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The University of Maryland Medicare Coordinated Care Demonstration Program After One Year

Final Report

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

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

The ultimate 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, and 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 the University of Maryland's Medicare Coordinated Care Demonstration for Heart Failure Management (MCCD/HFM). The program operates from the University's School of Medicine, which is part of the University of Maryland Medical System based in Baltimore. The prototype for the MCCD/HFM program was a care coordination program developed by the Visiting Nurse Association of Maryland for CareFirst Blue Cross/Blue Shield, for which the University of Maryland was a consultant.

Program Organization and Approaches. The MCCD/HFM program operates from offices in the University of Maryland Medical Center in downtown Baltimore. Three staff members run the entire program. The medical director, a cardiologist, provides medical and

administrative oversight for the program and recruits physician practices and hospitals as referral sources but does not have day-to-day program responsibilities. The program's single care manager, a nurse practitioner, supervises patient recruitment and initial assessments, sets the parameters for the in-home monitoring device used by all treatment group participants, and monitors patient data transmitted by the in-home device. The enrollment coordinator is a research nurse who is responsible for making initial telephone contacts with potential enrollees, performing initial patient assessments, and collecting follow-up data after enrollment. Only minimal collaboration with physicians is required to implement the program's approach, and it does not expect to influence physicians' clinical practice patterns.

The University of Maryland Medical Center is a tertiary care hospital and the MCCD/HFM program's medical director and care manager have relationships not only with the physicians in the University of Maryland Medical System, but also with a large number of hospitals and physician practices within the system's catchment area. The program has used these relationships to identify sources of patient referrals.

The program's approach to preventing hospitalizations and reducing health costs is to directly manage patients' CHF-related symptoms through telemonitoring. The program does not emphasize patient education because the staff believe that direct management is more efficient and that patient behavior and lifestyle change is very difficult to achieve. The telemonitoring intervention provides daily, accurate clinical data for each patient. The care manager uses this information to adjust the amount of diuretic medication program participants take to keep their weight, blood pressure, and heart rate within acceptable ranges. (She does not make changes to patients' other medications.) Through this intervention, the program staff hope to decrease the severity of patients' CHF symptoms, improve their quality of life, and ultimately reduce hospitalizations. Because the University of Maryland's MCCD/HFM program tests the effectiveness of telemonitoring in and of itself, the program tries to ensure that treatment and control group patients are alike in every other respect. Therefore, for *all* patients, prior to random assignment, the program (1) shares with physicians the assessment data it collects as well as its recommendations for care, (2) provides patients with written educational materials, and (3) refers those patients needing other Medicare and non-Medicare covered services to the University's Heart Failure Service.

Patient Identification. The MCCD/HFM program began enrolling patients in June 2002. The program targets Medicare beneficiaries in the greater Baltimore area who have been hospitalized within the last year for CHF. Also as for all the MCCD programs, beneficiaries must 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 potential patients through hospitals and physician group practices. The program has identified most of its patients from the computerized information systems of the University of Maryland and Veterans Affairs Medical Centers. In addition, the research coordinator at a large physician group practice has identified several patients. The program's care manager also checks the daily census of the University of Maryland Medical Center for patients admitted with a CHF diagnosis and the roster of patients scheduled for outpatient visits in the university's Heart Failure Service clinic. The program has recently recruited several more physician practices to participate, which identify patients mostly through direct physician referrals.

The program provides each referral source with a list of inclusion and exclusion criteria and asks the source to verify these criteria before making the referral. After the program receives a referral, the care manager verifies Medicare eligibility and passes the name and telephone number to the program's enrollment coordinator, who then phones potential patients to explain the program and determine whether they are interested in participating. The program does not send an introductory letter or brochure to potential patients prior to this call. Interested patients are invited to the program's offices where the enrollment coordinator obtains informed consent; conducts the initial assessment; and provides some patient education materials. The enrollment coordinator then submits the patient's name to MPR for randomization. MPR randomly assigns patients either to the treatment group, in which they receive telemonitoring in addition to the usual Medicare-covered services, or to the control group, in which they continue to receive their usual Medicare-covered services.

Assessment, Care Planning, and Monitoring. The initial assessment is done for all patients *prior* to random assignment. The assessment takes approximately two hours and includes a medical history, physical examination, and administration of the SF-36 and the Minnesota Living with Heart Failure Questionnaire. The assessment also requires a blood sample to measure a blood chemical associated with CHF. The program develops a limited plan of care for patients in which the care manager uses the results of the initial assessment to set individualized parameters for the in-home telemonitoring device. The care manager arranges for delivery of the in-home telemonitoring device, which consists of a modem and three components: a scale, blood pressure monitor, and heart rate monitor. Nurses from a medical staffing company go to patients' homes to set up the device and to teach patients how to measure and send their data.

If a patient's data are outside of the pre-set parameters, the clinical review software provided by the device's manufacturer alerts the care manager. The care manager responds to out-of-range values by telephoning the patient. Because the most common problem for patients with CHF is weight gain due to fluid retention, she usually tells them to increase the amount of diuretic they are taking to correct their fluid level. For patients whose monitoring data continue within normal ranges, the care manager calls once a month to monitor their condition. She asks patients to tell her if they are admitted to the hospital or emergency room. Even if they do not do so, she is alerted to their absence from home by the lack of telemonitoring data and calls the patient immediately to determine why no data were sent. This way, if an adverse event has occurred, she can quickly determine its cause and whether any changes are needed to the telemonitoring parameters. Of the 16 treatment group patients enrolled in the program's first six months of operation, 13 had at least one contact with the care manager. Among all 16 patients, 63 percent had a contact in which the care manager responded to out-of-range monitoring data and 81 percent had a care manager contact for routine monitoring.

Staffing and Program Quality Management. Maintaining and improving care quality and ensuring that programs attain their goals both require that staff have adequate qualifications, training, and supervision and that management has the tools and support to monitor program progress toward its goals. The care manager for the University of Maryland's MCCD/HFM program is an experienced nurse practitioner. The project director talks frequently with her, but does not supervise her work per se. The program uses few tools to monitor its operations. While the program can quickly access the data needed to track the progress of individual patients, it

does not have tools in place to track patient progress in the aggregate (such as levels of adverse events) or to assess whether its intervention is being implemented as intended (such as how many days the telemonitoring devices were not operational due to technical problems). Given the small number of treatment group patients, sophisticated monitoring systems probably are not needed at this time. However, the program does not have plans to develop such systems regardless of the number of patients it enrolls.

WHO ENROLLS IN THE PROGRAM?

After one year of operation, University of Maryland had enrolled 30 patients in the demonstration treatment group and 29 in the control group, falling far short of its target of 678. Three factors have contributed to the program's significant enrollment shortfall. First, hospitals and physician groups that had agreed to participate in the demonstration did not generate the level of referrals expected, and some provided no referrals at all. Second, a large number of referred patients were ineligible to participate. (Although program has not tracked reasons for ineligibility, staff believe that many patients did not meet the prior hospitalization requirement.) Finally, a large number of eligible patients declined to participate. Because the program has not consistently tracked patient referrals and reasons for nonenrollment, it is difficult to determine the dominant cause of the program's low enrollment. However, program staff believe that the cause is lack of referrals.

The program has made numerous changes to its procedures for identifying and recruiting patients. For the first year of the program, the time period for the prior hospitalization requirement was 90 days, which was later changed to 1 year. The program staff have sought out new sources of patient referrals. In addition, staff have asked physicians to discuss the program with the patients they are referring, so that patients are familiar with the program when the enrollment coordinator telephones them. Despite these efforts, program enrollment continues to be slow.

To gain another perspective on the proportion of eligible beneficiaries enrolling in the program, and to describe their characteristics, the evaluation simulated the program's eligibility criteria using Medicare enrollment and claims data. (The evaluation used September 15, 2002, the midpoint of the six-month enrollment period used in this analysis, as a pseudo-enrollment date for nonparticipants; it is roughly the midpoint of the 6-month enrollment period considered here.) The simulation showed that, during the program's first 6 months of operation, less than1 percent of an estimated 6,977 eligible beneficiaries enrolled in the MCCD/HFM. (The time lag associated with processing Medicare claims data precluded the use of a longer reference period for this report.)

For the most part, participants were similar to eligible nonparticipants. The one exception is that participants were twice as likely as nonparticipants to be male: 81 percent of participants were male, compared with 38 percent of nonparticipants (Table 1). Ninety-four percent of participants had been treated for CHF—the program's target diagnosis—during the two years prior to enrolling, compared with 100 percent of eligible nonparticipants (by definition). Both participants and eligible nonparticipants have high rates of comorbid conditions including coronary artery disease, diabetes, and chronic obstructive pulmonary disease (Table 1).

Participants and nonparticipants had comparable average monthly expenditures for Medicare services in the year before enrollment (roughly $2,700 and $3,200, respectively). In the year before enrollment, 84 percent of participants, and 100 percent of nonparticipants were hospitalized. (The five participants who did not have hospitalizations may have had hospitalizations in the year before enrollment that were covered by Medicare managed care plans or other insurance sources and did not appear in the fee-for-service claims data analyzed here.)

Table 1

Characteristics of MCCD/HFM Participants and Eligible Nonparticipants During First Six Months of Program Intake (Percent, Except as Noted) [a]

	Participants	Eligible Nonparticipants
Age at Intake		
Younger than 65	6.5	15.2
65 to 74	41.9	28.9
75 to 84	45.2	38.4
85 or older	6.5	17.5
Male	80.7	37.8
Nonwhite	32.3	33.4
Medicaid Buy-In for Medicare A or B	9.7	20.2
Medical conditions treated in last two years		
Coronary artery disease	87.1	84.7
Congestive heart failure	93.6	100.0
Diabetes	48.4	55.9
Chronic obstructive pulmonary disease	64.5	52.0
Hospital admission in last year	83.9	100.0
Hospital admission in last month	22.6	40.0
Total Medicare reimbursement per month (dollars)	$2,731	$3,156
Number of beneficiaries	**31**	**2,398**

Source: Medicare Enrollment Database and National Claims History.

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.

When developing the cost estimate for its waiver application, MPR estimated that Medicare costs would average $2,979 per month for eligible beneficiaries who did not participate in the program. It thus appears that the program has enrolled patients who are as sick as anticipated, with average monthly costs of $2,731 prior to enrollment.

Staff believe that most patients are satisfied with the program. No patients voluntarily disenrolled during the first six months of operations, and by the end of one year, only two patients had disenrolled, because they found the intervention too intrusive or disliked having the telemonitoring equipment in their homes.

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

The program's intervention requires little collaboration between physicians and care managers. Although the program identifies some patients from direct physician referrals, most are identified from lists compiled from hospital censuses or clinic rosters, or by a research coordinator within a physician practice. Once a patient is enrolled, the care manager is able to manage most of the patients' out-of-range monitoring values by making adjustments to their diuretic medications on her own. The care manager may ask the patient's physician to change other medications such as angiotensin-converting enzyme (ACE) inhibitors or beta blockers. The care manager reported that her interactions with physicians have been mostly positive. She calls physicians to discuss whether patients need a change in their medications. Physicians are generally responsive to her recommendations; only a few have resisted making what the care manager believed were necessary changes.

The program signed agreements with referral sources (that is, hospitals and physician practices) to pay them $100 per patient per month for referred patients assigned to the treatment group. Program staff believed that they needed to provide a sizable payment because physicians would be actively involved with the care manager. However, staff now feel that the payment probably is much too high, given the limited role physicians have been playing in the program. Moreover, the hospital or practice determines how that money is spent—either invested back into operations or divided among the physicians who referred patients. Therefore, the payment may not actually be working as an incentive for individual physicians.

Although the program does not expect to influence physicians' clinical practice patterns, the care manager hopes that her one-on-one interactions with physicians of treatment group members may prompt some physicians to improve their prescription of ACE inhibitors and beta blockers. The medical director and care manager believe that the program's close monitoring of patients is beginning to make some physicians more comfortable with trying patients on new medications.

