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Evaluation of Medicare Disease Management Programs: LifeMasters Final Report of Findings

Final Report

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DEFINITIONS OF KEY TERMS

Term	Definition
Terms Describing Patient Demonstration Status	
Eligible[a]	Patients who satisfied predetermined LifeMasters demonstration eligibility criteria that allowed for random assignment into the demonstration (see Appendix A for complete details).
Randomized	Eligible patients who were selected to either the treatment or control group according to a predetermined schedule. All randomized patients who were eligible for at least one day were included in impact analyses.
Enrolled[a]	Patients who were randomized and eligible for the demonstration. Enrollment began on the first day of the second calendar month after random assignment.
Active[b]	Enrolled treatment group patients for whom LifeMasters received a program management fee.
Mediated[b]	Active treatment group patients who agreed to participate fully in intervention activities and accept monthly telephone calls from LifeMasters staff.
Instructional[b]	Active treatment group patients who agreed only to receive a quarterly health magazine and an occasional telephone call from program staff or who LifeMasters was unable to reach.
Inactive[b]	Enrolled treatment group patients who opted not to participate in the demonstration or who LifeMasters inactivated. LifeMasters did *not* receive a program management fee for these patients.
Disenrolled[a]	Patients who were randomized but no longer met demonstration eligibility criteria. Once disenrolled, these patients could not be re-enrolled.
Term Describing the Demonstration	
Redesign	CMS-approved 10-month period from March 2007 to December 2007 during which demonstration eligibility criteria were revised from their original form. Only patients who resided in select Florida counties and who had claims for CHF or claims for two of the three target medical conditions (CHF, CAD, and diabetes) were eligible for the redesign.[c]
Term Describing the Impact Analysis	
Intent-to-treat	Impact analysis includes all enrolled treatment group (that is, active and inactive) and control group patients.

[a] Classification determined by Mathematica Policy Research, Inc.
[b] Classification determined by LifeMasters.
[c] Those counties included Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, and Volusia.

CAD = coronary artery disease; CHF = congestive heart failure; CMS = Centers for Medicare & Medicaid Services.

EXECUTIVE SUMMARY

OVERVIEW OF FINDINGS

From January 2005 to December 2007, the Centers for Medicare & Medicaid Services (CMS) sponsored a population-based disease management demonstration program implemented by LifeMasters Supported SelfCare (LifeMasters). The program targeted Medicare fee-for-service beneficiaries who were dually enrolled in Medicaid (dual eligibles); resided in Florida; and had congestive heart failure (CHF), coronary artery disease (CAD), diabetes, or a combination of the three. LifeMasters only enrolled beneficiaries from 11 Florida counties: Alachua, Brevard, Broward, Duval, Lake, Marion, Miami-Dade, Orange, Palm Beach, Seminole, and Volusia. The ultimate goals of the program were to improve beneficiaries' health and quality of care while reducing their Part A and Part B Medicare expenditures, primarily through reduced need for hospitalizations and emergency room use, and elimination of duplicative services. CMS paid LifeMasters a monthly, fixed management fee for all patients actively participating in the program, and it was required to be budget neutral. That is, cost savings to Medicare from reduced expenditures were required to offset the fees paid to LifeMasters. If they did not, LifeMasters was required to repay CMS for any net loss, up to the full amount of its fees. If net savings were generated, the savings would be shared between LifeMasters and CMS. The population-based design of the demonstration meant that cost savings were calculated on an intent-to-treat basis over *all* patients meeting the demonstration eligibility criteria and selected for the study, not simply those who chose to participate.

To formally test whether LifeMasters met its goals, the demonstration was designed as a randomized controlled trial. Mathematica Policy Research, Inc. (MPR) identified eligible beneficiaries in select counties using Medicare claims and enrollment data, randomized the beneficiaries to treatment and control (usual care) groups (in a 5:2 ratio) according to a pre-determined schedule, and provided LifeMasters with the list of treatment group members once random assignment was completed. Demonstration eligibility was limited to those dually enrolled in Medicare and Medicaid at the time of random assignment who met certain diagnostic criteria specified by LifeMasters and who resided in specific Florida counties at the time of enrollment, as determined by address data in the Medicare Enrollment Database (EDB). Beneficiaries were also required to meet other eligibility criteria pertaining to their Medicare coverage: having Medicare as the primary payer of medical care and not being enrolled in a managed care plan or any other CMS demonstration. Among beneficiaries meeting all of these inclusion criteria, the only individuals excluded from the demonstration were those having end-stage renal disease, those residing in a nursing home, and those receiving hospice care. Cases were enrolled in the study according to LifeMasters' desired schedule, which was based on its capacity to serve enrollees. Randomly assigned individuals who met demonstration criteria were classified as *enrolled*. Once an enrolled beneficiary failed to meet eligibility criteria, that person was classified as *disenrolled* and could never re-enroll in the demonstration.

Over the course of the intervention, enrolled treatment group patients were classifiedas either *active* or *inactive*. Active beneficiaries were those for whom LifeMasters received a monthly management fee; they received no fee for inactive patients (that is, those who opted out of the demonstration, were unable to be reached, or were inactivated by LifeMasters). Patients could switch their program status between active and inactive over time, with the status for each patient reported monthly by LifeMasters. For all analyses conducted as part of this evaluation, the treatment group included both active and inactive patients, as appropriate in intent-to-treat analyses.

LifeMasters classifiedactive beneficiaries as *mediated* or *instructional*. Mediated patients participated fully in the disease management program, which included patient health assessment and care planning, patient education, patient self-monitoring and reporting, care coordination, and assistance obtaining social services. Registered nurses conducted much of the intervention by telephone, although LifeMasters also provided in-home nurse visits for some patients, primarily those who LifeMasters classified as frail. Instructional patients received only a quarterly health magazine and an occasional phone call from program staff.

A previous report documented the challenges LifeMasters faced in engaging treatment group patients during the first two years of the program. Problems included poor contact information in administrative data, difficulties getting enrollees to return phone calls, high levels of medical complexity (including comorbid mental illness), and need for assistance with basic needs (such as food and rent) and mental health counseling that precluded effective disease management (Esposito et al. 2008). These problems engaging patients were at least partially responsible for a lack of program effects midway through the demonstration, as demonstrated by quarterly monitoring reports produced by Actuarial Research Corporation (ARC) and confirmed by a regression-adjusted analysis of utilization and expenditures in the first 18 program months conducted by MPR. In fall 2006, LifeMasters began addressing many of these issues through improved patient communication at enrollment (for example, by first informing patients of the demonstration rather than immediately inviting patients to participate), assigning dedicated staff to contact difficult-to-reach patients, and contacting physicians with at least 10 patients enrolled in the demonstration to request their assistance in encouraging patients to participate more actively in the program. In addition, to address some beneficiaries' other needs that superseded any need for disease management, LifeMasters began case management for patients with complex medical, financial, and psychosocial needs.

Despite having no impacts over the full population of treatment group members, ARC's quarterly estimates indicated that LifeMasters appeared to exhibit some cost savings for patients with CHF only and those who had at least two of the three target conditions. As a consequence of these reports and LifeMasters' own internal analysis in early 2007, LifeMasters proposed to limit program eligibility to patients meeting both these diagnostic and residence criteria in an attempt to achieve cost neutrality. CMS approved this program redesign effective March 1, 2007; treatment and control group members who did not meet these revised eligibility criteria based on disease and county of residence were disenrolled from the demonstration; enrollees who met redesign criteria remained in the research sample through the end of the demonstration or until they became ineligible for other reasons. The Florida counties eligible for the redesign included

Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, and Volusia. To be eligible for the redesign, beneficiaries must have resided in one of these counties and have claims for CHF or had claims for at least two of the three target conditions.

This report provides estimates of LifeMasters' effects on all enrollees' Medicare service use, expenditures, quality-of-care indicators, and mortality over the 36-month evaluation period (January 2005–December 2007). The analysis includes eligible patients under both the original design and during the first ten months of the redesign period.

