medicare data, and the 13,148 eligible nonparticipants. This table is identical to Table 2 in the

[4] This number includes both beneficiaries with invalid HIC numbers reported and those whose claims we could not obtain when we extracted the files due to the way the Medicare files are created (described in footnote 3). Those with incorrect HIC numbers may well be eligible, but we could not obtain the Medicare data for them to assess that; so they were excluded. HIC numbers have since been corrected, and those beneficiaries will be included in the final report.

TABLE B.4

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

	All Demonstration Participants (Treatments and Controls)[a]	Eligible Demonstration Participants (Treatments and Controls)[a,b]	Eligible Nonparticipants	Statistical Significance[c]
Age at Intake				
Average age (in years)	72.8	74.4	76.4	***
Younger than 65	8.3	0.0	0.0	
65 to 74	50.2	53.1	43.8	***
75 to 84	37.1	41.6	41.6	
85 or older	4.5	5.3	14.7	***
				*
Male	45.7	47.0	41.9	
				***
Nonwhite	11.1	10.3	18.6	
Original Reason for Medicare: Disabled or ESRD	18.3	14.1	13.9	
				***
State Buy-In for Medicare Part A or B	12.0	11.8	34.6	
Newly Eligible for Medicare (Eligible Less than Six Months)	0.30	0.00	0.20	
Enrolled in Fee-for-Service Medicare 6 or More Months During Two Years Before Intake	98.4	99.6	98.8	
Medical Conditions Treated During Two Years Before Month of Intake[d]				
Coronary artery disease	59.4	87.0	75.4	***
Congestive heart failure	23.2	28.4	34.2	**
Stroke	25.0	33.7	30.0	
Diabetes	29.8	36.8	31.5	*
Cancer	19.2	6.1	5.1	
Chronic obstructive pulmonary disease	25.3	29.1	35.4	**
Dementia (including Alzheimer's disease)	0.9	0.4	4.1	***
Peripheral vascular disease	10.4	14.2	14.1	
Renal disease	5.2	6.1	7.2	
Total Number of Diagnoses	2.0	2.4	2.4	

TABLE B.4 *(continued)*

	All Demonstration Participants (Treatments and Controls)[a]	Eligible Demonstration Participants (Treatments and Controls)[a,b]	Eligible Nonparticipants	Statistical Significance[c]
Days Between Last Hospital Admission and Intake Date[d]				
No hospitalization in past two years	67.0	55.9	57.2	
0 to 30	1.2	0.8	4.3	***
31 to 60	2.3	2.3	3.6	
61 to 180	9.8	12.6	10.5	
181 to 365	7.8	13.0	12.3	
366 to 730	11.9	15.3	12.1	
Annualized Number of Hospitalizations During Two Years Before Month of Intake[d,e]				
0	67.2	55.9	57.9	
0.1 to 1.0	23.2	29.9	28.7	
1.1 to 2.0	6.4	8.8	9.7	
2.1 to 3.0	2.1	3.8	2.4	
3.1 or more	1.1	1.5	1.3	
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[d]				
Part A	$345	$377	$646	*
Part B	$296	$291	$308	
Total	$641	$668	$954	*
Distribution of Total Medicare Reimbursement per Month Fee-for-Service During One Year Before Intake[d]				
$0	1.5	0.0	0.9	
$1 to 500	74.4	69.4	67.5	
$501 to 1,000	8.4	12.3	10.9	
$1,001 to 2,000	7.7	8.1	8.3	
More than $2,000	8.0	10.3	12.4	
Number of Beneficiaries	**666**	**262**	**13,148**	

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]Participants who do not meet the program's target criteria, as measured in the claims data, are also excluded from this column, as indicated in Table B.3. (See Note, above, concerning intake date definition.)

[c]The tests of statistical significance compare eligible participants an eligible nonparticipants.

[d]Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake.

[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 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 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.

text, except that the sample of 666 participants in Table 2 is shown alongside the 262 beneficiaries who meet the eligibility criteria according to Medicare claims data. The eligible participants and all participants differ on a number of dimensions at baseline. As mentioned in footnote 1, despite stating that it excludes beneficiaries under age 65, QMed enrolled patients under the age of 65. A smaller proportion of eligible participants than all participants were originally eligible for Medicare because of a disability or ESRD. Differences in the proportion of eligible participants and all participants having different medical conditions treated during the two years before month of intake existed between the two tables: a larger proportion of eligible participants had been treated for CAD, CHF, stroke, diabetes, peripheral vascular disease, or renal disease and a lower proportion of eligible participants had been treated for cancer.[5] As a result, the eligible participants were treated for an average of 0.4 more chronic conditions during the two years before the month of intake. Despite having more chronic conditions, eligible participants were more likely to have had a hospitalization in the two years before intake. Medicare costs for the eligible participants and all participants were comparable at about $650, and significantly lower than the costs for eligible nonparticipants ($954).