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

The program's approach to improving patient health is direct medical management of patients' CHF-related symptoms by in-home telemonitoring. The program appears to have developed the procedures needed to implement its intervention. According to program staff, telemonitoring devices are quickly installed in patients' homes, usually within about seven days from enrollment. Staff also believe that patients learn to use the device easily. Patients need not be able to read to use the device; nor do they need to speak or understand English. The program has had no complaints about the installation process, and no patients have complained that they

found the device difficult to use. Although the vendor supplying the telemonitoring devices has had to repair or replace some of the devices' components for technical problems of various types, the care manager still describes them as reliable.

The care manager believes she is able to manage her patient caseload well. At the time of MPR's site visit in January 2004, she reported that she had no difficulty managing the 50 treatment group patients then enrolled in the program. She estimates that it takes her two to three hours a day to review the monitoring data on these 50 patients, telephone patients whose data are out-of-range, and make routine monthly monitoring calls to patients whose data have remained within range. With her current responsibilities, the care manager believes that she would be able to comfortably manage up to 200 patients herself.

The care manager further believes that she has developed a rapport with patients' physicians and is able to communicate with them when she needs to discuss their medications. She will send a fax or e-mail to the physician when she has made adjustments to a patient's diuretic medications or if she has noticed that the patient is having a problem. If the patient's condition is more urgent, she will call or page the physician. The program asks physicians to notify the care manager if they make changes to a patient's medications and to send copies of the results of patients' laboratory tests. Some physicians have begun to send this information to her automatically. But for most physicians, she must call their offices to request this information.

Program staff believe that the intervention is running smoothly. However, the program does not collect data on process of care measures (such as the percent of patients who had monitoring device problems or the percent of patients who have had an adverse event since enrollment), which would allow them to determine if they were implementing the intervention effectively.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

There are too few enrollees on whom data are available to develop even preliminary estimates of the short-term effect of the MCCD/HFM program on Medicare service use and costs (10 treatment patients and 9 control patients during the first four months of intake). Average Medicare reimbursements for the 10 treatment patients, exclusive of demonstration costs, were $5,351 during the first two months after enrollment (or $2,675 per month). Average costs for the nine control patients over this period were $3,626 (or $1,813 per month). This difference, while large, is not statistically significant because so few patients are included.

CONCLUSION

Program Strengths and Unique Features. The University of Maryland's MCCD/HFM program appears to have some of the features associated with effective care coordination programs. The intervention is focused and straightforward: it uses an in-home monitoring device to manage patient care directly. The underlying philosophy of this intervention is that efforts to change patient behavior are time-consuming and expensive and frequently do not work. Moreover, staff believe that simply managing fluid retention for heart failure patients is sufficient to improve their health and keep them out of the emergency room or hospital.

Program staff report that patients typically start using the devices within a week of random assignment and that the program is implementing its intervention as planned. In addition:

- The program targets patients with a recent hospitalization for congestive heart failure, a diagnosis typically associated with high health care costs. In the year before their enrollment, participants' Medicare expenditures were quite high, similar to the estimates for eligible nonparticipants—which suggests that the program is enrolling high-cost patients from its target group.
- All patients receive an initial assessment, as well as a limited care plan which is used to set parameters for the telemonitoring device. The program monitors patients through an in-home telemonitoring device and monthly calls from the care manager, who reassesses patients regularly and will adjust the telemonitoring parameters in response to adverse events.
- The care manager is a nurse practitioner with 30 years of nursing experience. As a result, physicians have been responsive to her recommendations for changes in patients' medication regimens.
- The MCCD/HFM program is unique among the programs in the Medicare Coordinated Care Demonstration because it seeks to improve patient health and control costs through intensive monitoring, but it does not require patients or physicians to change their behaviors.

Potential Barriers to Program Success

The MCCD/HFM program focuses on direct medical management of patients' CHF-related symptoms. By design, its intervention does not provide patient education to improve self-care; nor does it try to improve communication between patient and physicians. The program's design requires only limited physician involvement. The care manager reports that physicians respond to her requests and concerns. However, physicians are less involved than the program had originally intended and paid for, through its high monthly payment to the hospitals and physician practices that refer patients.

The program may be hampered by a lack of data on the implementation of its intervention. While the program collects clinical outcome data on both treatment and control group patients that will allow it to determine whether the program is clinically effective, it has little data that will allow a determination as to whether the intervention is being implemented as planned. Program staff believe that they do not need these data because the program's small size allows them to have a good overall sense of whether it is being implemented properly. However, as the program grows, it will be increasingly difficult to monitor implementation.

The program's low patient enrollment will make it difficult for the evaluation to detect any but very large reductions in patient service use and costs. Despite several significant changes in its procedures, the rate of enrollment has not increased substantially. A lack of comprehensive data on the number of patients referred to the program from each source, reasons why referred

patients are ineligible and why potential patients decline to participate have hindered the program's ability to refine its enrollment procedures effectively.

The program also has been hampered by inadequate financial resources. Out of its $350 per patient per month payment from CMS, the program pays $200 for use of the telemonitoring device and clinical review software and $100 to the source referring the patient. This leaves only $50 per patient per month to cover the program's operating expenses. All staff salaries are paid from the project director's research funds. Expenses related to billing and patient initial assessments must be covered from the CMS payment. The program cannot hire additional staff to work on patient recruitment because it does not have the financial resources.

Obviously, it is too early, and samples are too small, to draw any inferences about program impacts at this time. For all sites, savings in hospitalizations and other expensive Medicare services will have to be large enough not only to cover direct program fees, but also any higher Part B expenses incurred if care managers refer treatment patients for Medicare-covered services they would not have otherwise sought.

INTRODUCTION

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 and Medicaid Services (CMS). The programs are hosted by organizations as diverse as hospital systems, disease management vendors, and retirement communities and 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 improve patient health and reduce Medicare costs? What were enrollees' Medicare service use and costs during the first six months of the program? The report concludes with a discussion of the program's strengths and unique features, as well as potential barriers to its success.

This report describes the University of Maryland's demonstration project, the Medicare Coordinated Care Demonstration Project for Heart Failure Management (MCCD/HFM). The

[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.

demonstration project is operated by the university's School of Medicine, which is part of the University of Maryland Medical System. The program's offices are located in the University of Maryland Medical Center, the University of Maryland Medical System's flagship hospital located in downtown Baltimore, Maryland. The MCCD/HFM began enrolling Medicare beneficiaries with congestive heart failure (CHF) in June 2002.

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 and in-person interviews conducted approximately six months later.[2] For each program, one of three MPR implementation team members conducted the telephone and in-person interviews using semi-structured protocols. The interviews covered (1) organization and staffing; (2) targeting and patient identification; (3) program goals; (4) care coordination activities (such as assessment, patient education, and service arranging); (5) physicians' attitudes toward the program and interventions with physicians; (6) quality management; (7) recordkeeping and reporting; and (8) 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 issues of specific importance to each program. The structure of the protocols also makes the process of synthesizing findings across programs more efficient. MPR staff also reviewed written materials provided by each program, including: (1) its proposal to CMS, (2) its operational protocol, (3) materials it provided to patients and physicians, and (4) forms used in its operation. (Appendix Table A.2

[2]Because of its low enrollment, we conducted the in-person interviews for the University of Maryland approximately 18 months after the program's start to allow it to accumulate more experience in providing its intervention.

contains a full list.) This analysis also includes an examination of data each program collected specifically for the evaluation describing care coordinator contacts with patients, patient disenrollment, 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 MCCD/HFM service area who were eligible for the program and the percentage who actually enrolled during the program's first six months of operations. Beneficiaries are identified as eligible if, for any month between June and December 2002, 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 evaluation uses September 15, 2002, the midpoint of the six-month enrollment period examined in this analysis, as a pseudo-enrollment date for nonparticipants; it uses the actual enrollment date 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 either receive the program intervention in addition to their regular Medicare benefits, or to receive 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, in order 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 operations). 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 necessitated the short intake and observation period for this report.) Third, program interventions may change over time as staff gain more experience with the specific patients they have enrolled. Finally, if programs change their eligibility criteria or the type of outreach they conduct, they may enroll different types of patients over time.

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

OVERVIEW OF THE UNIVERSITY OF MARYLAND MCCD/HFM PROGRAM

Program Organization and Relationship to Physicians. The MCCD/HFM program is based on a congestive heart failure disease management program that the Visiting Nurse Association of Maryland developed for CareFirst Blue Cross/Blue Shield. MCCD/HFM staff provided expert clinical consultation to this program regarding the treatment and management of heart failure, but they were not involved in day-to-day disease management activities. This program, which operated between 1997 and 2000, served 199 individuals with CHF who were enrolled in CareFirst's commercial managed care plans. The program's goals were to identify and respond to patient problems when they were still relatively minor, thus reducing the need for hospitalization. Home health nurses conducted in-home assessments, developed care plans, provided patient education, and monitored patients. The program increased the proportion of patients taking angiotensin-converting enzyme (ACE) inhibitors and beta blockers and decreased hospital admissions and emergency room visits (relative to national averages for patients with advanced CHF).

In its application for the MCCD, the University of Maryland proposed a three-way comparison of nurse-based care coordination (as used in the CareFirst prototype program), telemonitoring-based care management, and a control group receiving usual Medicare services. However, CMS judged the proposed nurse-based care management intervention too costly and decided to fund the telemonitoring intervention alone. Thus, the university redesigned its program to focus on solely on the effects of telemonitoring.

The MCCD/HFM program operates with a staff of three—the project director/medical director, the care manager, and an enrollment coordinator. The medical director, a cardiologist, directs the cardiac care unit and the Heart Failure Service at the University of Maryland Medical Center. He provides medical and administrative oversight for the program and is its principal investigator. His primary responsibility has been to recruit physician practices and hospitals into the study as sources of patients. He does not have day-to-day program responsibilities. The program's care manager is a nurse practitioner who was previously the clinical practice coordinator for disease management programs and clinical effectiveness in the University of Maryland Medical System. She is responsible for the day-to-day operation of the demonstration, including supervising patient recruitment and initial assessments, setting the parameters for the in-home monitoring device, and monitoring patient data transmitted by the in-home device. She is also the program's co-principal investigator. The enrollment coordinator is a research nurse who joined the program in July 2003, replacing two part-time research nurses. She is responsible for making initial telephone contacts with potential enrollees, performing initial patient assessments, and collecting follow-up data after enrollment.

Because the University of Maryland Medical Center is a tertiary care hospital, the MCCD/HFM program's medical director and care manager have professional relationships not only with the physicians in the University of Maryland Medical System but also with a large number of hospitals and physician practices within the system's catchment area. During its first year of operation, the MCCD/HFM program used these relationships to identify sources of patient referrals. Both the medical director and care manager made numerous presentations to hospitals and physician groups to build support for the program.

Program Approaches. The program's approach to preventing hospitalizations and reducing health costs is to have a care manager directly manage patients' CHF-related symptoms

through daily home monitoring of patients' clinical indicators, follow up on out-of-range indicator values, and adjust medications. Patient adherence to medication regimens may improve as a result of daily home monitoring, but this is not the focus of the program's intervention. The program's medical director described patient education as probably beneficial, but expensive. His approach is to focus on patients' fluid control because he believes "that if you can control a patient's fluids in heart failure, it will control costs." Only minimal collaboration with physicians is required to implement the program's approach, and it does not expect to influence physicians' clinical practice patterns. Therefore, physicians have a limited role in the program.

The University of Maryland's MCCD/HFM program tests the effectiveness of telemonitoring in and of itself. Therefore, the program tries to "level the playing field" to ensure that treatment and control group patients are alike in every other respect. To that end, the program shares with physicians the patient assessment data it collects prior to random assignment and recommendations for care that it makes for all treatment and control group patients at that time (including recommendations about heart failure medications). The program gives all patients written educational materials and refers all patients needing other Medicare and non-Medicare covered services to the university's Heart Failure Service. Moreover, if patients have difficulty paying for their medications, the program will refer them to a pharmaceutical company-sponsored assistance program or will provide them with free medication samples.