Demonstration Enrollment

Throughout the 36-month demonstration period, 55,997 patients were randomly assigned, including 39,998 treatment group members and 15,999 control group members. Total monthly enrollment in the treatment group, including active and inactive patients, reached approximately 30,000 patients (the maximum number allowed by CMS) by February 2006. Enrollment remained fairly stable until March 2007, when disenrollment of those not eligible under the redesign reduced the size of the treatment group to about 10,000 patients. Through September 2006, about 85 percent of currently enrolled treatment group members were classified as active, but this dropped to about 60 percent over the next nine months (October 2006 to June 2007), as LifeMasters inactivated patients with whom they had difficulty engaging, per CMS' request. The number of active treatment group members rose to about 75 percent in the last six program months with the redesign population. Over the six six-month periods (36 total months) of the demonstration, the share of enrolled patients with at least one mediated month ranged from as little as 14 percent in the first six months after demonstration startup to nearly 35 percent in the last six months of the demonstration.

Frequency of Program Contact

Program contacts data confirm that the LifeMasters intervention was focused (by definition) on mediated patients and became more intensive as the program matured (Esposito et al. 2008). In the first 18 program months, mediated patients always had more contacts per active month than instructional patients. For example, in the first six program months and among sample members randomly assigned in those months, mediated patients had an average of 2.1 contacts per month compared with 0.3 contacts for instructional patients. Among mediated beneficiaries, those who were enrolled in the second year of the demonstration had more contacts per active month, on average, than those assigned in the first year. The mean number of contacts per active month, over the first 18 program months, was 2.1 for the earliest cohort (those enrolled in the first six months) while the average number of contacts was 3.7 among sample members enrolled in the first six months of 2006. Contacts data for mediated patients in the first cohort reinforce the notion that the intervention was more intensive as it matured. In the first 12 program months, the average contacts per active month among mediated patients in the first cohort was slightly less than 2, but in the next 6 months this rose to 2.3.

The intensity of the intervention during the 10-month redesign period (during which revised eligibility criteria were implemented) may have dropped compared with the first 18 program months. Based on a limited amount of data provided by LifeMasters in its monthly reports to CMS, we estimated that the rate of program contacts among mediated patients during the redesign period from March 2007 to November 2007 was about 1.4 contacts per month. This is about half as large as the rate of 2.7 contacts per active month among mediated patients in the first 18 months of the program. However, the share of total enrolled months during which beneficiaries were mediated during the redesign period (28.1 percent) was about 30 percent greater than during the first 18 months (21.8 percent). While the larger mediation rate should enhance LifeMasters' ability to generate savings, this may be offset somewhat by the reduction in the average number of contacts per person, though this is more likely related to program tenure than a true drop in intensity. That is, as patients' length of enrollment rises, there is less of a need for frequent contact with nurses. We also have no data on the quality of contacts during either period; any improvements in the quality of contacts due to refinements in the intervention may also lead to improved outcomes.

Methodological Approach to Estimating Impacts

Analyses examined outcomes through December 2007, the originally-planned end of the demonstration, and included all beneficiaries enrolled in the demonstration between January 2005 and September 2006 (the last enrollment month). The treatment group included active (whether classified as medicated or instructional) and inactive patients, and the control group included all randomly assigned patients who were eligible on their first day of enrollment. Medicare claims data were the primary source of data for this evaluation. In addition, we used monthly enrollment data drawn from the EDB. To control for chance differences between the treatment and control groups at enrollment, and to improve the precision of the estimates, all impact estimates are obtained from multivariate regressions that control for demographic and health status characteristics as well as health care use and expenditures in the 24 months before enrollment. Estimates are calculated over various lengths of time since enrollment to identify any dependence of impacts on duration of exposure to the intervention. Estimates are also calculated for various subgroups of patients defined by entry cohort, eligibility for the redesign, diagnoses, severity of illness as defined by number of chronic conditions, and geographic area, to draw inferences about targeting.

Key Findings from the Impact Analysis

Overall, program impacts on Medicare expenditures were scattered, inconsistent, and small. There were no treatment-control differences in Medicare Part A or total Medicare expenditures for the full sample of enrollees over all three years of operation. The program appears to have reduced some Part B expenditures, particularly in months 13 to 24 and 25 to 36 after enrollment. Specifically, expenditures for "other part B services" (such as hospice and lab and radiology services) were significantly lower in the treatment group compared with the control group in months 13 to 24 after enrollment; expenditures for outpatient services and home health were also significantly lower for the treatment group in months 25 to 36 after enrollment.

Given these limited and scattered impacts, it is not surprising that the program was not cost neutral over the full demonstration period (Table 1).

TABLE 1

ESTIMATED EFFECTS ON MEAN MONTHLY MEDICARE EXPENDITURES, BY DEMONSTRATION YEAR
(Regression Adjusted)

	12-Month Periods After Enrollment			
	1 to 12	13 to 24	25 to 36	Overall
Number of patients	51,756	32,940	10,829	51,756
Mean monthly treatment group expenditures without fee	$1,653	$2,043	$2,747	$1,846
Mean monthly control group expenditures	$1,649	$2,088	$2,929	$1,867
Gross Difference in Mean Monthly Expenditures	**$4**	**-$45**	**-$182***	**-$22**
Mean fee received per enrolled month	$144	$82	$68	$127
Net Difference in Mean Expenditures[a]	**$147****	**$40**	**-$112**	**$98***

*$p<0.05$
**$p<0.01$

[a]We calculated the average monthly fee for each patient during each period and added it to their total Part A and B expenditures to create the mean-expenditure-with-fee measure. The sum of the gross difference and unadjusted mean monthly fee differ slightly from the net difference in mean expenditures because the net treatment-control difference is estimated with a regression.

The observed reductions in expenditures among treatment group enrollees occurred in months 13 to 24 and 25 to 36 after enrollment and were not large enough to offset the full amount of monthly fees paid throughout the demonstration period. However, the program may have been cost neutral during these periods, as total treatment-control differences in expenditures including the disease management fee were not statistically significant. Specifically, treatment-control differences were $40 and -$112 during months 13 to 24 and 25 to 36 after enrollment, respectively ($p = 0.257$ and $p = 0.122$, respectively). The growth in net savings over the three years occurred because both the gross savings in Part A and B services grew and the average fee received shrank. The decline in the effective fee was due to both a decrease in the negotiated rate in 2006 and 2007 and to the fact that LifeMasters received no further fees for the many patients it inactivated, but these patients remained in the study under the intent-to-treat design. These results suggest that the program required three years to reach a level of savings in Medicare expenditures sufficient to cover its fees, and that it would take several more years of sustained or growing savings at the level observed during months 25 to 36 after enrollment to cover the fees

for the full period. The results also point out the importance of inactivating patients who cannot be reached or engaged, because no savings can be achieved on this group.

Consistent with the lack of effects on expenditures, we found no consistent evidence of improvements in other outcomes of interest. For example, the intervention did not reduce emergency room use, inpatient hospitalizations, or readmissions in the treatment group compared with the control group. In addition, the intervention did not improve the quality of care received by treatment group patients throughout the demonstration period. Analyses of indicators such as preventive care and preventable hospitalizations showed only small treatment-control differences that were rarely statistically significant. We also found no effects on mortality rates at 12 or 24 months after enrollment.

Impact analyses for patient subgroups defined by redesign eligibility, diagnosis, county of residence, and demographic factors revealed that the program had its largest favorable effects on expenditures for patients eligible for the redesign. For this group, the program had statistically significant reductions in total expenditures of about 4.3 percent ($107 per member per month [pmpm]) over the life of the program, with the effects increasing with enrollees' length of exposure to the program. Savings increased from a statistically insignificant $85 pmpm in enrollees' first 12 months to a highly significant $182 pmpm (6.1 percent) in months 25 to 36 after enrollment. These savings are enough to offset the $120 average monthly fee that LifeMasters received over the life of the program for these beneficiaries. They are also considerably larger than the $75 average monthly fee that the program received for patients in months 25 to 36 after enrollment. However, even for this subgroup, the program did not have a significant effect on either hospitalizations or quality of care indicators. The savings were concentrated in Part B services (home health care and outpatient department services).