B. 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).

[5] Not all eligible participants or nonparticipants are shown as having CAD in Table B.4 because the standard definition the evaluation used to measure CAD for all MCCD programs contains a narrower set of codes than those used by QMed.

The cost of the intervention was estimated as the amount CMS paid to QMed for the treatment group patients, using G-coded claims in the physician claims file.

1. 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 QMed randomized during the first four months of enrollment. The four-month enrollment window covers July 12, 2002 through November 8, 2002. The follow-up time covered the two calendar months after the month of randomization. For example, for a beneficiary randomized on July 30, we examined outcomes in August and September.

Second, we estimated treatment – control differences by calendar month over the first six months of QMed'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 July 2002 through December 2002, we identified the patients who were enrolled in QMed's coordinated care program and analyzed their Medicare-covered service use. For example, a person randomized in July would be present in July through December, provided that person is eligible and alive in each month.[6] Someone randomized in August would not be part of the calculations for July but would be included in August through December, again provided that the person is eligible during those months.

[6] 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).

The sample used to analyze treatment – control differences in outcomes differs from that used to analyze participation. Like the participation analyses, we excluded from the analysis sample randomized individuals for whom we have an invalid HIC number, because we could not obtain their Medicare claims data. We also excluded those people who enrolled but were ineligible for the demonstration according to CMS's insurance criteria (as determined from data on the EDB). However, we also excluded beneficiaries flagged as a household member of a participant, since they were not part of the research sample and thus were not used for the outcomes analysis.[7] Also, 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, of the 473 people randomized in the first four months of QMed's demonstration, the sample for analyzing treatment-control differences contained 419 people. For the six-month sample, 617, or 86.4 percent of the 714 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 5).

[7] Household members were excluded from treatment-control comparisons to keep the two groups balanced. Household members were assigned to the same experimental status to avoid the contamination that might occur if one person in the household was in the treatment group and another was in the control group. As a result, we expected to find fewer household members in the control group than in the treatment group, since household members have less incentive to join the demonstration if they know a household member has already been assigned to the control group and they will not receive care coordination.

TABLE B.5

SAMPLES FOR TREATMENT-CONTROL COMPARISONS

	First Four Months	First Six Months
Number of beneficiaries who were randomized	473	714
Minus Those Who:		
Were members of the same household as research sample members	–27	–53
Had invalid HIC numbers on MPR's enrollment file	–8	–12
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	–19	–32
Number of Usable Sample Members	**419**	**617**

2. 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.

As expected under random assignment, the treatment and control groups had similar characteristics in both the four- and six-month samples. There were no statistically significant differences in the baseline characteristics for the four-month sample. For the six-month sample, there were two differences that were statistically significant at the 10 percent level: (1) the proportion of beneficiaries whose last hospital discharge before intake occurred 61 to 180 days earlier and (2) the share of people who had monthly total Medicare reimbursements in the year before intake of more than $2,000. 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 early sample create any cause for concern.

3. 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 July, we tabulated the individual's outcomes in August and September. 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, the results are not sensitive to how the month of randomization is treated.

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)	72.4	71.9	72.1	72.8	72.6	72.7
Younger than 65	8.5	10.1	9.3	8.7	8.9	8.8
65 to 74	51.2	51.4	51.3	49.0	50.2	49.6
75 to 84	38.4	36.1	37.2	38.1	36.4	37.3
85 or older	1.9	2.4	2.1	4.2	4.6	4.4
Male	48.8	50.0	49.4	45.2	46.9	46.0
Original Reason for Medicare: Disabled or ESRD	23.2	17.3	20.3	20.8	17.4	19.1
State Buy-In for Medicare Part A or B	10.4	10.6	10.5	12.2	12.1	12.2
Newly Eligible for Medicare (Eligible Less than Six Months)	0.0	0.5	0.2	0.0	0.3	0.2
Enrolled in Fee-for-Service Medicare Six or More Months During Two Years Before Intake	98.1	98.1	98.1	98.4	98.4	98.4
Medical Conditions Treated During Two Years Before Month of Intake[a]						
Coronary artery disease	67.6	65.2	66.4	61.6	59.0	60.3
Congestive heart failure	23.7	28.4	26.0	21.2	25.3	23.2
Stroke	24.6	26.0	25.3	24.4	25.3	24.9
Diabetes	28.0	33.8	30.9	28.3	31.7	30.0
Cancer	21.3	21.1	21.2	19.5	19.7	19.6
Chronic obstructive pulmonary disease	23.2	26.0	24.6	25.1	26.0	25.5
Dementia (including Alzheimer's disease)	0.5	1.0	0.7	1.0	1.0	1.0
Peripheral vascular disease	10.6	10.8	10.7	11.4	9.7	10.5
Renal disease	5.8	3.4	4.6	6.2	4.0	5.1
Total number of diagnoses (number)	2.1	2.2	2.1	2.0	2.0	2.0