Target Criteria and Patient Identification. To be eligible for the MCCD/HFM, beneficiaries must meet CMS's insurance payer and coverage requirements for the 16 programs in the demonstration—be enrolled in Medicare Parts A and B, not be in a Medicare managed care plan of any kind, and have Medicare as their primary payer—as well as the program's specific targeting criteria. The program targets beneficiaries in the greater Baltimore area who

have been hospitalized within the last year for CHF (either systolic or diastolic dysfunction).[3] Patients must also have a telephone in order to use the monitoring device. The program excludes beneficiaries who would be physically or cognitively unable to participate in the intervention and those who have comorbid conditions so advanced that the intervention would have little impact. In addition, the program excludes individuals who are in skilled nursing facilities or hospices, have alcohol or substance abuse problems, or weigh more than 300 pounds (because of the limitations of the scale used with the telemonitoring device).

The program has used a variety of approaches to identify potential patients. At the start of the demonstration, five hospitals (University of Maryland Medical Center, Baltimore Veterans Affairs Medical Center, Union Memorial Hospital, North Arundel Hospital, and Maryland General Hospital) and two physician group practices (Potomac Physicians and Mid-Atlantic Cardiovascular) had agreed to identify patients for the program. The program signed written agreements with each of these sources, describing the program, how the source would identify patients, and how the program would pay the source the $100 per patient per month fee. If the referral source was able, it identified patients from a computerized information system (for example, the University of Maryland Medical Center and the Veterans Affairs Medical Center). Otherwise, the source reviewed patient medical records manually to identify eligible patients (for example, Mid-Atlantic Cardiovascular). In addition, the program's care manager checks the daily census of the University of Maryland Medical Center for patients admitted with a CHF diagnosis and the roster of patients scheduled for outpatient visits in the University of Maryland Medical Center Heart Failure Service's clinic. As the demonstration has progressed, the program recruited more physician offices as sources of referrals. All the patients from these new

[3]The original hospitalization reference period was 90 days. In March 2003, however, the program changed the time period to one year to increase the number of patients eligible for the demonstration.

sources are either directly referred by their physician or manually identified by a physician office staff member.

The program sends each referral source (hospital or physician practice) a description of the program, a list of the inclusion and exclusion criteria, an explanation of how to refer a patient, and a form to be completed for each patient giving contact information for the patient and referring physician (see Appendix C for copies of the program description, criteria, and referral procedures). The program asks the referral source to verify its inclusion and exclusion criteria before making the referral.

The program does not require physicians to give formal consent for their patients to participate; it has, however, asked physicians to discuss the program with their patients before referring them. For those referral sources that generate patient lists, the hospital's or practice's agreement to participate is all that is required. The physicians in these settings may not be aware that their patients have been referred to the program. It appears, though, that all physicians of patients enrolled in the program in its first year are cooperating with the program to the extent that they allow the care manager to adjust their patients' diuretic medications and are open to her recommendations about changes in their patients' other medications.

When the program receives the names of eligible patients from a referral source, the care manager verifies their Medicare eligibility by checking this information in Medicare's Common Working File. If they are eligible, the care manager passes their names and telephone numbers to the program's enrollment coordinator. The enrollment coordinator phones potential patients to explain the program, verify that they meet the program's target criteria, and determine whether they are interested in participating. (The program does not send an introductory letter or brochure to potential patients prior to this call, but some patients will have been told about the program by their physicians.) If patients are identified while hospitalized or when they have

come into the clinic for an outpatient visit, the enrollment coordinator describes the program to them in person. If the patient's physician has already talked to him or her about the program, the enrollment coordinator's first contact with potential patients will be brief; but it will take longer if the coordinator needs to review the exclusion criteria and explain the program in more detail.

The enrollment coordinator invites interested patients to an initial assessment at the program's office at the University of Maryland Medical Center or, if the patient is unable to travel to this office, the office of the patient's physician. During this visit, the enrollment coordinator obtains informed consent from patients; conducts the program's assessment (described in detail below); and gives patients a brochure describing the program, dietary recommendations, and a list of symptoms to watch for, with guidelines regarding when to call their physician (see Appendix C for copies of the informed consent form and the patient education handouts).[4] Following consent, the enrollment coordinator submits the patient's name to MPR for randomization. MPR randomly assigns patients either to the treatment group, in which they receive telemonitoring in addition to the usual Medicare-covered services, or to the control group, in which they continue to receive their usual Medicare-covered services.

The program identified most of the patients who enrolled during the first year from the University of Maryland Medical Center and the Veterans Affairs Medical Center, which provided lists of patients currently hospitalized or recently discharged. The other major source of referrals in the first year was a large cardiology practice that provided both direct physician referrals and lists of potentially eligible patients compiled by the practice's research coordinator. The other hospitals and physician practices, which had initially agreed to participate, either never provided referrals or referred only a small number of patients who were found to be ineligible

[4]The care manager will explain the materials if it appears that the patient would have difficulty reading them, and will answer patient's questions; but usually this is the extent of the patient education provided by the program.

because they were homeless or had no telephone. The program's medical director stated that his plan to generate lists of potentially eligible patients from hospitals other than the University of Maryland Medical Center and the Veterans Affairs Medical Center turned out to be impractical because of institutional review board requirements and concerns over compliance with the Healthcare Insurance Portability and Accountability Act's (HIPAA) requirements.

Within the first year of the demonstration, it became apparent that the hospitals and physician practices originally targeted by the program as sources of patient referrals would not provide the number of patients needed. The program approached additional physician practices and signed formal agreements with several of them to become sources of patient referrals. However, these new sources have identified few patients (five each, at most). These practices typically do not have a research nurse or coordinator who can take on the responsibility of identifying eligible patients; or, if they do, this person can devote only a small amount of time to the project. Thus, most of the referrals that come from these practices are direct referrals from physicians. The program continues to expand the geographic area in which it seeks to recruit physician practices to Delaware and southeastern Pennsylvania.

Assessment, Care Planning, and Monitoring. The program's intervention is direct medical management of CHF-related symptoms by a care manager using a home telemonitoring device. After patients provide informed consent, but *prior* to random assignment, the program conducts an extensive assessment for each consenting beneficiary. The enrollment coordinator conducts the assessment, which takes about two hours, and includes a medical history, physical examination, and administration of the SF-36, and the Minnesota Living with Heart Failure Questionnaire.[5] The assessment also includes an echocardiogram if patients have not had one in

[5]See Appendix C for copies of the program's assessment forms.

the previous year and a blood draw to measure brain natiuretic peptide (BNP) levels.[6] The program conducts formal reassessments of treatment and control group members at 6 and 12 months after enrollment. The reassessment includes re-administration of the SF-36 and Minnesota Questionnaire, and re-measurement of BNP levels. The results of the initial and two follow-up assessments are entered into a Microsoft Access database. For both treatment and control group members, the results of the initial assessment are sent to the patients' physicians. The care manager also includes her recommendations for changes in patients' medication regimens (to add or delete medications, change dosages, or eliminate duplicate medications) based on evidence from clinical practice guidelines.[7] The care manager estimated that she makes recommendations regarding changes in medications for approximately 10 percent of all enrolled patients. She believes that this is because most of the patients enrolled in the program are cared for by physicians in the University of Maryland Medical System who may be more likely to provide care that adheres to guideline recommendations.

The program develops a plan of care for treatment group patients after the initial assessment. The plan contains the recommendations sent to physicians regarding medications and diet, as well as individualized parameters for the in-home telemonitoring device. Because the care manager is a nurse practitioner with extensive cardiac care experience and because the program does not require physicians to participate, the care manager sets the parameters with no input from the patient's physician.

[6]The program plans to measure the intervention's impact on disease severity by comparing the BNP levels of treatment and control group patients. Clinical evidence suggests that BNP levels are an indicator of elevated pressures within the heart's left ventricle which, in turn, are associated with increased signs and symptoms of heart failure (Hunt et al. 2001).

[7]See Appendix C for copies of the letters sent to physicians following random assignment and the initial plan of care form.

After a patient has been assigned to the treatment group, the care manager arranges for delivery of the in-home telemonitoring device, which is manufactured by Philips Medical Systems. The program's leasing arrangement with Philips includes having a nurse from Nursefinders, a medical staffing company, go to patients' homes to set up the device and teach patients how to measure and send data on their weight, blood pressure, and heart rate. The program's care manager estimated that it takes approximately 15 minutes for the nurse to set up the telemonitoring equipment and teach a patient to use it.

The telemonitoring device consists of a modem and three components: a scale, a blood pressure monitor, and a heart rate monitor. The modem is attached to the patient's telephone, but the other components are wireless and can be placed, at the patient's convenience, anywhere in the room. The components use radio transmitters to send data to the modem. At the same time each day, the patient measures his or her weight, blood pressure, and heart rate and then presses one button on the modem to transmit the data to the program office. The device does not remind the patient to take measurements, but the care manager will call patients if they forget to send their data. The care manager estimates that, over the first 30 days of enrollment, patients transmit data on their weight and blood pressure 93 percent and 80 percent of the time, respectively.

If a patient's data are outside of the parameters set by the care manager, the clinical review software provided by Philips alerts the care manager. When the care manager logs onto the system software each day, the first screen displays a list of patients whose data are out of range. If the care manager is sick or on vacation, another nurse practitioner associated with the University's Heart Failure Service logs into the software and monitors the demonstration patients. In addition, because the software is Internet-based, the care manager logs in from her home computer to monitor patients on weekends.

The care manager responds to out-of-range values by telephoning the patient. She asks if the patient is having any symptoms (such as swelling or difficulty breathing), how the patient is feeling, and whether the patient can think of a reason why his or her weight, blood pressure, or heart rate is out-of-range. For example, if the patient's weight is up, the patient may respond that he or she ate salty foods such as a hot dog and potato chips at a cookout the previous day. In that case, the care manager usually tells the patient to increase the amount of diuretic being taken to correct the fluid level.[8]

The care manager may also talk with patients about changing their behavior (for example, limiting their intake of salty foods) to prevent weight gain due to fluid retention; but patient education and behavior change are not the focus of the program's intervention. Moreover, the care manager believes that lifestyle and diet changes are difficult for patients to make and that trying to educate patients has little impact on these behaviors. She said that many of the patients in the program read at a minimal level and have a poor understanding of abstract concepts. While she will answer patients' questions, she does not try to enhance their overall understanding of their condition.

If the patient's blood pressure or heart rate is elevated, the care manager tries to determine whether this is an isolated event. If the patient's values are consistently too high, the care manager contacts the patient's physician to determine if a change is needed in the type or dose of the patient's other medications. Because program patients are still under the care of their own physicians, the care manager does not feel that it would be appropriate for her to make changes

[8]Weight gain among patients with heart failure is most often due to water retention. Thus, increasing the dose of the diuretic will reduce water retention and ease CHF-related symptoms including edema, shortness of breath, and fatigue.

in patients' medications (other than diuretics) without contacting their physicians. Therefore, she will not make changes to medications such as beta blockers or ACE inhibitors.

For patients whose monitoring data continue within normal ranges, the care manager calls once a month to check in. The care manager indicated that these calls are usually brief (two to three minutes). She asks patients how they feel and whether they are having any symptoms or problems, have been to their physician recently, have changes in their medications, or have appointments scheduled.[9] The results of these monitoring calls are documented as free text notes in the Philips software.

The care manager encourages patients to tell her when they have been admitted to the hospital or have been to the emergency room. However, even if the patient does not call, the care manager is alerted to the patient's absence from home by the lack of telemonitoring data. The care manager then follows up with the patient to identify the reason for their absence. She may tighten the patient's monitoring parameters if the patient had a CHF exacerbation that required hospitalization. This would have the effect of alerting her sooner to potential problems and, thus, possibly preventing a future hospitalization.