Implications for Disease Management Interventions in Medicare Fee for Service

The findings from the demonstration do not offer encouragement that a population-based disease management intervention for Medicare beneficiaries is likely to generate net savings for Medicare. To simply cover the average fees of approximately $127 pmpm, a program serving a population such as the one in this demonstration (which had average Medicare expenditures of approximately $2,000 pmpm) would require a reduction in costs of about 6.4 percent. Such a reduction could be obtained by reducing hospitalizations by about 10 percent—a result that would improve the lives of beneficiaries as well. However, the results show no evidence of a reduction in hospital use, emergency room use, or readmissions, or of a downward trend as enrollees' exposure to the program grows. The absence of effects on hospital use even by months 13 to 24 after enrollment and later suggests that inadequate length of followup is not the reason that no effects on Part A utilization were observed.

The general absence of favorable effects on the quality of care received by beneficiaries is also disappointing. When coupled with the negative findings to date for the Medicare Health Support population-based disease management program for Medicare beneficiaries publicly reported by CMS in early-2008, the findings cast serious doubts about whether such programs can be counted on to help Medicare improve care and lower costs (CMS 2008). Moreover,

relatively new evidence suggests that care coordination interventions are more likely to reduce hospitalizations if they have the following features: (1) fairly frequent in-person contact with patients (about one contact per month); (2) a relationship with area hospitals that ensures they notify the program when a patient has been admitted so the program can conduct transitional care planning; (3) colocation of care coordinators with patients' primary care physicians or, at least, the opportunity for frequent in-person interaction; and (4) teaching patients about how to take their medications (Peikes et al. 2008). LifeMasters lacked the first three of these features, and could only provide education about taking medications to the 30 percent or less of patients who were mediated.

The results do suggest that there may be sufficient savings to cover program fees during patients' second and third years after enrollment (that is, not including expenditures during the first year and the first and second year from calculations, respectively) among the subgroup of beneficiaries who had CHF and resided in very high-cost areas (average monthly Medicare expenditures of about $2,700 per beneficiary). However, even for this subgroup, savings were limited to "other" Part B services in the second year after enrollment, and home health and outpatient services in the third year of enrollment. The program did not reduce Part A expenditures or hospital use for this subgroup of beneficiaries. These results raise questions about how such savings were generated and whether they are sustainable. Even if they are sustainable, without impacts on expensive services such as hospitalizations, disease management programs are unlikely to generate sizeable net savings for Medicare.

The lack of overall savings and improvements in quality of care is not surprising when coupled with the result that only about 30 percent of the population were ever fully engaged (that is, classified as mediated) by LifeMasters. Effects for this group would have to be quite large in order to offset program fees, if, as LifeMasters did, the program continued to receive fees for most of those who were not mediated. To generate net savings, disease management programs must engage a higher proportion of their populations than LifeMasters did, and quickly inactivate (that is, stop taking fees for) those patients they cannot engage meaningfully. Other factors may have contributed to LifeMasters' inability to generate savings, such as poor contact information and inability to routinely establish a close relationship with patients' primary care providers. Unless disease management firms can find ways to address these and other factors that limit their programs' effectiveness, disease management programs cannot be viewed as part of the solution to Medicare's problem of controlling cost growth.

Extension of the LifeMasters Demonstration

LifeMasters has substantially enhanced its program to increase patient engagement, resulting in an increase in the proportion of enrolled patients who are mediated from 25 percent in July 2006 to 30 percent in December 2007. It continues to operate under a three-year extension granted by CMS to serve the redesign population (made up of beneficiaries enrolled during its first three years and newly assigned patients as of 2008) where it has been most successful, conditional on continued findings of cost neutrality for this group. Average health care utilization of beneficiaries in the redesign region differed considerably from those residing in the North Florida counties dropped from the demonstration. In North Florida, average monthly costs per

beneficiary were lower than in South Florida and LifeMasters staff reported that enrollees residing in North Florida appeared to be underserved. Even with a much larger mediation rate, generating savings in these counties would prove challenging. On the other hand, health care use in South Florida counties (those in the redesign) was high and some of it was likely unnecessary, creating an opportunity for LifeMasters to achieve its goals, as long as it can continue to engage treatment group members to actively participate. However, although focusing on increasing its mediation rate and inactivating patients who do not engage is clearly critical, to achieve sizeable net savings that are likely to be sustainable over an extended period, LifeMasters must also focus on ways to reduce hospitalizations and the expensive post-acute services that often follow inpatient care.

I. BACKGROUND

A. LIFEMASTERS' DISEASE MANAGEMENT DEMONSTRATION PROGRAM

Under a demonstration program sponsored by the Centers for Medicare & Medicaid Services (CMS), LifeMasters Supported SelfCare (LifeMasters) provided disease management services to fee-for-service Medicare beneficiaries in 11 Florida counties who were also enrolled in Medicaid and who had congestive heart failure (CHF), coronary artery disease (CAD), or diabetes.[1] The demonstration, which operated between January 2005 and December 2007, was designed to test whether disease management services could (1) improve quality of care, (2) improve health, and (3) reduce Medicare spending for beneficiaries with these common and costly chronic health problems. During this period, CMS paid LifeMasters a monthly, fixed management fee for each patient actively participating in the intervention. The program was required to be budget neutral, meaning that if the cost savings to Medicare from reduced Parts A and B expenditures for these patients did not offset the fees paid, LifeMasters would be required to repay the net shortfall to CMS, up to the amount of its fees.

The demonstration was designed as a randomized controlled trial to determine whether LifeMasters' disease management program affected health care quality, use, and expenditures. Throughout the demonstration, Mathematica Policy Research, Inc. (MPR) used the Medicare Enrollment Database (EDB) to identify beneficiaries who met basic eligibility criteria—residence in one of the targeted Florida counties, eligibility for Medicare Parts A and B, enrollment in fee-for-service Medicare, absence of end-stage renal disease (ESRD), and not residing in a nursing home, and not using the Medicare hospice benefit.[2] Within this universe of patients, MPR identified those who met LifeMasters' clinical eligibility criteria (Appendix A) using Medicare claims data for the most recent two-year period available.[3]

From November 2004 through July 2006, MPR randomly assigned eligible beneficiaries in select Florida counties (see Footnote 1) in a 5:2 treatment-to-control ratio according to a pre-determined schedule. All randomly assigned patients who remained eligible on the first day of

[1] These counties included Alachua, Brevard, Broward, Duval, Lake, Marion, Miami-Dade, Orange, Palm Beach, Seminole, and Volusia.

[2] We also used Medicaid enrollment data to determine dual enrollment in Medicaid and data collected by Fu Associates that indicated whether or not beneficiaries have had a 90-day nursing home assessment, known as the long-term institutionalized indicator. Appendix A includes complete eligibility information for the demonstration.

[3] In November 2004, using Medicare claims data from June 2002 through June 2004 and November 2004 Medicare and Medicaid enrollment data, we identified 103,914 beneficiaries as eligible for the demonstration. In August 2005, we identified an additional 87,623 eligible patients using Medicare claims data from calendar years 2003 and 2004 and Medicare and Medicaid enrollment data from August 2005.

enrollment were *enrolled* in the study.[4] Patients in both the treatment and control groups who died or otherwise no longer met initial eligibility criteria after enrollment (according to CMS enrollment files) were *disenrolled* from the demonstration and dropped from the evaluation from that point forward.

All treatment group patients were initially categorized as *active*, as LifeMasters attempted to engage them in the disease management program. Patients who opted out of the program or with whom the program felt it was unlikely to succeed were classified as *inactive*. Treatment group patients could opt out at any time by telephone, in writing, or via the LifeMasters website. CMS limited the maximum number of active patients to 30,000 during any month. LifeMasters received payment only for active beneficiaries.

LifeMasters further classified active patients as either *mediated* or *instructional*. Mediated patients participated fully by agreeing to accept telephone calls from LifeMasters' nurse disease management staff and measuring and reporting to LifeMasters their vital signs and symptoms. Instructional patients agreed only to receive a quarterly health magazine and an occasional phone call from program staff.