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	62.8	65.7	64.2	66.1	66.7		66.4
0 to 30	0.5	2.0	1.2	1.0	1.7		1.3
31 to 60	2.4	2.5	2.4	2.3	2.0		2.1
61 to 180	9.2	13.7	11.4	7.8	12.0	*	9.9
181 to 365	9.7	5.9	7.8	9.1	6.7		7.9
366 to 730	15.5	10.3	12.9	13.7	11.0		12.4
Annualized Number of Hospitalizations During Two Years Before Month of Intake[a,b]							
0	62.8	66.2	64.5	66.1	67.0		66.6
0.1 to 1.0	26.6	24.0	25.3	25.1	22.7		23.9
1.1 to 2.0	5.8	5.9	5.8	5.5	6.7		6.1
2.1 to 3.0	3.4	2.9	3.2	2.3	2.3		2.3
3.1 or more	1.5	1.0	1.2	1.0	1.3		1.2
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]							
Part A	$369	$409	$389	$330	$385		$357
Part B	$272	$377	$324	$245	$353		$298
Total	$641	$786	$713	$575	$737		$655
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]							
$0	2.4	1.0	1.7	2.0	1.0		1.5
$1 to 500	71.5	73.8	72.6	74.3	74.2		74.2
$501 to 1,000	8.2	9.4	8.8	9.8	7.7		8.8
$1,001 to 2,000	9.2	6.4	7.8	7.8	7.1		7.4
More than $2,000	8.7	9.4	9.0	6.2	10.1	*	8.1
Location During Program Intake Period							
California							
San Joaquin	95.7	93.8	94.7	89.4	88.9		89.1
Stanislaus	0.0	0.0	0.0	3.9	4.9		4.4
Outside catchment area	4.3	6.3	5.3	6.7	6.2		6.5
Number of Beneficiaries	**211**	**208**	**419**	**312**	**305**		**617**

TABLE B.6 *(continued)*

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.

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)	6.6	4.3	2.3	
Mean number of admissions	0.09	0.05	0.03	
Mean number of hospital days	0.46	0.20	0.27	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	3.3	2.4	0.9	
Not resulting in admission	4.3	4.8	–0.5	
Total	6.6	6.7	–0.1	
Mean number of emergency room encounters				
Resulting in admission	0.04	0.02	0.02	
Not resulting in admission	0.05	0.05	0.00	
Total	0.09	0.07	0.02	
Skilled Nursing Facility Services				
Any admission (percent)	1.4	0.0	1.4	*
Mean number of admissions	0.01	0.00	0.01	*
Mean number of days	0.14	0.00	0.14	*
Hospice Services				
Any admission (percent)	0.5	0.0	0.5	
Mean number of days	0.03	0.00	0.03	
Home Health Services				
Any use (percent)	0.5	0.5	0.0	
Mean number of visits	0.02	0.16	–0.14	
Outpatient Hospital Services[b]				
Any services (percent)	59.2	64.9	–5.7	
Physician and Other Part B Services[c]				
Any use (percent)	98.1	93.8	4.4	**
Mean number of visits or claims	8.5	6.3	2.2	***
Mortality Rate (Percent)	0.0	0.0	0.0	
Total Medicare Reimbursement[d]				
Part A[e]	$702	$524	$178	
Part B	$722	$845	–$123	
Total	$1,424	$1,369	$55	
				***
Reimbursements for Care Coordination[f]	$254	$0	$254	
Number of Beneficiaries	**211**	**208**		

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

Practice medical director’s endorsement letter to physicians

Physician participation agreement form

Patient invitational letter

Informed consent meeting (invitation) script

“Welcome call” script

“Healthy Heart Profile” form

Patient report

Ohms|cad report

Full assessment script

Mailed written assessment

Example of staff meeting minutes

Aggregated physician compliance report

Overall patient clinical characteristics report (sample)

Enrollment report (sample)

Patient and physician satisfaction surveys

Practice guidelines for physicians

Wallet card

AHA fact sheet

Education script

Education assessment

Education checklist

Example of quarterly educational newsletter

Ohms|cad report and laboratory reminder cards

CareMark pamphlet