Of the 16 patients enrolled in the program's first six months of operation, 13 had at least one contact with the care manager. Among the 16 enrolled patients, 63 percent had a contact in which the care manager responded to out-of-range monitoring data and 81 percent had a care manager contact for routine monitoring (Table 1).

Staffing and Program Quality Management. To monitor and improve the care they provide, care management programs must require their staff to have adequate qualifications,

[9]Note that the program makes no real distinction between routine monitoring and reassessment. It generally records non-urgent follow-up contacts, both as reassessment and as routine monitoring (Table 1).

TABLE 1

CARE COORDINATOR CONTACTS WITH PATIENTS
DURING FIRST SIX MONTHS

Number of Patients Enrolled[a]	16
Number of Patients with at Least One Care Coordinator Contact (Percent)	13 (81)
Total Number of Contacts for All Patients, Among Those Contacted	106
Average Number of Contacts per Patient	8
Number of Care Coordinators Contacting Patients	1
Among Those Patients with at Least One Contact:	
Percentage of contacts care coordinator initiated	85.8
Percentage of contacts by telephone	95.3
Percentage of contacts in person at patient's residence	0.0
Percentage of contacts in person elsewhere	4.7
Of all Patients Enrolled, Percentage with Assessment Contact after Randomization[b]	75.0
Among Those Patients with an Assessment, Percentage of Patients Whose First Assessment Contact Is:	
Within a week of random assignment	0.0
Between one and two weeks of random assignment	16.7
More than two weeks after random assignment	83.3
Of All Patients Enrolled, Percentage of Patients with Contacts for:	
Routine patient monitoring	81.3
Providing emotional support	6.3
Providing disease-specific or self-care education	18.8
Explaining tests or procedures	12.5
Explaining medications	37.5
Monitoring abnormal results[c]	62.5
Identifying need for non-Medicare service	0.0
Identifying need for Medicare service	0.0
Monitoring services	6.3
Average Number of Patients Contacted per Care Coordinator	13
Average Number of Patient Contacts per Care Coordinator	106

Source: University of Maryland program data received October 2002 and updated July 2003. Covers six-month period beginning June 28, 2002 and ending December 24, 2002.

[a]Number of patients enrolled in the treatment group as of December 24, 2002.

[b]The program classifies reassessments conducted during routine patient monitoring as assessment contacts. It makes no distinction between routine monitoring and reassessment. It generally records non-urgent followup contacts both as reassessment and as routine monitoring.

[c]The program classifies the care manager's calls to followup on out-of-range telemonitoring values as a contact to monitor abnormal results.

training, and supervision. Similarly, to ensure that program goals are met, managers must have tools and support with which to monitor the program's operations.

The care manager for the MCCD/HFM program is a nurse practitioner who has more than 30 years of nursing experience and holds a nursing doctorate with a minor in business management. Although the program has no plans to hire another care manager at this time, if more staff are needed, it would likely hire additional nurse practitioners. The program does not have a training program for care managers but would develop one if it hired more staff. Because the care manager also functions as the program's co-principal investigator and manages day-to-day program operations, her relationship with the project director is relatively informal. The project director talks frequently with the care manager but does not supervise her work per se. Neither of them is required to report on the status of the demonstration to any individual or group within the University of Maryland's administration.

The program has a few tools to monitor its operations. Although it has tried to track the number of patients referred from each source, it does not collect data on the reasons for patients' ineligibility or their reasons for declining to participate. The program can use the Philips software to track and trend an individual patient's monitoring data to assess his or her progress. On the other hand, it has not developed a process to track or trend patients' monitoring values in the aggregate or monitor program implementation measures (for example, the percentage of patients who had monitoring-device problems, the percent of patients whose monitoring data are within acceptable ranges, or the number of patients who have had an adverse event since enrollment).

To generate the data on patient contacts required by the evaluator, the care manager makes a text note in the Philips software each time she has a contact with a patient. Then she prints the notes for each patient and, using the date of the contact, goes to the hard copy to manually record

the nature of the contact. The program has been working with Philips to automate this process, but the needed software modifications are still under discussion.[10]

WHO ENROLLS IN THE PROGRAM?

The program fell far short of its enrollment target for its first year of operation due to difficulties identifying sufficient numbers of eligible beneficiaries and to a high refusal rate among those eligible. However, those patients who have enrolled have had expenditures in the prior year that are as high as anticipated. Anecdotally, treatment patients also appear satisfied with the program, and none disenrolled voluntarily in the first six months of operation.

Enrollment After One Year. After one year of operation, the University of Maryland had enrolled 30 patients in the demonstration treatment group and 29 in the control group (MPR Weekly Enrollment Report, week ending July 6, 2003).[11] This falls far short of the program's target of enrolling 678 patients in the first year.

There are several reasons for the shortfall in enrollment; the first of which was that the seven organizations (five hospitals and two physician groups) that had agreed to identify patients for the program have not generated the referrals expected. Only three of the seven original organizations (the University of Maryland Medical Center, the Baltimore Veterans Affairs Medical Center, and the Mid-Atlantic Cardiology group) have referred any patients to the program. Although the program's medical director met repeatedly with representatives of the other four organizations to encourage them to identify patients, these discussions were not

[10]While not a monitoring tool, the program is beginning to analyze the baseline assessment data collected on treatment and control group patients. They have found no differences in demographic characteristics or BNP levels at the time of enrollment.

[11]The program did not have an estimate of the number of Medicare beneficiaries in the area who would be eligible to participate in the program. Thus, it is not possible to say what percent of the estimated, eligible beneficiaries the program has enrolled.

productive. It appears that, while the administrators of these organizations were enthusiastic about the demonstration, for at least two organizations there appeared to be some "bad blood" between their physicians and the physicians at the University of Maryland. Some of the ill feeling may have stemmed from the prototype disease-management program. Many patients who enrolled in this program began seeing University of Maryland Medical Center cardiologists rather than the physicians who referred them. The referring physicians believed that the University was intentionally "stealing" their patients. While patients in the current program are not seen by University cardiologists, physicians in the community may still be distrustful of the program's intentions and thus, reluctant to identify their patients.

Another factor contributing to the shortfall in enrollment is that many of the patients referred to the program have been ineligible to participate. Program staff estimated that approximately 60 percent of the patients identified in the first three months of program operations did not meet the inclusion criteria or had one or more of the exclusion criteria despite the fact that the referring organizations were asked to check these criteria. In particular, during the early months of program operations the care manager believed that many patients were not eligible because by the time referral sources sent lists of potentially eligible patients and the program verified their Medicare eligibility and contacted them, more than 90 days had elapsed since hospital discharge (the original reference period for their hospitalization criterion). In March 2003, the program changed the hospitalization criterion to one year; this change, however, has not increased the number of patients enrolling in the program.

The care manager also reported that many patients are ineligible because they are homeless, do not have a permanent address, or do not have a telephone; but that the referring organizations did not know this. The MCCD/HFM staff decided that it would not be worthwhile to continue

pursuing referrals from one referring organization because the majority of the patients it identified were ineligible to participate.

The third factor contributing to the shortfall in enrollment was a high refusal rate in the early months of the program. While the program does not collect data on the number of individuals who refuse to participate, or why, it seems likely that at least some refusals may have been due to the program's approaching potential participants directly, without sending them materials or asking physicians to introduce the program beforehand. In the early months of the program, patients simply received a telephone call from the demonstration's care manager introducing the study and asking them to participate. Moreover, physicians of patients referred to the program by hospitals did not know they had been referred to the program, and, therefore, were not able to discuss it with them or provide encouragement to participate. The care manager believes that only about a quarter of the patients who were approached in this manner agreed to participate.

After the first few months, the program changed its method of approaching patients. Since then it has been able to identify many patients while they are still hospitalized (at the University of Maryland Medical Center or the Veterans Affairs Medical Center) or while they are in University of Maryland's Heart Failure Service clinic for an outpatient visit. The enrollment coordinator visits these patients while they are in the hospital or clinic and introduces the program to them. The care manager believes that the acceptance rate has been much higher among patients approached in this way. In addition, some patients are now being referred directly by their physicians. These patients have had a chance to discuss the program with their physician and have received the physician's encouragement to participate. Thus, staff believe that the patient refusal rate is less of a barrier to enrollment at this point in the demonstration.

In addition, when it became apparent that the three sources that were referring patients would not generate the expected number of referrals, the program began to look for new sources

of patients. They chose not to pursue hospitals as sources of referrals because of the time and expense associated with obtaining approval from institutional review boards. Instead, they have concentrated on recruiting physician practices. They have signed agreements with eight additional cardiology practices, but none of them have referred more than five patients. This may be because these practices rely mostly on individual physicians to make referrals to the program rather than manually or electronically generating lists of patients from practice rosters. It is likely that most physicians either do not remember to mention the program to their patients or do not have the time to discuss it with them. The program continues to try to recruit additional practices into the demonstration.

Because the program has not consistently kept track of the data on enrollment since operations began, it has been more difficult to determine whether the dominant cause of the program's low level of enrollment is due to insufficient referrals, referrals of a high proportion of ineligible beneficiaries, or a high refusal rate among eligible beneficiaries.

Percent of Eligible Beneficiaries Participating. To gain another perspective on the proportion of eligible beneficiaries enrolling in the program and their characteristics, the evaluation simulated the program's eligibility criteria using Medicare enrollment and claims data. (Appendix B contains a detailed description of the simulation.) The simulation identified 6,977 beneficiaries eligible for the program between June and December 2002, the program's first six months of operation. That is, the beneficiaries lived in the program's service area, were not in Medicare managed care, and met the program's diagnostic and service use criteria.[12]

[12]Between June and December 2002, 348,641 beneficiaries were living in the program's service area. Of those, 45,703 (13 percent) would have been ineligible for the program because they did not meet one of CMS's demonstration-wide criteria. Of the remaining 302,938 beneficiaries who met these criteria, 6,977 (2 percent) also met the program's diagnostic and service use criteria at some point during the six-month intake window, and had none of its exclusion criteria (to the extent they could be simulated with the Medicare data). Many of the criteria

During the same six months, 15 of these "eligible" beneficiaries enrolled in the demonstration (less than 1 percent of the 6,977 eligible beneficiaries).[13] (See Tables B.2 and B.3.)

Comparison of Participants and Eligible Nonparticipants. An analysis of Medicare enrollment and claims data shows few differences between program participants and eligible nonparticipants. The one exception is that males comprised a much higher proportion of the participant group than of the nonparticipant group (81 percent versus 38 percent) (Table 2). Participants and nonparticipants were the same age, on average, and had statistically similar proportions of minority group members (about a third of each group were non-white) and of dual enrollment in Medicare and Medicaid.

Participants were about as likely as eligible nonparticipants to have had certain diagnoses, including coronary artery disease, stroke, diabetes, and cancer. Ninety-four percent of participants, and 100 percent of eligible nonparticipants, had been treated for CHF—the program's target diagnosis—during the two years prior to enrolling.[14,15] Among participants,

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(continued)
(lack of a telephone, severe comorbid conditions, homelessness, cognitive deficits) could not be assessed with claims data. Thus, the actual number of eligibles is probably substantially less than 6,977. (See Table B.2.)

[13]In fact, 33 beneficiaries actually enrolled in the program during its first six months. When estimating the participation rate, the evaluation excludes enrollees with incorrect Health Insurance Claim (HIC) numbers on MPR's enrollment file, and those who did not meet CMS's demonstration-wide criteria or the program's geographic, diagnostic, utilization, or exclusions criteria (as measured with Medicare data). These enrollees were excluded from the participation analysis in order to use a consistent definition of eligibility for the numerator and denominator of the ratio. (Beneficiaries with invalid HIC numbers may well be eligible, but their Medicare data could not be obtained to assess that, so they were excluded. Their HIC numbers have now been corrected.) This leaves 15 *known eligible* participants. More than half of the reduction was due to failure to be hospitalized in the last year or to meet one of the exclusion criteria. (While hospitalization in the past year could be confirmed for patients identified from hospital sources, the program had to rely on individual practices to confirm prior hospitalization for patients referred from non-hospital sources.) The comparison of participants and eligible nonparticipants in Table 2, however, excludes only participants with invalid HIC numbers and those who did not meet the CMS's demonstration-wide criteria, leaving 31 participants. Thus, the comparison more closely reflects the differences between all actual participants and those who were eligible to participate but did not.