B. DESCRIPTION OF THE LIFEMASTERS INTERVENTION

1. Program Features

The LifeMasters intervention consisted of several integrated components, including patient assessment, care planning, routine nurse monitoring, patient self-monitoring, patient education, care coordination, and (limited) service arrangement. Unless otherwise noted, the descriptions of the LifeMasters intervention components below refer to those activities, which are conducted only with mediated patients. (See Esposito et al. 2006 and Esposito et al. 2008 for more comprehensive descriptions.)

Intervention Staff. LifeMasters assigns each mediated patient his or her own nurse care manager, all of whom are registered nurses, because it believes that a patient becomes engaged, builds a relationship with the program, and learns self-care skills faster when he or she works exclusively with one nurse. This nurse remains the patient's care manager throughout the patient's enrollment.[5] Nurses are responsible for assessing patient needs, providing patient education, and alerting physicians about important changes to patients' health. These staff members are located in the LifeMasters' San Antonio, Texas, nurse call center (nurse consultants), communicating with patients by telephone only, or in Florida (community nurses),

[4] Eligible beneficiaries' enrollment periods began on the first day of the second calendar month after random assignment. For example, the enrollment period for beneficiaries randomly assigned at the end of March 2005 began on May 1, 2005. This approach was taken at LifeMasters' request, given that it did not feel it could reach most patients and begin the intervention within the first month after random assignment.

[5] LifeMasters reported that nurse turnover was less than 5 percent since the start of the demonstration.

meeting with patients in person as well as calling them.[6] Based on a screening tool, patients classified as frail are assigned a community nurse who visits them in their homes. Less-frail patients are assigned a telephonic nurse consultant. LifeMasters also employs nonclinical staff to assist the nurses with collecting patients' vital signs by telephone and arranging ancillary community services related to activities of daily living, such as meal delivery and home care services, as requested by nurses.

Assessment and Care Planning. LifeMasters uses patient assessments to determine health education needs and monitoring priorities for each patient. Assessments consist of asking enrollees disease-specific questions on symptoms, current medication use, recent utilization of medical services, and laboratory data (such as blood pressure, cholesterol levels, and HbA1c levels for enrollees with diabetes). LifeMasters' initial assessment may be conducted in person or over the telephone, depending on how initial contact is made with each patient, and includes screens for frailty, cognitive ability, depression, and nutrition. After a nurse conducts an initial patient health history, the LifeMasters data system assesses a patient's level of clinical risk and develops an individualized care plan for the patient that addresses all of his or her medical conditions. When necessary, LifeMasters' nurses conduct reassessments as a part of routine monitoring. Thus, nurses could assess patients by telephone and in person over time, and each patient could have more than one assessment throughout his or her enrollment in the program. Among active patients over the first 18 program months, 84 percent had at least one assessment contact after enrollment (Esposito et al. 2008). Among those with assessment contacts, a larger percentage had an assessment via telephone (90 percent) than in person (53 percent) among enrollees enrolled during the first half of 2005.[7] More than 50 percent of active patients with at least one assessment contact were assessed within three weeks of activation and about 70 percent had a contact within six weeks.

In July 2006, perhaps too far into the demonstration to dramatically alter the overall findings for the original 36-month period of operations, LifeMasters instituted a complex case management (CCM) program to help meet the complex medical, financial, and psychosocial needs of specific patients that precluded disease management. The CCM program included nurse case managers or masters-trained social workers who worked directly with high-risk beneficiaries to address basic life needs (for example, food and shelter) as well as other medical care needs (for example, rehabilitation services; medical equipment; home care; physical, speech, or occupational therapy; pain management; or psychiatric services) in order to stabilize patients so they could better participate in the program. By fall 2006, LifeMasters targeted improvements in the rate of pneumonia vaccination, wound care, and monitoring of swelling in the extremities for patients with diabetes or heart failure. LifeMasters also provided its nurses

[6] One-third of nurses who work with treatment group patients are community nurses while two-thirds are nurse consultants. Typical nurse caseloads are 150:1 for nurse consultants and 60:1 for community nurses.

[7] Because each patient could have more than one assessment of different types, the number assessed by telephone and number assessed in person does not necessarily add to 100 percent.

with special training to be better able to discuss end-of-life issues with patients and their families.

Routine Monitoring by Nurses. Registered nurses in the LifeMasters call center and in the community provide routine patient monitoring using tools designed by LifeMasters, with the frequency determined by patients' care plans. Nurses attempt to contact mediated patients as often as once a week and no less than every other week, as called for in the LifeMasters protocol, but staff reported that some patients prefer less frequent contact. Instructional patients are contacted once per quarter. Typical monitoring tasks include collection of data from the patient, reassessment by the nurse, and followup of abnormal test results as reported by the patient. These tasks are embedded in a data system that prompts nurses to ask particular questions during monitoring calls; for in-person visits, nurses use hard copies of scripts.

Patient Self-Monitoring. LifeMasters nurses attempt to teach patients better self-management skills by instructing and encouraging them to monitor their health. LifeMasters expects patients to monitor and report certain vital signs, such as blood pressure, weight, and symptoms, on a weekly basis. Patients can report these data over the telephone (to a nurse, clinical service assistant, or LifeMasters' integrated voice response system) or via the Internet, although more than 90 percent of respondents report by telephone. Typical monitoring calls by nurses include vital sign data collection. If a nurse detects a clinical change that might present an immediate risk to the patient, the nurse will contact that patient's physician. LifeMasters also provides patients with a variety of equipment and materials to assist them in monitoring their vital signs and symptoms.

Patient Education. Nurses provide education to patients on the recognition of signs and symptoms of their disease that suggest a need for medical attention; how to monitor vital signs; the cause of diseases; how to better adhere to diet, exercise, and medication regimens; and strategies to cope with chronic illness. When providing education to patients, nurses use disease-specific scripts embedded in the LifeMasters data system that are geared toward educating patients on how to attain clinical goals.

Care Coordination. A primary component of the LifeMasters intervention is to teach patients how to better communicate with their health care providers. (LifeMasters' direct contact with physicians is relatively limited.) To accomplish this, nurses assist patients in preparing for physician office visits by encouraging them to ask questions about their care, to use journals provided by the program to write down questions for their doctors and document instructions from them, and to use medication lists to document the medications (prescription and over-the-counter) they use regularly.

LifeMasters also will contact a patient's physician if the patient had a hospitalization that involved new symptoms. LifeMasters learns about patient hospitalizations by speaking to family members or caregivers when a patient is not available for a scheduled program contact and, sometimes, when it receives new claims data, although the latter method is less timely. After a hospitalization, nurses ask patients about their discharge instructions and educate them on those instructions. If a patient was deemed frailer after the hospitalization than before and that patient

had previously been contacted only by telephone, LifeMasters may refer the patient to the community services group to be contacted in person.

LifeMasters reviews patients' self-reported medication use (including over-the-counter drugs) to confirm that drug utilization meets accepted clinical practice guidelines for CHF, CAD, and diabetes and that patients are using the drugs properly. If staff identify a problem with patient drug use (such as a potential drug-to-drug interaction or poor adherence), the nurse contacts the patient's physician.

Service Arrangement. During the course of monitoring contacts, nurses may identify patients who need additional services beyond those provided by LifeMasters. Such services may include safety assessments, transportation, meal delivery, spiritual care, and home health care services. Nonclinical staff will arrange for such services for patients, rather than simply referring them to an appropriate provider. LifeMasters will pay for some meals but does not pay for other services.