[14]Not all participants are shown as having CHF in Table 2 because the standard definition used by the evaluation to measure CHF for all MCCD programs contains different ICD-9 codes than those used by the MCCD/HFM program.

[15]As noted, the evaluation uses September 15, 2002, the midpoint of the six-month enrollment period used for this analysis, as a pseudo-date of enrollment for nonparticipants.

TABLE 2

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

	All Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants
Age at Intake		
Average age (in years)	74.4	74.4
Younger than 65	6.5	15.2
65 to 74	41.9	28.9
75 to 84	45.2	38.4
85 or older	6.5	17.5
Male	80.7	37.8***
Nonwhite	32.3	33.4
Original Reason for Medicare: Disabled or ESRD	22.6	26.6
State Buy-In for Medicare Part A or B	9.7	20.2
Newly Eligible for Medicare (Eligible Less than 6 Months)	0.0	0.0
Enrolled in Fee-for-Service Medicare 6 or More Months During 2 Years Before Intake	100.0	100.0
Medical Conditions Treated During 2 Years Before Month of Intake[b]		
Coronary artery disease	87.1	84.7
Congestive heart failure	93.6	100.0***
Stroke	45.2	42.2
Diabetes	48.4	55.9
Cancer	9.7	11.5
Chronic obstructive pulmonary disease	64.5	52.0
Dementia (including Alzheimer's disease)	9.7	1.2***
Peripheral vascular disease	29.0	33.0
Renal disease	16.1	32.9**
Total Number of Diagnoses	4.0	4.1
Days Between Last Hospital Admission and Intake Date[b]		
No hospitalization in past two years	9.7	0.0***
0 to 30	22.6	40.0**
31 to 60	19.4	34.5*
61 to 180	38.7	25.6*
181 to 365	3.2	0.0***
366 to 730	6.5	0.0***

TABLE 2 *(continued)*

	All Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants
Annualized Number of Hospitalizations During 2 Years Before Month of Intake[b,c]		
0	9.7	2.0***
0.1 to 1.0	38.7	34.9
1.1 to 2.0	22.6	29.7
2.1 to 3.0	22.6	14.6
3.1 or more	6.5	18.9*
Medicare Reimbursement per Month in Fee-for-Service During 1 Year Before Intake[b]		
Part A	$2,287	$2,283
Part B	$445	$874**
Total	$2,731	$3,156
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During 1 Year Before Intake[b]		
$0	6.5	0.1***
$1 to 500	12.9	11.2
$501 to 1,000	19.4	16.8
$1,001 to 2,000	19.4	21.4
More than $2,000	41.9	50.5
Number of Beneficiaries	**31**	**2,398**

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 September 15, 2002, the midpoint of the six-month enrollment period examined.

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

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

[c]Calculated as 12 × (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.

10 percent had been treated for dementia or Alzheimer's disease, and 16 percent for renal disease, compared with 1 percent and 33 percent, respectively, of nonparticipants.[16] Participants and nonparticipants had similar, average monthly expenditures for Medicare Part A services in the year before enrollment ($2,300), despite participants' somewhat lower rate of hospitalization. In the year before enrollment, 84 percent of participants and 100 percent of nonparticipants were hospitalized. Although participants' average monthly Medicare Part B expenditures were lower than nonparticipants' ($445 versus $874), their average monthly Medicare expenditures for Parts A and B combined were comparable ($2,731 and $3,156 respectively).

When developing the cost estimate for Medicare's waiver application, MPR estimated that Medicare's costs would average $2,979 per month for eligible beneficiaries who did not participate in the program.[17] It thus appears that the program has enrolled patients who are as sick as was expected, with average monthly costs of $2,731 prior to enrollment.

Satisfaction and Voluntary Disenrollment. The program does not collect data on patient complaints about the program, but the program staff cannot recall there being any complaints thus far. To the contrary, the care manager believes, based on anecdotal evidence, that most patients are satisfied with the program. No patients voluntarily disenrolled during the first six months of operations (Table 3). Moreover, at the end of one year, only two patients disenrolled because they found the intervention too intrusive or because they disliked having the

[16]Some eligible nonparticipants have dementia despite its being one of the program's exclusion criteria, because the program excluded only Alzheimer's disease, Pick's disease, senile degeneration of the brain, and other classified cerebral degenerations. The definition of "dementia" used in Tables 2 and B.4 includes additional types of cerebral degenerations that are also commonly termed "dementia," such as unspecified cerebral degeneration.

[17]Waiver cost calculations for all the demonstration programs assume that each program will reduce Medicare costs by 20 percent. If the assumptions are correct, the program will save Medicare an average of $282 per patient per month, or approximately $2,717,861 over the four-year life of the demonstration, assuming 339 beneficiaries will be randomly assigned to the treatment group. These estimates are net of the demonstration's costs of $350 per patient per month (the fee paid by CMS to the program), but do not include the program's startup costs or the costs of the evaluation.

TABLE 3

DISENROLLMENT FOR TREATMENT GROUP PATIENTS
ENROLLED DURING FIRST SIX MONTHS

Number of Treatment Group Patients Enrolled[a]	16
Length of Enrollment as of October 15, 2002 (Percentage of Patients Enrolled)	
10 weeks or less	37.5
11 to 20 weeks	37.5
21 or more weeks	25.0
Mean Length of Enrollment (Weeks)	13.1
Number of Patients Who Disenrolled	0

Source: University of Maryland program data received October 2002 and updated July 2003. Covers six-month period beginning June 28, 2002 and ending December 24, 2002.

[a]Number of patients enrolled in the treatment group as of December 24, 2002.

telemonitoring equipment in their homes. The care manager reported that many families like the program because they know someone is monitoring the patient's condition on a daily basis. They find it reassuring to know that the program can identify health problems quickly. The care manager cited an example of a 96-year-old patient whose niece called her to tell her how well her aunt was doing because of the program. There are no plans to survey patients or physicians regarding their satisfaction with the program.

Patients may stay in the University of Maryland's MCCD/HFM program for the duration of the demonstration (that is, until June 2006). Of the 16 (treatment group) patients who enrolled over the first six months of operation, 38 percent had been enrolled 10 weeks or less, 38 percent had been enrolled between 11 and 20 weeks, and 25 percent had been enrolled 21 weeks or more (Table 3).

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

While the importance to program success of engaging eligible beneficiaries is self-evident, engaging physicians is less critical. Care 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) and to feel that the information they get from the care managers 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 will also facilitate care managers' access to physicians when urgent problems arise and will facilitate communication and coordination across medical care providers (Chen et al. 2000). Moreover, to increase acceptance of care management among physicians in general, care managers, would naturally need to engage physicians.

The University of Maryland's MCCD/HFM program seeks to improve patient outcomes through direct management of patient's heart failure symptoms; only minimal collaboration with physicians is required to achieve this goal. The program does not expect to influence physicians' clinical practice patterns. Thus, its success is less dependent than other MCCD programs on engaging physicians.

Relationship Between Physicians and the Care Manager. Physicians have a limited role in the MCCD/HFM program. Although the program identifies some potential patients from direct physician referrals, most patients are identified from hospital census lists or clinic rosters, or by a research coordinator within one of the physician practices. Program staff recognize that most physicians do not think about research studies and are thus unlikely to talk to their patients about the demonstration or to encourage them to enroll. As noted, physicians do not have to provide consent in order for individual patients to participate in the program. The program expects that physicians will respond to the care manager's requests for information or consultation. In addition, the program asks physicians to send the care manager notification of changes in patients' medications and updated laboratory values.

The care manager believes that she has developed a rapport with patients' physicians and is able to communicate with them when she needs to discuss patients' medications. She believes she is able to do this because many of the patients' physicians know her from previous projects and because her experience and position allows her to communicate with physicians in an authoritative manner. After making her initial recommendations regarding a patient's medications prior to random assignment, the care manager communicates with physicians only as needed. She will send a fax or e-mail to the physician when she has made adjustments to a patient's diuretics or if she has noticed that the patient is having a problem. If the patient's condition is more urgent, she will call or page the physician.

The program asks physicians to notify the care manager if they make changes to a patient's medications and to send copies of the results of patients' laboratory tests. Some physicians have begun to send this information to her automatically. But for most physicians, she must call their offices to request this information. The care manager has found that cardiologists, who make up the majority of physicians with patients in the program, are more responsive than primary care physicians to both her calls about patient problems and her requests for information.

The care manager reported that her interactions with physicians have been mostly positive. She calls physicians to discuss whether patients need a change in their medications other than diuretics. Physicians are generally responsive to her recommendations, and some physicians have begun to send her patients' laboratory results and notes indicating changes in medications. However, a few have resisted making what she believed were necessary medication changes. In one case, she went to the program's medical director who called the patient's physician directly. When the physician did not make the medication change, the program's medical director prescribed it for the patient himself.

The program signed agreements with referral sources (that is, hospitals and physician practices) to pay them $100 per patient per month for referred patients assigned to the treatment group.[18] The hospital or practice determines how that money is spent—either invested back into operations or divided among the physicians who referred patients. Therefore, the payment may not actually be working as an incentive for individual physicians.

The program staff believed that they needed to provide a sizable payment because they initially believed physicians would want to be more actively involved with the care coordinator and that a financial incentive was required to encourage that involvement. However, physicians

[18]The University of Maryland Medical Center allows the program to keep this payment for patients it refers and use this money to fund program operations.

have not been very involved. The care manager, on her own, is able to manage most of the patients' out-of-range monitoring values by making adjustments to their diuretic medications. Before the start of the demonstration, the program thought physicians would be more involved in making these adjustments. Moreover, program staff believe that the payments have not provided much incentive to physicians to participate and think that the incentive payment to physicians could have been lower, perhaps $50 per patient per month.

Improving Practice. Although changing provider practice is not a focus of the program, the program does provide treatment recommendations to physicians of all patients who enroll in the demonstration. In addition, the care manager hopes that her one-on-one interactions with physicians of treatment group members will also prompt some physicians to improve their prescription of ACE inhibitors and beta blockers. The medical director and care manager believe that physicians often under-prescribe ACE inhibitors, especially for patients with low blood pressure or renal insufficiency. They also think that physicians need to be better educated about beta blockers and which patients are appropriate to receive this medication. They say that physicians tend to start patients on too high a dose of beta blockers, leading to CHF exacerbations. They believe that the program's close monitoring of patients may have helped to make a few physicians more comfortable with trying patients on new medications, in contrast to starting new medication when they had to rely on seeing the patient only every two to three months during office visits.

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

Managing Heart Failure Symptoms. The focus of the MCCD/HFM program's intervention is to improve patient health and reduce costs through direct medical management of patients' CHF-related symptoms. The intervention uses an in-home telemonitoring system to

monitor patients' weight, heart rate, and blood pressure against individualized parameters determined by using data collected at the initial assessment. The care manager then responds to out-of-range monitoring values, especially weight gain, by increasing the amount of diuretic medication the patient is taking. The intervention does not focus on improving patient adherence to treatment recommendations, improving access to Medicare or non-Medicare services, or improving patient-physician communication or care coordination. As noted, to the limited extent that program staff engage in these activities, their efforts occur before randomization and are geared to both treatment and control group patients.

The program appears to have developed the structures and procedures needed to implement direct medical management. For example, it is able to install the telemonitoring devices in patients' homes quickly. Program staff report that they usually can install the device within seven days after enrollment (although occasionally up to two weeks elapses before installation). Staff also believe that the patients learn to use the device easily. Patients do not need to be able to read or to speak or understand English to use it.[19] The care manager estimates that, in the first 30 days after installation, patients are about 90 percent compliant in using the device daily. After about one year, the compliance rate drops to about 70 percent. The program has had no patient complaints about the installation process or difficulty using the device. However, two patients disenrolled because they did not like having the device in their homes, finding the device too intrusive.