2. Redesign of the Program

Treatment-control differences in Medicare expenditures were monitored on a quarterly basis by Actuarial Research Corporation (ARC). Throughout 2005 and 2006, monitoring reports showed little effect on Medicare expenditures, with the exception of some subpopulations with CHF or CAD and diabetes who resided primarily in South Florida. Based on these monitoring reports, LifeMasters negotiated with CMS to restrict demonstration participants, beginning on March 1, 2007, to beneficiaries who (1) resided in one of 7 (of the original 11) demonstration counties located in south Florida—Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, and Volusia; and (2) had pre-enrollment claims for treatment of CHF or two or more of the three targeted chronic conditions (CHF, CAD, or diabetes). All other patients were disenrolled from the study as of March 1, 2007. With the goal of increasing mediation rates to 30 percent by the end of 2007, LifeMasters also reactivated 2,700 heart failure patients in the redesign counties who had been inactivated earlier.[8]

The redesign included many activities to increase mediation rates and other intervention enhancements that were already under way. These included reviewing enrollment scripts with recruitment experts (including psychologists and voice analysts), adding two experienced patient locators to its staff, conducting additional outreach to providers, assessing whether it would be more effective to have welcome calls conducted by nurses rather than nonclinical staff, adding engagement incentives (such as providing groceries to patients), and contracting with a vendor (QualPro) to refine engagement activities. In addition, the proposal identified several enhancements to the LifeMasters disease management intervention that were already under way

[8] The program reactivated these enrollees because it believed that improvements to its engagement strategy would result in more mediated patients than earlier in the demonstration. These beneficiaries had been inactive for a few months to more than a year, depending on when they enrolled and their initial level of engagement.

since the fall of 2006: the wound care and end-of-life planning programs, and Complex Case Management, including a greater focus on geriatric social work for patients who required additional community services, had recently lost a caregiver, or were in functional decline.

3. Frequency of Program Contact

Using data submitted by LifeMasters, MPR previously estimated the frequency of telephone or in-person contacts between treatment group enrollees and LifeMasters' staff. For inclusion in this analysis, patients had to have been enrolled early enough to have had at least six months of follow-up contact data as of December 2006. Program data were organized for each patient in terms of "months following enrollment," aggregated into six-month periods. For example, if a patient enrolled in January 2005, that patient's first six-month period of observation was January through June 2005, the second period was July through December 2005, and the third period was January through June 2006. We defined three cohorts for the analysis—early, middle, and late—and these cohorts had at least 18, 12, and 6 months of follow-up data, respectively (see Esposito et al. 2008).

Program contacts data indicate that the LifeMasters intervention was focused (by definition) on mediated patients and became more intensive as the program matured. In the first 18 program months, mediated patients always had more contacts per active month than instructional patients. For example, in the first six program months and among sample members randomly assigned in those months, mediated patients had an average of 2.1 contacts per month compared with 0.3 contacts for instructional patients. Among mediated beneficiaries, those who were enrolled in the second year of the demonstration had more contacts per active month, on average, than those assigned in the first year. The mean number of contacts per active month, over the first 18 program months, was 2.1 for the earliest cohort (those enrolled in the first six months of 2005) while the average number of contacts was 3.7 among sample members enrolled in the first six months of 2006. Contacts data for mediated patients in the first cohort reinforce the notion that the intervention was more intensive as it matured. In the first 12 program months, the average contacts per active month among mediated patients in the first cohort was slightly less than two, but in the next six months this rose to 2.3 contacts per active month.

The intensity of the intervention during the 10-month redesign period may have dropped compared with the first 18 program months. Based on a limited amount of data (for mediated and instructional patients) provided by LifeMasters in monthly reports to CMS, we estimated that the rate of program contacts among mediated patients during the redesign period from March 2007 to November 2007 was about 1.4 contacts per month.[9] This was about half as large as the rate of 2.7 contacts per active month among mediated patients in the first 18 months of the program. In

[9] LifeMasters only provided CMS with data on the total number of contacts per month for active participants. Based on the analyses of the first 18 program months and our understanding from LifeMasters that instructional patients were only contacted quarterly, we assumed that about one of every four instructional patients had a contact each month.

addition, it should be noted that even the upper end of this range for meditated patients was lower than the minimum called for in LifeMasters' protocol (at least once every two weeks, as described earlier). Thus, the program had substantially less contact, on average, with the most engaged patients than it recommends. However, the share of enrolled months during which patients were mediated during the redesign period (28.1 percent) was about 30 percent greater than during the first 18 months (21.8 percent).[10] While the larger mediation rate should enhance LifeMasters' ability to generate savings, this may be offset somewhat by the reduction in the average number of contacts per person, though this is more likely related to program tenure than a true drop in intensity. That is, as patients' length of enrollment rises, there is less of a need for frequent contact with nurses. We also have no data on the quality of contacts during either period; any improvements in the quality of contacts due to refinements in the intervention may also lead to improved outcomes.

C. PATIENT ENROLLMENT

Table I.1 shows the distribution of beneficiaries randomly assigned to the treatment and control groups overall and by region and month of enrollment. Between January 2005 and September 2006, 36,959 patients were assigned to the treatment group and 14,797 to the control group. During the first six months of the demonstration, all randomly assigned beneficiaries resided in Miami-Dade County, as requested by LifeMasters.[11] Enrollment of patients from other counties began in July 2005. The absolute number of active treatment group members rose steadily throughout 2005 (Figure I.1) and then leveled off through September 2006. By February 2006, program enrollment reached approximately 30,000 treatment group patients, with almost 90 percent of these patients classified as active by LifeMasters. The total number of active treatment group members remained fairly stable until October 2006, when LifeMasters inactivated approximately 7,000 patients it had had difficulty contacting or engaging despite months of effort. Similarly, in December 2006, LifeMasters inactivated another 3,000 patients. Both instances were at the request of CMS. In March 2007, the first month of the redesign period, the number of enrolled beneficiaries fell from about 28,000, of whom about half were active, to slightly less than 10,000 total enrolled beneficiaries, including 7,700 active patients.

[10] The percentage of total enrolled months during which all enrolled beneficiaries were mediated. For example, if 300 of 1,000 enrolled beneficiaries are mediated in Month 1 and 400 of 1,000 are mediated in Month 2, the cumulative proportion of mediated months would be 35 percent (700 ÷ 2,000).

[11] The statistics on Table I.1 represent the numbers of patients who were randomly assigned and eligible on their first day of enrollment.

TABLE I.1

DISTRIBUTION OF LIFEMASTERS ENROLLEES BY COUNTY AND MONTH OF ENROLLMENT

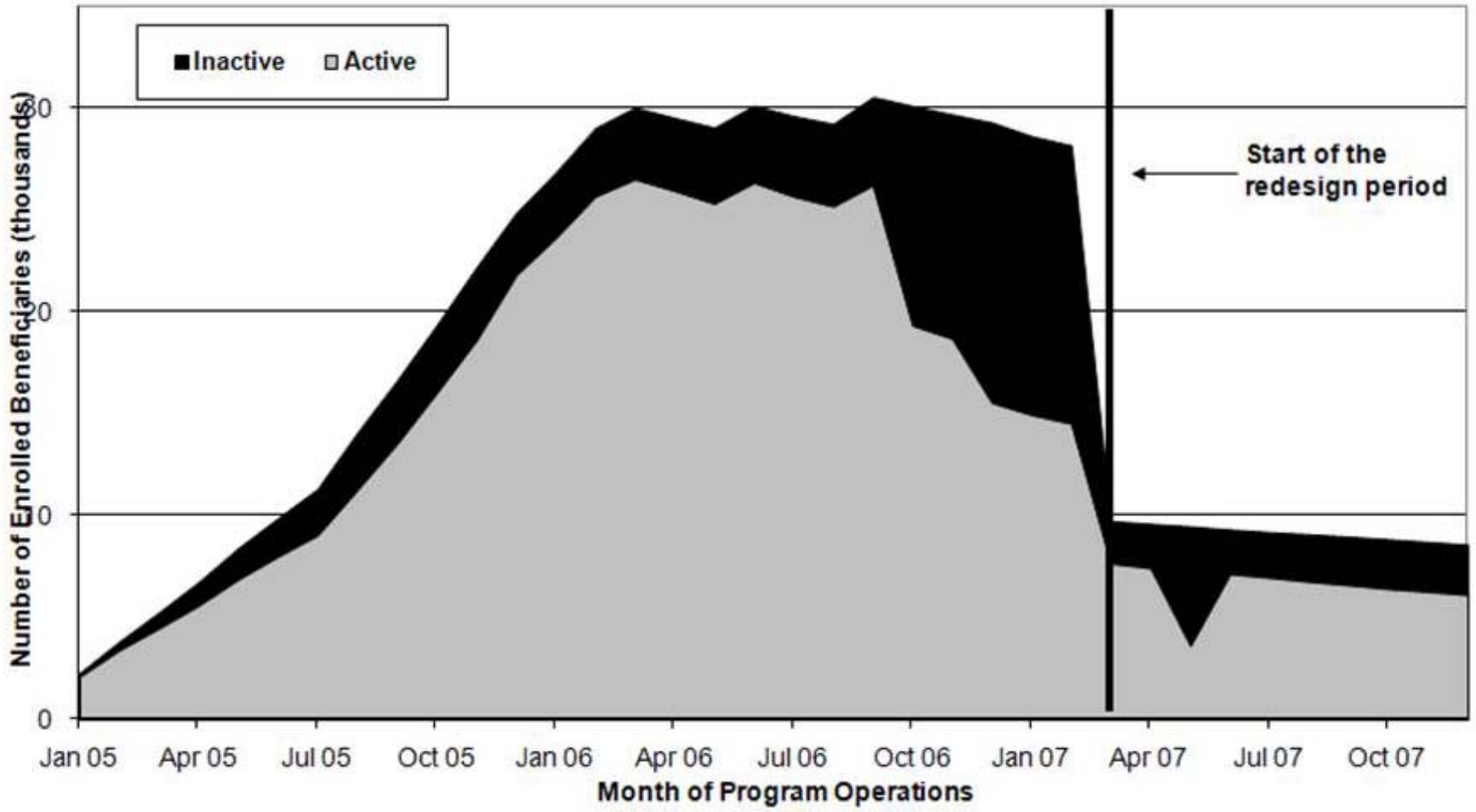
	Total		Miami-Dade		Broward and Palm Beach		North Florida[a]	
Month of Enrollment	Treatment	Control	Treatment	Control	Treatment	Control	Treatment	Control
January 2005	2,246	906	2,246	906	—	—	—	—
February 2005	1,574	629	1,574	629	—	—	—	—
March 2005	1,477	600	1,477	600	—	—	—	—
April 2005	1,539	623	1,539	623	—	—	—	—
May 2005	1,747	704	1,747	704	—	—	—	—
June 2005	1,567	629	1,567	629	—	—	—	—
July 2005	1,524	597	92	35	1,432	562	—	—
August 2005	2,854	1,143	102	41	2,752	1,102	—	—
September 2005	2,727	1,109	—	—	316	129	2,411	980
October 2005	2,914	1,154	—	—	2,133	846	781	308
November 2005	3,063	1,222	—	—	271	105	2,792	1,117
December 2005	3,109	1,246	—	—	316	124	2,793	1,122
January 2006	3,004	1,197	—	—	231	87	2,773	1,110
February 2006	2,801	1,103	—	—	—	—	2,801	1,103
March 2006	1,501	600	—	—	—	—	1,501	600
June 2006	1,593	643	—	—	797	313	796	330
September 2006	1,719	692	1,208	486	—	—	511	206
Total	**36,959**	**14,797**	**11,552**	**4,653**	**8,248**	**3,268**	**17,159**	**6,876**

Source: MPR Enrollment File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

[a]North Florida counties include Alachua, Brevard, Duval, Lake, Marion, Orange, Seminole, and Volusia. In March 2007, LifeMasters dropped Brevard, Duval, Lake, and Orange counties from its catchment area.

FIGURE I.1
NUMBER OF TREATMENT GROUP BENEFICIARIES IN THE LIFEMASTERS PROGRAM BY ACTIVE STATUS ACROSS ALL MONTHS OF PROGRAM OPERATIONS



Source: LifeMasters monthly program enrollment file.

Note: Active beneficiaries were those for whom LifeMasters received a monthly management fee. LifeMasters received no fee for inactive patients (those who opted out of the demonstration, were unable to be reached, or were inactivated by LifeMasters).

Enrolled patients could switch between active and inactive status throughout the demonstration, but once they were disenrolled (that is, were no longer eligible), they could not be reenrolled. Table I.2 shows the most common reasons for becoming inactive, based on the last inactive month for the 12,376 treatment group patients who were ever inactive for at least one month (excluding the 16,804 who were disenrolled by LifeMasters due to the redesign or were otherwise ineligiblet). The most common reasons for inactivation were a change in Medicare or other program eligibility status (7,923 or 64 percent of patients with an inactive spell) and self-termination or declining to participate (4,075 or 33 percent). [12]

Less than half of all active treatment group patients in any month throughout the demonstration were mediated (Figure I.2). The share mediated was lowest during the first year of the program and increased over time, particularly after the redesign and as LifeMasters inactivated patients with whom it had difficulty engaging. The percentage of member months mediated, as calculated in six-month intervals, increased from approximately 10 percent during the first six months of the demonstration to about 30 percent by the last six months of the demonstration (Table I.3). Similarly, the proportion of patients with any mediated months during the six-month intervals increased from approximately 14 percent to 35 percent from the beginning to the end of the demonstration (Table I.3).

Figures I.3 and I.4 provide a snapshot of patient status for the treatment and control groups at the midpoint and end of the demonstration in July 2006 and December 2007, respectively. By July 2006, the total number of patients randomized to treatment and control groups was 35,240 and 14,105, respectively. The share disenrolled by July 2006 was approximately 16 percent for both groups. Among treatment group patients still enrolled in July 2006, approximately 25 percent were classified as mediated. By December 2007, the total number of patients randomized to treatment and control groups was 36,959 and 14,797, respectively, and the share disenrolled was 77 percent for both groups. Of the remaining 8,558 treatment group patients enrolled in December 2007, approximately 30 percent were categorized as mediated.

By the end of the demonstration, the most common reason for patient disenrollment (among two-thirds of disenrollees) was being ineligible for the redesign (Table I.4). The second most common reason was managed care enrollment (about 17 percent). Patient death (7.3 percent), election of hospice care (4.3 percent), and no longer residing in the service area (4.1 percent) followed as other common reasons. Disenrollment patterns, as expected, were similar for the treatment and control groups.

D. SUMMARY OF EARLY FINDINGS FROM THE PATIENT SURVEY

The primary goal of this final report is to report our findings on program effects on Medicare service use and expenditures. However, we also conducted a patient survey with a small sample of 304 treatment and 309 control group members about midway through the

[12] These reasons were reported by LifeMasters but they may not always accurately reflect true eligibility for the demonstration.

TABLE I.2

LIFEMASTERS PROGRAM STATUS AMONG ENROLLED TREATMENT GROUP PATIENTS AND REASON FOR INACTIVATION AMONG INACTIVE PATIENTS

	Number	Percentage
LifeMasters Program Status (Active/Inactive), Among All Treatment Group Patients Ever Enrolled		
Patients with at least one inactive month after having at least one active month	12,376	33.5
Patients with no inactive months		
Switched directly from active to disenrolled[a]	16,804	45.5
Always classified as active	6,136	16.6
Patients who were never active, but enrolled[b]	1,643	4.5
Total Treatment Patients Ever Enrolled	**36,959**	**100.0**
Reasons for Inactive Status as Reported by LifeMasters, Among Patients with at Least One Inactive Month[c]	12,376	100.0
Medicare status changed or patient otherwise ineligible for the demonstration[d]	7,923	64.0
Self-termination or patient declined to participate	4,075	32.9
Other[e]	378	3.1

Source: LifeMasters Enrollment Data.

[a]Approximately 53 percent of these treatment group members were disenrolled on March 1, 2007 because they did not meet program redesign criteria.

[b]LifeMasters classified these patients as inactive during all months of enrollment.