Program staff also report that the telemonitoring device transmits data reliably. Although Philips (the provider of the device) has had to repair or replace the components of some of the telemonitoring devices for technical problems of various types (for example, damage to modems

[19]The program does not have any patients who are not English-speaking; but, if any do enroll, the program's care manager believes that they should be able to participate in the intervention.

from power surges, scales damaged from moving them around, loose wires on blood pressure cuffs), the care manager still describes the devices as quite reliable. She said that occasionally, when a patient has difficulty using the equipment, Nursefinders (the installer of the device) will do a home visit to retrain the patient. The care manager reports that they had problems with two patients' telephone lines, but the telephone company was able to fix them.

The care manager believes that she would be able to comfortably manage up to 200 patients herself. At the time of MPR's site visit in January 2004, the care manager reported that she had no difficulty managing the 50 treatment group patients then enrolled in the program. She estimated that it takes her two to three hours a day to review the monitoring data from the Philips software on the 50 treatment group patients, telephone patients whose data are out of range, and make routine monthly monitoring calls to patients whose data have remained within range. If the care manager is on vacation, another nurse practitioner associated with the University's Heart Failure Service logs into the Philips software to monitor the patients' data. Program patients do not have access to the care manager outside of normal office hours. The care manager instructs patients that, if they have an urgent problem, they should call their physician or dial 911.

Program staff believe that the intervention is running smoothly; they do not anticipate changing it in any way. However, as previously described, the program does not collect data on any process of care measures that would allow it to determine whether it is implementing the intervention as planned. For example, program staff have no data to assess the percentage of patients who had monitoring device problems, the percentage whose monitoring data are within acceptable ranges, or the number who have had an adverse event since enrollment.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

The evaluation provides preliminary estimates of the effect of the MCCD/HFM program on Medicare service use and expenditures. These early estimates must be viewed with caution, as

they are not likely to be reliable indicators of the true effect of the program over a longer period. Due to lags in data availability, analysis for this report included only an early cohort of enrollees (those enrolling during the first four months of program operation), and allowed observation of their experiences during their first two months in the program. The estimates thus include patients' experiences during the program's first six months of operation, when staff may have been fine-tuning the intervention. Moreover, the program may also enroll patients with quite different characteristics over time.

The research sample enrolled in the first four months (10 treatments and 9 controls) is too small to draw conclusions about early program effects. That said, there were no statistically significant differences between treatment and control group members in the use of or reimbursement for regular Medicare services during the first two full months after random assignment.[20] To be successful, however, the program must have an effect on the percentage of treatment group patients being admitted to the hospital, as well as the number of hospital admissions among treatment group patients (Table 4) to result in savings on total Medicare reimbursements. In the first two months after random assignment, total Medicare reimbursement was about $2,600 per month, on average, for treatment group members, and about $1,800 for control group members, excluding reimbursement for care coordination (Table 4). Although CMS pays the program $350 per patient per month ($700 for two months), the evaluation calculated the program's actual average Medicare reimbursement per patient to be $630 over the first two months. The difference is likely due to errors or lags in program billing.

The evaluation also examined monthly trends in treatment-control differences from June through December 2002, the first six months of program operation (Table 5). Again, the sample

[20]As would be expected with random assignment, the characteristics of the treatment and control groups were statistically similar (see Appendix Table B.6). Note that the results cover the first two full months after enrollment. The first partial month is excluded.

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)	30.0	12.5	17.5
Mean number of admissions	0.60	0.13	0.48
Mean number of hospital days	2.40	0.63	1.78
Emergency Room Services			
Any emergency room encounters (percent)			
Resulting in admission	20.0	0.0	20.0
Not resulting in admission	0.0	12.5	–12.5
Total	20.0	12.5	7.5
Mean number of emergency room encounters			
Resulting in admission	0.20	0.00	0.20
Not resulting in admission	0.00	0.13	–0.13
Total	0.20	0.13	0.08
Skilled Nursing Facility Services			
Any admission (percent)	0.0	0.0	0.0
Mean number of admissions	0.00	0.00	0.00
Mean number of days	0.00	0.00	0.00
Hospice Services			
Any admission (percent)	0.0	0.0	0.0
Mean number of days	0.00	0.00	0.00
Home Health Services			
Any use (percent)	10.0	12.5	–2.5
Mean number of visits	0.50	0.13	0.38
Outpatient Hospital Services[b]			
Any use (percent)	20.0	37.5	–17.5
Physician and Other Part B Services[c]			
Any use (percent)	70.0	62.5	7.5
Mean number of visits or claims	9.4	4.0	5.4
Mortality Rate (percent)	0.0	0.0	0.0
Total Medicare Reimbursement[d]			
Part A[e]	$4,445	$3,182	$1,263
Part B	$906	$444	$462
Total	$5,351	$3,626	$1,725
Reimbursement for Care Coordination[f]	$630	$0	$630***
Number of Beneficiaries	**10**	**9**	

TABLE 4 *(continued)*

Source: Medicare National Claims History File.

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

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

[a]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) suggest 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.

[b]Includes both emergency and nonemergency visits to outpatient hospital facilities, as well as use of laboratory and radiology services.

[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. The difference between the recorded amount and what the program was allowed to charge per-member-per-month may reflect billing errors or delays.

*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	Jun 02	Jul 02	Aug 02	Sep 02	Oct 02	Nov 02
Mean Number of Beneficiaries Who Were Enrolled In or Before the Month	Treatment		3	6	10	11	13
	Control	1	2	7	9	10	14
Mean Number of Beneficiaries Enrolled Who Meet Medicare Coverage and Payer Requirements and are Alive that Month	Treatment		3	6	10	11	13
	Control	1	2	6	7	8	12
Average Medicare Reimbursement During the Month[a]	Treatment		$2,588	$3,717	$4,434	$2,027	$1,591
	Control	$238	$360	$4,542	$1,770	$237	$941
Average Reimbursment for Care Coordination During the Month[a,b]	Treatment		$350	$350	$315	$286	$350
Whether Admitted to Hospital This Month[a] (Percentage)	Treatment		33.3	16.7	40.0	18.2	15.4
	Control	0.0	0.0	16.7	14.3	0.0	16.7
Treatment - Control Difference[c]							
Average Medicare Reimbursement[a]			$2,228	–$824	$2,664	$1,790	$651
Average Reimbursement for Medicare plus Care Coordination[a]			$2,578	–$474	$2,979	$2,076*	$1,001
Percentage Hospitalized[a]			33.3	0.0	25.7	18.2	–1.3

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 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.

TABLE 5 *(continued)*

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[b]This is the average amount paid to the program as recorded in the Medicare claims data. The difference between the recorded amount and what the program was allowed to charge per-member-per-month may reflect billing errors or delays.

[c]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) suggest 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.

enrolled in each of these months is too small to draw inferences; this table is included only to demonstrate the types of analyses that will be conducted in the future.

CONCLUSION

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

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

Second, successful programs tend to have a comprehensive, structured intervention that can be adapted to individual patient needs. Key features include: 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 (Chen et al. 2000); and a process for providing aggregate and patient-level feedback to care coordinators, program leaders, and physicians about patient outcomes (Chen et al. 2000). Another critical aspect 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; and 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; and Hagland 2000).

The third and fourth characteristics that have been associated with successful programs are having highly trained staff and actively involved providers. Strong programs typically have care 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; and Schore et al. 1997).

Finally, periodic feedback during the demonstration can motivate providers and care managers and enable the program to modify or intensify the intervention if it appears that it is not having the expected effect on intermediate or ultimate outcome indicators. Financial incentives also can help encourage physicians and program staff to look for creative ways both to meet patient goals and reduce total health care costs (Schore et al. 1997).

Program Strengths and Unique Features. The University of Maryland's MCCD/HFM program appears to have some of the features associated with effective care coordination programs. The intervention is focused and straightforward: it uses an in-home monitoring device to directly monitor patients' critical health indicators. The underlying philosophy of this intervention is that efforts to change patient behavior are time-consuming and costly, and frequently do not work. Moreover, staff believe that simply managing fluid retention for heart failure patients is sufficient to improve their health and keep them out of the emergency room or hospital. Program staff report that patients typically start using the devices within a week of random assignment and that the program is implementing its intervention as planned. In addition:

- The program targets patients with a recent hospital stay for congestive heart failure, a diagnosis typically associated with high health care costs. Participants' average

monthly Medicare expenditures in the year before their enrollment were quite high ($2,731), and similar to estimates for eligible nonparticipants—suggesting that the program is enrolling high-cost patients from its target group.

- All patients receive an initial assessment and a limited care plan that is used to set parameters for the telemonitoring device. The program conducts patient monitoring through an in-home telemonitoring device and monthly calls from the care manager. The care manager reassesses patients regularly and will adjust the telemonitoring parameters in response to adverse events.
- The care manager is a nurse practitioner with 30 years of nursing experience. As a result, physicians have been responsive to her recommendations for changes in patients' medication regimens.
- The MCCD/HFM program is unique among the programs in the Medicare Coordinated Care Demonstration. Other programs for patients with CHF use telemonitoring devices, but they also emphasize either changing patient behaviors or physician practice. Both types of change are difficult to make and sustain. The MCCD/HFM program's intervention seeks to improve patient health and control costs through intensive monitoring but does not require patients or physicians to change their behaviors.

Potential Barriers to Program Success. The MCCD/HFM program focuses on direct medical management of patients' CHF-related symptoms. By design, its intervention does not provide patient education to improve self-care, nor does it try to improve communication between patient and physicians. The program's design requires only limited involvement on the part of the physician. The care manager reports that physicians respond to her requests and concerns. Physicians, however, are less involved than the program had originally intended, and paid for, through its high monthly payment to the hospitals and physician practices that referred patients.

The program collects little data that would allow it to determine whether the intervention is being implemented as planned. Program staff believe that it is being implemented as planned, a belief that may be true to date, since the program's small size allows staff to clearly understand what is happening with patients. As the program grows, though, it will become increasingly difficult to monitor it's the program's implementation. Without the ability to report data on

program implementation, it will be difficult to say, for example, whether consistent use of the telemonitoring device is associated with better patient outcomes.

The program's low patient enrollment will make it difficult for the evaluation to detect any but large reductions in patient service use and costs. Despite several significant changes in its referral and recruitment processes, the rate of enrollment has not increased substantially. Lack of comprehensive data on the number of patients referred to the program from each source, reasons why referred patients are ineligible, and reasons why they decline to participate have all hindered the program's ability to refine its enrollment procedures.

Further, the program has been hampered by the way it chose to allocate its financial resources. Out of its $350 per patient per month payment from CMS, the program pays $200 to Philips for use of the telemonitoring device and clinical review software and $100 to the patient's physician. This leaves only $50 per patient per month to cover the program's operating expenses. All staff salaries are paid from the project director's own research funds. However, expenses related to billing and patient initial assessments must be covered from the CMS payment. The program cannot hire additional staff to work on patient recruitment because it does not have the financial resources.

A key challenge is to enroll enough patients to achieve some economies of scale and be able to demonstrate their effects on outcomes. It is obviously too early, and samples are too small, to draw any inferences about program impacts at this time. For all MCCD programs, savings in hospitalizations and other expensive Medicare services will have to be large enough not only to cover direct program fees, but also any higher Part B expenses incurred when care managers refer treatment group patients for Medicare-covered services that the patient may not have otherwise received.

Plans for the Second Site-Specific Report. MPR will prepare a second report on the University of Maryland's MCCD/HFM program activities during the second and third years of operation that will focus more heavily on program impacts based on additional claims data. This report will also describe changes made to the program over time and the reasons for those changes, as well as staff impressions of program successes and shortcomings. This report is due in mid-2005.