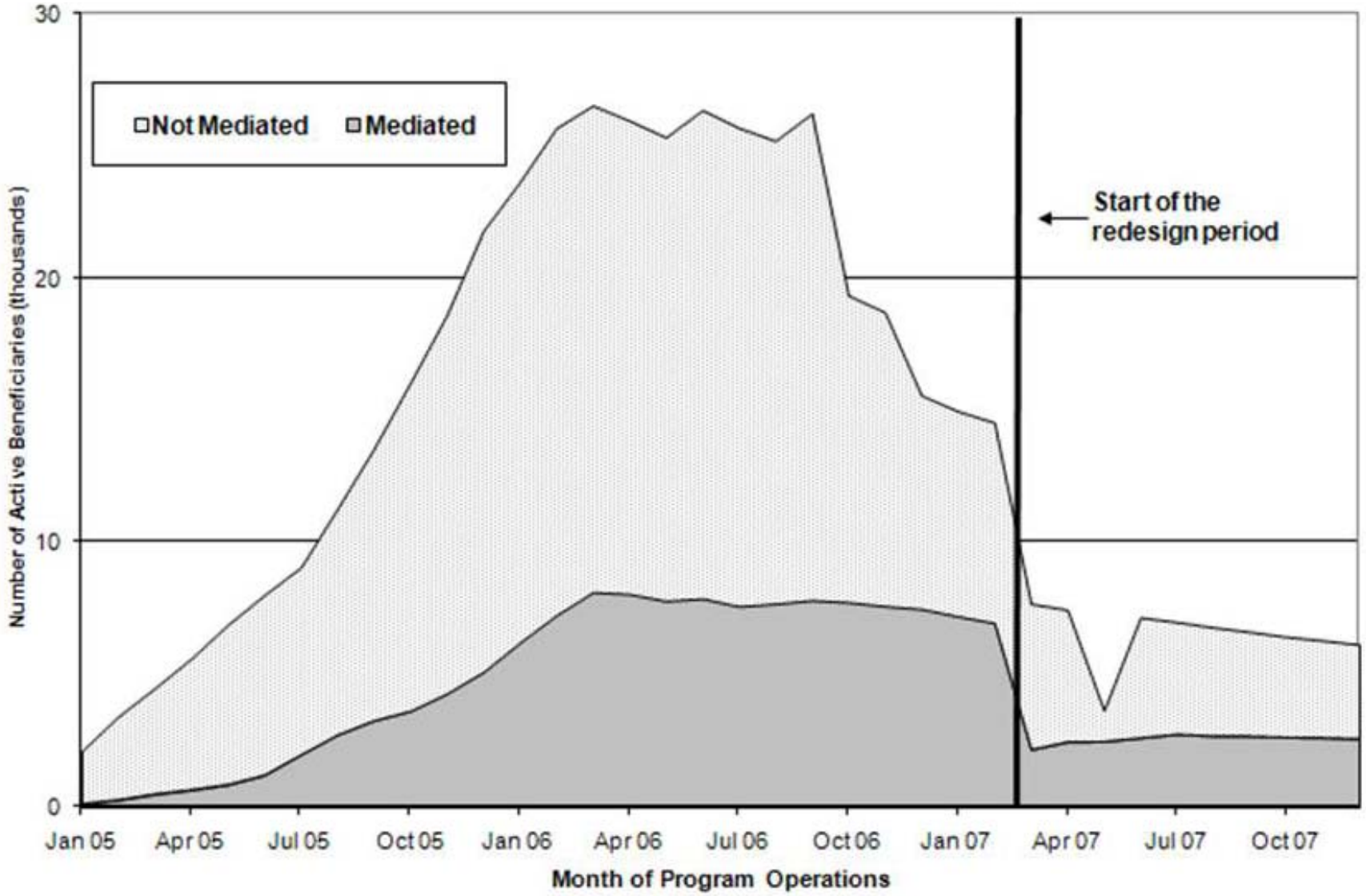
[c]Among inactive patients whose program status switched from active to inactive. Reasons are based on the last inactive month for each patient from January 2005 to December 2007.

[d]Reasons for Medicare status change and patient ineligibility (for example, death, patient admitted to psychiatric facility, ESRD, entered hospice, admitted to SNF/ICF, not medically eligible, does not have condition, and transplant) were reported by LifeMasters and may not always accurately reflect true ineligibility.

[e]Other reasons for inactivity included: patient relocated out of state or out of the service area, patient was being managed by another program, and LifeMasters rejected the patient.

ESRD = end-stage renal disease; ICF = intensive care facility; SNF = skilled nursing facility.

FIGURE I.2
NUMBER OF ACTIVE TREATMENT GROUP BENEFICIARIES IN THE LIFEMASTERS PROGRAM BY MEDIATION STATUS ACROSS ALL PROGRAM MONTHS



Source: LifeMasters monthly program enrollment file.

Note: Mediated patients were those who participated fully in the disease management program. Active patients include those for whom LifeMasters received a monthly management fee which includes mediated and instructional patients. This figure excludes inactive patients.

TABLE I.3

AVERAGE MEDIATION RATES AMONG THE TREATMENT GROUP THROUGHOUT DEMONSTRATION PERIOD

	Total Enrolled Member Months	Percentage of Member Months Mediated[a]	Number of Patients Enrolled for at Least One Month	Patients Mediated for at Least One Month	
				Number	Percentage
Jan 05 – June 05	36,236	9.9	10,150	1,384	13.6
July 05 – Dec 05	108,487	19.3	25,973	6,262	24.1
Jan 06 – June 06	174,892	25.9	32,785	10,093	30.8
July 06 – Dec 06	178,788	25.7	31,383	9,132	29.1
Jan 07 – June 07	94,953	25.2	28,675	8,164	28.5
July 07 – Dec 07	53,262	29.9	9,176	3,166	34.5

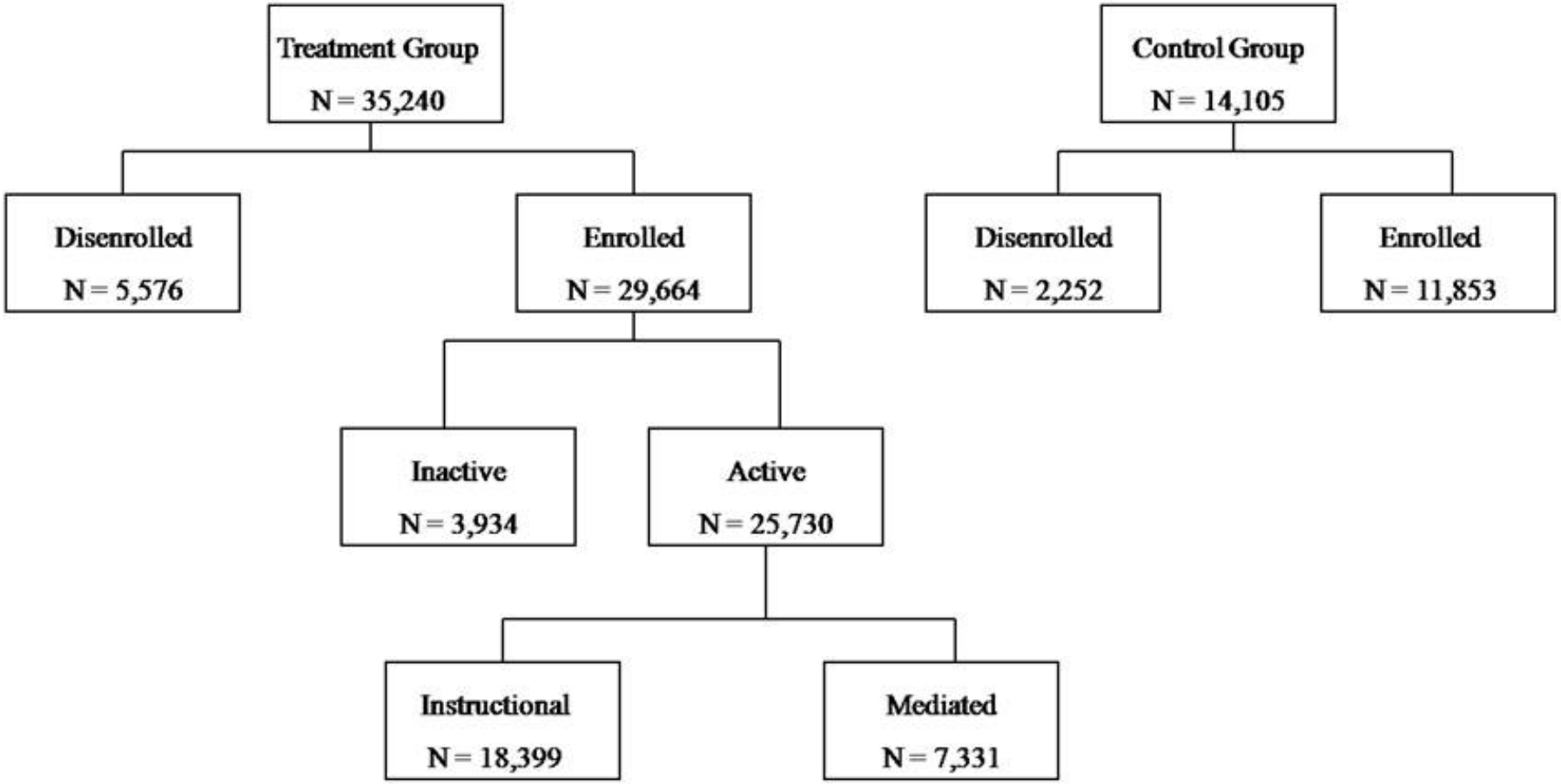
Source: LifeMasters Enrollment Data and MPR Enrollment File.