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APPENDIX A

ADDITIONAL TABLES

A.1 DEMONSTRATION PROGRAMS PARTICIPATING IN THE EVALUATION

A.2 LIST OF DOCUMENTS REVIEWED FOR THIS REPORT

TABLE A.1

DEMONSTRATION PROGRAMS PARTICIPATING IN THE EVALUATION

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

TABLE A.1 *(continued)*

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

TABLE A.1 *(continued)*

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

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

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

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

TABLE A.2

LIST OF DOCUMENTS REVIEWED FOR THIS REPORT

University of Maryland Medicare Care Coordination Demonstration Project for Heart Failure Management (proposal submitted to the Health Care Financing Administration, October 2000)

Site Operational Protocols

Informed consent form*

Initial assessment forms
- History*
- Medications*
- Mini-Mental State Exam
- SF-36
- Living with Heart Failure Questionnaire
- McMaster Overall Treatment Score

Patient Education handout*

Sample letters to physicians of treatment and control group patients (initial evaluation)*

Sample letters to treatment and control group patients*

Initial Plan of Care*

Description of the Project (for referring physicians)*

Sample letter to physician discussing medication changes*

Examples of screens from Philips clinical review software*

* 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 eligible beneficiaries enrolled in the program by calculating the participation rate and comparing the characteristics of participants and eligible non-participants. The participation rate was calculated as the number of beneficiaries who met the program's eligibility criteria and enrolled 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 June 28, 2002, through December 24, 2002. We explored patterns of participation by comparing eligible participants and eligible nonparticipants 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 the University of Maryland's MCCD/HFM program-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, University of Maryland 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

TABLE B.1

ELIGIBILITY CRITERIA

Inclusion Criteria	Meets all three criteria: 1. Hospital admission for CHF within the last 90 days. Codes: 428.0-428.9, 402.00-402.91, 404.00-404.93 2. Has a telephone 3. Has systolic or diastolic dysfunction **Revised 4/15/2003:** Criteria 1: Hospitalization within the last *year* for a heart failure related diagnosis (extended from 90 days to 1 year).
Exclusion Criteria	Meets any of following criteria: 1. Diagnosis of HIV/AIDS, cancer (other than stable prostate cancer), or Alzheimer's disease or other dementias 2. Bed-fast or resides in a hospice or skilled nursing facility 3. Has open wounds that require regular dressing changes 4. Weighs over 300 pounds Codes: 140-172.9, 174-208.91, 492.0, 492.8, 491.20, 491.21, V08, 042
Providers/Referral Sources	Hospitals, cardiologists, a few internal medicine doctors
Geographic location	Baltimore Metropolitan Area (Baltimore City and Baltimore, Ann Arundel, Carroll, Harford and Howard Counties, Maryland)

al. 2001). The program confirmed these criteria in spring 2003. Until April 15, 2003, to be considered for the program's demonstration, beneficiaries must have had a hospital admission for CHF within the last 90 days, systolic or diastolic dysfunction and have a telephone.[1] Along

[1]University of Maryland changed its inclusion criteria on April 15, 2003, extending the time frame for the CHF hospitalization from 90 days to 1 year. This report does not reflect this

with the diagnosis criteria, at the time of enrollment beneficiaries could not have one of the following exclusion criteria: (1) diagnosis of HIV or AIDS, cancer (other than stable prostate cancer), or Alzheimer's disease or other dementia,[2] (2) bedfast or resident of a skilled nursing facility or hospice, (3) presence of an open wound requiring regular dressing changes, or (4) weight over 300 pounds.

We could approximate most of University of Maryland's criteria using Medicare data with some exceptions. We first identified all area patients who had the target condition, CHF, by examining whether a beneficiary had any Medicare claim for treatment for CHF at any point during the 30-month period beginning July 1, 2000, two years before enrollment began, and ending six months after enrollment started (December 31, 2002). To identify whether a beneficiary met the program's utilization (hospital admission for CHF) or medical exclusion criteria, we examined hospital claims over a 9-month period starting April 1, 2002 and ending December 31, 2002. We did not limit eligible beneficiaries to people who had used the specific hospitals or doctors who were expected to refer patients to the program. Thus, our estimates overstate the number of people University of Maryland is likely to have approached about participating. We could not approximate four of University of Maryland's exclusion criteria using Medicare data: (1) was bed-fast or residing in skilled nursing facilities, (2) had open wounds that require regular dressing changes, (3) weighed over 300 pounds, and (4) has a

(continued)
change because we examine the first six months of program operations, before this change was made.

[2]Just over 1 percent of eligible nonparticipants have dementia despite it being one of the program's exclusion criteria because the program excluded Alzheimer's disease, Pick's disease, senile degeneration of the brain, and other classified cerebral degenerations. The definition of dementia used in Tables 2 and B.4 includes additional types of cerebral degenerations that are also commonly termed dementia, such as unspecified cerebral degeneration.

telephone. These additional restrictions are not likely to reduce the estimated number of eligibles substantially below our estimates.

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). All claims files were accessed through CMS's Data Extract

System. At the end of June 2003, we requested Medicare claims from 2000 through 2002. We received all claims that were updated by CMS through March 2003. This allowed a minimum of a three-month lag between a patient's receipt of a Medicare-covered service in the last month we examined—December 2002—and the appearance of the claim on the Medicare files.

Medicare claims and eligibility information were summarized as monthly variables from July 2000 through December 2002, for a total of 30 months. This enabled us to look at the eligibility status and the use of Medicare-covered services during any month in the two years before the program's start, to analyze participation in the first six months of program operation and to analyze treatment-control differences in Medicare service use and reimbursement following enrollment.

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

The Medicare claims data in the NCH files were used to construct measures of Medicare-covered service use and reimbursement by type of service (inpatient hospital, skilled nursing facility, home health, hospice, outpatient hospital, and physician and other Part B providers). When the services spanned months, the monthly variables were allocated based on the number of days served in that month, as documented in the CLAIM FROM and CLAIM THRU dates. The length of stay for a month represented actual days spent in the facility in that month; costs were prorated according to the share of days spent in each month. Ambulatory visits were defined as the number of unique provider-date of service combinations, as determined from the physician/supplier and hospital outpatient claims. That is, the number of ambulatory visits was defined as the number of different days on which a patient saw a given provider, summed over

all providers. Thus, multiple visits to the same provider on a given date were treated as a single visit. Durable medical equipment (DME) reimbursements were counted in other Part B reimbursement. A very small number of patients had negative values for total Part A and Part B reimbursements during the past two years due to errors or missing claims. Any negative Part A and Part B totals for the 2 year period 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 September 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 348,641 beneficiaries who lived in University of Maryland's catchment area at some point during the first six months of enrollment (Table B.2). We then excluded 45,703 people (13.1 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 222,743 of the remaining people (63.9 percent of all area beneficiaries) were dropped from the

TABLE B.2

SAMPLE OF ALL ELIGIBLE BENEFICIARIES FOR PARTICIPATION ANALYSIS

Sample	Number
Full Sample of Eligible Beneficiaries Who Live in Catchment Area One or More Months During the First Six Months of Enrollment	348,641
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	–45,703
Did not have one or more of the target diagnoses on any claim during the two years before the program started or during the six-month enrollment window	–222,743
Did not meet the inpatient or outpatient hospital utilization criteria during the 9 months from April 2002 through December 2002	–64,956
Met at least one of the exclusion criteria during the 9 months from April 2002 through December 2002	–8,262
Eligible Sample[a]	**6,977**

[a]Beneficiaries were considered eligible if at any time during the 6-month enrollment window they would have met the eligibility criteria. Thus, the estimate of 6,977 eligibles differs from the sample size used in Table 2 because that table restricts the sample to those who met the eligibility criteria as of their enrollment date (for participants) or as of September 15, 2002 (the midpoint of the 6-month enrollment period), for nonparticipants, in order to define a "pre-enrollment" period for these non-participants.

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	16	17	33
Minus those who:			
Had an invalid HIC number on MPR's enrollment file	–0	–0	–0
Not in geographic catchment area during the month of intake	–2	–4	–6
In a Medicare managed care plan, or did not have Medicare Part A and B coverage, or Medicare is not primary payer during the month of intake	–0	–1	–1
Did not have one or more of the target diagnoses on any claim during the two years before the program started or during the six-month enrollment window	–0	–0	–0
Did not meet the inpatient or outpatient hospital utilization criteria during the 9 months from April 2002 through December 2002	–3	–2	–5
Met at least one of the exclusion criteria during the 9 months from April 2002 through December 2002	–0	–6	–6
Eligible Sample	**11**	**4**	**15**

Note: The number of sample members reported as excluded at each point reflects *people in the previous line* who did not meet the additional eligibility criteria according to Medicare data. Thus, the table applied sequential criteria. The program actually used patient self-reports of diagnosis and service use. The total number of people who failed to meet a particular exclusion criterion may have been greater than the number reported in this table for program criteria that we could not fully assess using claims data (for example, patient weight).

sample, as they were not treated for any claims for the target diagnoses that the program identified as necessary for inclusion during the two years before the program began or the first six months of enrollment. Eighty one percent of the remaining beneficiaries (64,956 people) did not meet the utilization requirements we measured (hospital admission) during the nine-months from April 1, 2002 through December 2002 (which includes three months of the current year as well as the six-month enrollment window). Finally, 8,262 people were identified as having at least one of University of Maryland's exclusion criteria, leaving us with a sample of 6,977 beneficiaries we estimated would have been eligible to participate in University of Maryland's program.

University of Maryland randomized 33 beneficiaries who enrolled in the demonstration program during the first six months of operation (Table B.3). All beneficiaries reported valid HIC numbers and could be matched to their Medicare claims data. University of Maryland randomized six 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 one participant who did not meet CMS's insurance requirements for participation in the program during the month of intake. We also dropped five beneficiaries for not meeting the utilization criteria and six beneficiaries because they met one of the program's medical exclusion criteria during the nine-month period, April 1, 2002 through December 2002.[3] Thus, among the 33 participants randomized by University of Maryland into

[3]Among the 31 who enrolled in the first six months, who had valid Health Insurance Claim (HIC) numbers reported and who met CMS's insurance requirements at intake, 3 percent were enrolled in Medicare FFS 12 or less of the previous 24 months before they enrolled in the demonstration; no participants were in FFS less than 6 of the 24 months before enrolling.

the program, after exclusions, only 15 people are included in the numerator of the participation rate.

University of Maryland's participation rate for the first six months of enrollment is therefore calculated as the number of participants who met the eligibility requirements (15), divided by the number of eligibles who live in the catchment area (6,977), or 0.2 percent.

We next compare the preenrollment characteristics and service use of eligible participants and nonparticipants in Table B.4.[4] Table B.4 describes the characteristics of the 11 participants who were enrolled by University of Maryland during the first six months and who appear to meet University of Maryland's eligibility requirements, as measured in Medicare data, and the 2,398 eligible nonparticipants. This table is identical to Table 2 in the text, except that the participant sample has been restricted to the beneficiaries who meet the eligibility criteria according to Medicare claims data. The results are similar to those in Table 2, except that fewer differences between the participants and nonparticipants are statistically significant.

B. METHOD FOR CALCULATING IMPACTS

Sample sizes are too small, and the follow-up period too short, to estimate program impacts. Examining the treatment and control groups on mean outcomes, however, gives an early indication of the types of patients enrolled. 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). However, it includes *all* participants enrolled in the first 4 months for

[4]The sample in Table B.4 differs from that used in Table B.2 to calculate the participation rate. Table B.4 further limits the sample of beneficiaries to those who met the target criteria (as measured using Medicare claims data) during the three months before intake. The enrollment date used for eligible nonparticipants is chosen to be three months after the program began enrollment (that is, the middle of the six-month window). This results in 11 eligible participants and 2,398 eligible nonparticipants in Table B.4.

TABLE B.4

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

	Eligible Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Age at Intake			
Average age (in years)	76.9	74.4	
Younger than 65	0.0	15.2	
65 to 74	36.4	28.9	
75 to 84	63.6	38.4	*
85 or older	0.0	17.5	
Male	72.7	37.8	**
Nonwhite	36.4	33.4	
Original Reason for Medicare: Disabled or ESRD	18.2	26.6	
State Buy-In for Medicare Part A or B	18.2	20.2	
Newly Eligible for Medicare (Eligible Less than Six Months)	0.00	0.00	
Enrolled in Fee-for-Service Medicare 6 or More Months During Two Years Before Intake	100.0	100.0	
Medical Conditions Treated During Two Years Before Month of Intake[b]			
Coronary artery disease	90.9	84.7	
Congestive heart failure	100.0	100.0	
Stroke	54.6	42.2	
Diabetes	36.4	55.9	
Cancer	18.2	11.5	
Chronic obstructive pulmonary disease	72.7	52.0	
Dementia (including Alzheimer's disease)	0.0	1.2	
Peripheral vascular disease	27.3	33.0	
Renal disease	9.1	32.9	*
Total Number of Diagnoses	4.1	4.1	
Days Between Last Hospital Admission and Intake Date[b]			
No hospitalization in past two years	0.0	0.0	
0 to 30	45.5	40.0	
31 to 60	36.4	34.5	
61 to 180	18.2	25.6	
181 to 365	0.0	0.0	
366 to 730	0.0	0.0	

TABLE B.4 *(continued)*

	Eligible Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants
Annualized Number of Hospitalizations During Two Years Before Month of Intake[b,c]		
0	0.0	2.0
0.1 to 1.0	36.4	34.9
1.1 to 2.0	36.4	29.7
2.1 to 3.0	18.2	14.6
3.1 or more	9.1	18.9
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[b]		
Part A	$1,845	$2,283
Part B	$375	$874
Total	$2,219	$3,156
Distribution of Total Medicare Reimbursement per Month Fee-for-Service During One Year Before Intake[b]		
$0	0.0	0.1
$1 to 500	9.1	11.2
$501 to 1,000	27.3	16.8
$1,001 to 2,000	27.3	21.4
More than $2,000	36.4	50.5
Number of Beneficiaries[d]	**11**	**2,398**

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 September 15, 2002, 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. Participants who are excluded from the research sample because they are members of the same household as a research sample member are included here.

[b]Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. Eligible patients included only those who had a hospital stay for CHF within the 90 days preceding enrollment. (See Note, above, concerning intake date definition.)

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

TABLE B.4 *(continued)*

[d]The eligible participants are required to have a hospitalization within the 90 days preceding enrollment. Eligible non-participants are required to have a hospitalization within the 90 days preceding their pseudo enrollment date (September 15, 2002).

*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.

whom we have data, not just those who meet the eligibility criteria. The cost of the intervention was estimated as the amount CMS paid to University of Maryland 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 and control group means in Medicare-covered service use and cost outcomes. First, we estimated means over a two-month follow-up period for all patients University of Maryland randomized during the first four months of enrollment. The four-month enrollment window covers June 28, 2002 through October 25, 2002. The follow-up time covered the two calendar months after the month of randomization. For example, for a beneficiary randomized on June 30, we examined outcomes in July and August.

Second, we estimated treatment and control group means by calendar month over the first six months of University of Maryland's enrollment to look at how outcomes 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. When more data are available, analyzing costs by program month will allow us to examine such patterns. For each month from June 2002 through November 2002, we identified the patients who were enrolled in University of Maryland's demonstration program and analyzed their Medicare-covered service use. For example, a person randomized in June would be present in June through November, provided that person is eligible and alive in each month.[5] Someone

[5]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).

randomized in July would not be part of the calculations for June but would be included in July through November, again provided that the person is eligible during those months.

The sample used to analyze treatment – control differences in outcomes differs from that used to analyze participation. 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 because their data would be incomplete or missing). 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.[6] 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 20 people randomized in the first four months of University of Maryland's demonstration, the sample for analyzing treatment-control differences contained 19 people. For the six-month sample, 31, or 94 percent of the 33 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).

[6]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	20	33
Minus those who:		
Were members of the same household as research sample members	–0	–0
Had invalid HIC numbers on MPR's enrollment file	–0	–0
In a Medicare managed care plan, or did not have Medicare Part A and B coverage, or Medicare is not primary payer during the month of intake	–1	–2
Number of usable sample members	**19**	**31**

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. These analyses are primarily illustrative, since sample sizes are so small.

As expected under random assignment, the treatment and control groups had similar characteristics in both the four- and six-month samples. There were statistically significant differences in two baseline characteristics for the four-month sample: (1) the proportion of beneficiaries who were treated for coronary artery disease in the two previous years and (2) the proportion of beneficiaries who had an annual number of hospitalizations during the two years before the month of intake of between 2.1 to 3.0. These differences were significant at the 10 percent level. For the six-month sample, there were also two statistically significant differences: the proportion of beneficiaries who were treated in the two previous for (1) coronary artery disease and (2) dementia. We would expect this number of false-positive differences to occur by chance, given the number of characteristics examined. Thus, none of the differences in this small, early sample create any cause for concern.

3. Sensitivity Tests

To assess outcomes, we calculated Medicare-covered service use and cost in the first two full months after the month of randomization. For example, for an individual who was randomized in the month of June, we tabulated the individual's outcomes in July and August. 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 full months

TABLE B.6

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

	Four-Month Sample			Six-Month Sample		
	Treatment Group	Control Group	Total Research Sample	Treatment Group	Control Group	Total Research Sample
Age at Intake						
Average age (in years)	73.5	74.2	73.8	74.1	74.7	74.4
Younger than 65	10.0	11.1	10.5	6.3	6.7	6.5
65 to 74	50.0	33.3	42.1	50.0	33.3	41.9
75 to 84	30.0	44.4	36.8	37.5	53.3	45.2
85 or older	10.0	11.1	10.5	6.3	6.7	6.5
Male	80.0	77.8	78.9	81.3	80.0	80.6
Nonwhite	30.0	33.3	31.6	31.3	33.3	32.3
Original Reason for Medicare: Disabled or ESRD	30.0	33.3	31.6	25.0	20.0	22.6
State Buy-In for Medicare Part A or B	20.0	11.1	15.8	12.5	6.7	9.7
Newly Eligible for Medicare (Eligible Less than Six Months)	0.0	0.0	0.0	0.0	0.0	0.0
Enrolled in Fee-for-Service Medicare Six or More Months During Two Years Before Intake	100.0	100.0	100.0	100.0	100.0	100.0
Medical Conditions Treated During Two Years Before Month of Intake[a]						
Coronary artery disease	100.0	66.7 *	84.2	100.0	73.3 **	87.1
Congestive heart failure	100.0	88.9	94.7	93.8	93.3	93.5
Stroke	30.0	44.4	36.8	43.8	46.7	45.2
Diabetes	60.0	33.3	47.4	56.3	40.0	48.4
Cancer	20.0	0.0	10.5	12.5	6.7	9.7
Chronic obstructive pulmonary disease	70.0	88.9	78.9	56.3	73.3	64.5
Dementia (including Alzheimer's disease)	0.0	11.1	5.3	0.0	20.0 *	9.7
Peripheral vascular disease	30.0	11.1	21.1	25.0	33.3	29.0
Renal disease	20.0	11.1	15.8	18.8	13.3	16.1
Total Number of Diagnoses	4.3	3.6	3.9	4.1	4.0	4.0

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	10.0	22.2	15.8	6.3	13.3	9.7
0 to 30	30.0	22.2	26.3	18.8	26.7	22.6
31 to 60	10.0	11.1	10.5	18.8	20.0	19.4
61 to 180	50.0	33.3	42.1	43.8	33.3	38.7
181 to 365	0.0	11.1	5.3	0.0	6.7	3.2
366 to 730	0.0	0.0	0.0	12.5	0.0	6.5
Annualized Number of Hospitalizations During Two Years Before Month of Intake[a,b]						
0	10.0	22.2	15.8	6.3	13.3	9.7
0.1 to 1.0	40.0	33.3	36.8	43.8	33.3	38.7
1.1 to 2.0	20.0	22.2	21.1	25.0	20.0	22.6
2.1 to 3.0	30.0	0.0 *	15.8	25.0	20.0	22.6
3.1 or more	0.0	22.2	10.5	0.0	13.3	6.5
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]						
Part A	$1,744	$1,117	$1,447	$1,785	$2,822	$2,287
Part B	$433	$265	$353	$369	$525	$445
Total	$2,177	$1,381	$1,800	$2,154	$3,346	$2,731
Distribution of Total Medicare Reimbursement per Month Fee-for-Service During One Year Before Intake[a]						
$0	0.0	11.1	5.3	6.3	6.7	6.5
$1 to 500	20.0	11.1	15.8	18.8	6.7	12.9
$501 to 1,000	20.0	33.3	26.3	18.8	20.0	19.4
$1,001 to 2,000	30.0	22.2	26.3	18.8	20.0	19.4
More than $2,000	30.0	22.2	26.3	37.5	46.7	41.9
Location During Program Intake Period						
Maryland						
Baltimore City	50.0	22.2	36.8	50.0	33.3	41.9
Baltimore	20.0	44.4	31.6	25.0	33.3	29.0
Ann Arundel	10.0	11.1	10.5	6.3	6.7	6.5
Carroll	0.0	0.0	0.0	0.0	0.0	0.0
Harford	0.0	0.0	0.0	6.3	6.7	6.5
Howard	0.0	0.0	0.0	0.0	0.0	0.0
Outside catchment area	20.0	22.2	21.1	12.5	20.0	16.1
Number of Beneficiaries	**10**	**9**	**19**	**16**	**15**	**31**

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 September 15, 2002, 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.

after randomization (Table B.7). Other than the percent and number of emergency room visits resulting in an admission, which are significant at the 5 percent level in the three-month period and not significant in the two-month period shown in Table 4, the results were similar to those for outcomes measured over the two-month period (text Table 4). These small differences between the two methods likely reflect the small sample sizes used in this report.

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)	40.0	22.2	17.8	
Mean number of admissions	1.00	0.22	0.78	
Mean number of hospital days	3.60	1.33	2.27	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	40.0	0.0	40.0	**
Not resulting in admission	0.0	11.1	–11.1	
Total	40.0	11.1	28.9	
Mean number of emergency room encounters				
Resulting in admission	0.50	0.00	0.50	**
Not resulting in admission	0.00	0.11	–0.11	
Total	0.50	0.11	0.39	
Skilled Nursing Facility Services				
Any admission (percent)	0.0	0.0	0.0	
Mean number of admissions	0.00	0.00	0.00	
Mean number of days	0.00	0.00	0.00	
Hospice Services				
Any admission (percent)	0.0	0.0	0.0	
Mean number of days	0.00	0.00	0.00	
Home Health Services				
Any use (percent)	20.0	11.1	8.9	
Mean number of visits	1.10	0.11	0.99	
Outpatient Hospital Services[b]				
Any services (percent)	40.0	33.3	6.7	
Physician and Other Part B Services[c]				
Any use (percent)	90.0	77.8	12.2	
Mean number of visits or claims	16.4	7.1	9.3	
Mortality Rate (percent)	0.0	11.1	–11.1	
Total Medicare Reimbursement[d]				
Part A[e]	$6,504	$4,048	$2,456	
Part B	$1,563	$723	$840	
Total	$8,067	$4,771	$3,297	
Reimbursements for Care Coordination[f]	$980	$0	$980	***
Number of Beneficiaries	**10**	**9**		

TABLE B.7 *(continued)*

Source: Medicare National Claims History File.

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

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

[a]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

TABLE C.1

DOCUMENTS INCLUDED

University of Maryland Medicare Care Coordination Demonstration Project for Heart Failure Management description of the Project (for referring physicians)

Informed consent form

Patient Education handout

Sample letters to physicians of treatment and control group patients (initial evaluation)

Sample letters to treatment and control group patients

Initial assessment forms
- History
- Medications

Initial Plan of Care

Examples of screens from Philips clinical review software

Sample letter to physician discussing medication change