Notes: Includes all randomly assigned treatment group members who were eligible on their first day of enrollment. Partial months of enrollment count as a full month. Mediated patients were those who participated fully in the disease management program.

[a]For example, if 300 of 1,000 are mediated in Month 1 and 500 of 1,000 are mediated in Month 2, than the cumulative percentage of mediated months is 40 percent (800 ÷ 2,000).

FIGURE I.3
PATIENT STATUS IN THE LIFEMASTERS DEMONSTRATION:

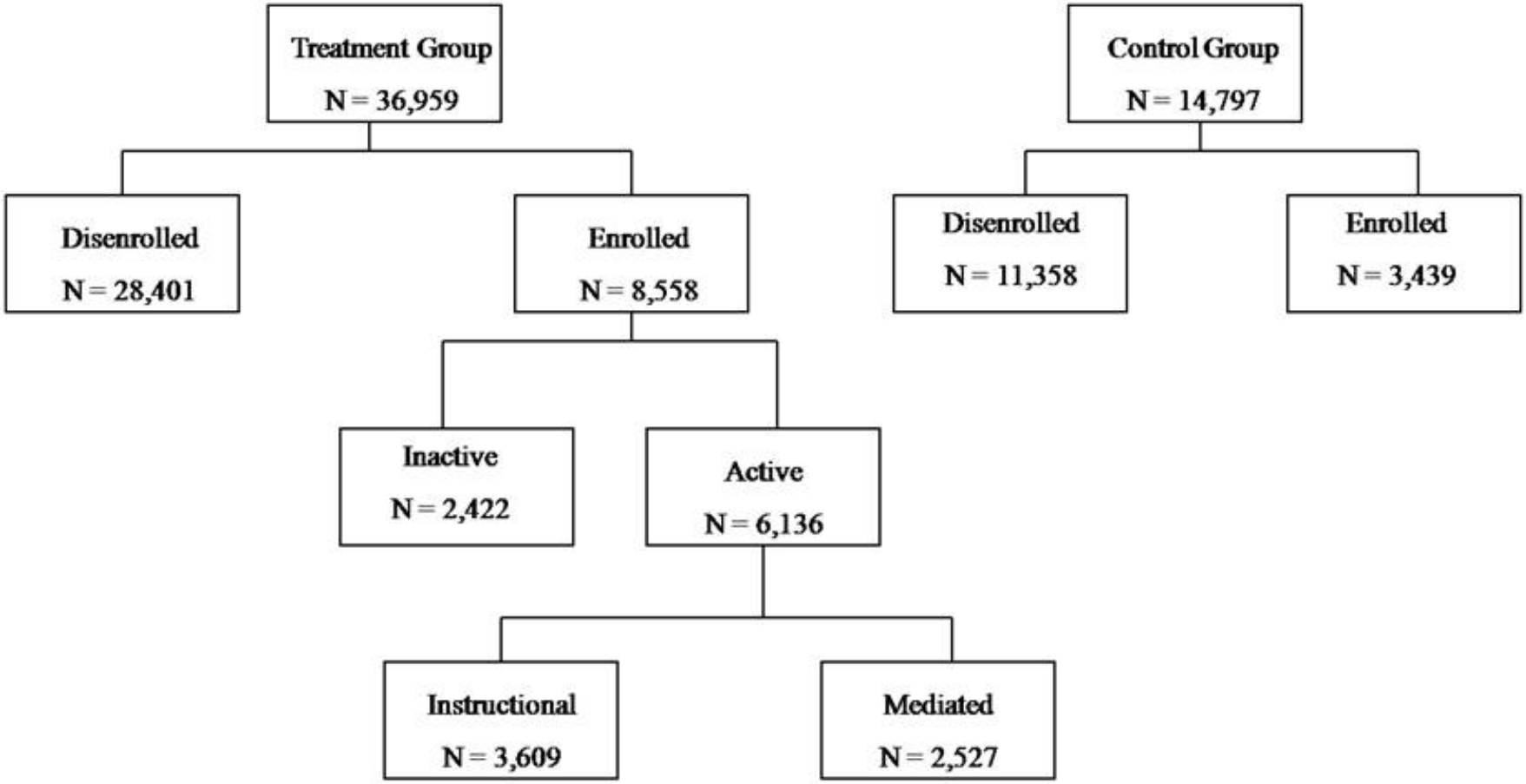
JULY 2006



Note: Patients are disenrolled from the study at the point at which they die or become ineligible for the study (for example, by joining a Medicare Advantage plan, no longer having Medicare as their primary payer, spending 90 consecutive days in a nursing home, entering hospice, having an inpatient psychiatric stay of more than 14 days, or having an organ transplant). LifeMasters receives payment only for active patients, who may either be mediated (receives regular contacts from LifeMasters care manager) or instructional (receives only mailings and an occasional phone call from LifeMasters). LifeMasters classifies patients it is unable to reach as instructional.

FIGURE I.4
PATIENT STATUS IN THE LIFEMASTERS DEMONSTRATION:

DECEMBER 2007



Note: Patients are disenrolled from the study at the point at which they die or become ineligible for the study (for example, by joining a Medicare Advantage plan, no longer having Medicare as their primary payer, spending 90 consecutive days in a nursing home, entering hospice, having an inpatient psychiatric stay of more than 14 days, or having an organ transplant). LifeMasters receives payment only for active patients, who may either be mediated (receives regular contacts from LifeMasters care manager) or instructional (receives only mailings and an occasional phone call from LifeMasters). LifeMasters classifies patients it is unable to reach as instructional.

TABLE I.4

REASONS FOR DISENROLLMENT AMONG PATIENTS THE TREATMENT AND CONTROL GROUP BY THE END OF THE LIFEMASTERS DEMONSTRATION

	Treatment		Control	
Disenrollment Reasons	Number	Percent	Number	Percent
Death	2,119	7.5	831	7.3
Nursing home enrollment[a]	776	2.7	274	2.4
No longer eligible for Part B Medicare	124	0.4	55	0.5
Managed care enrollment	4,674	16.5	1,897	16.7
Medicare no longer primary payer	22	0.1	12	0.1
Elected hospice care	1,272	4.5	494	4.3
Moved from service area[b]	992	3.5	462	4.1
Organ transplant	5	0.0	2	0.0
Long-term psychiatric stay[c]	330	1.2	134	1.2
Ineligible for LifeMasters redesign[d]	18,087	63.7	7,197	63.4
Total	**28,401**	**100.0**	**11,358**	**100.0**

Source: Mathematica Policy Research enrollment file for the LifeMasters demonstration.

Note: Disenrollment calculated for all patients who were enrolled from January 2005 through September 2006.

[a]As determined by the 90-day nursing home assessment indicator collected for CMS by Fu Associates.

[b]Before March 1, 2007, the service area included all of Florida. On and after this date, the service area included only the seven redesign counties: Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, and Volusia counties.

[c]Defined as an inpatient stay of 14 or more days.

[d]Patients were eligible for the redesign if they had claims for CHF or claims for at least two or more of the three target conditions, and if they resided in Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, or Volusia counties.

demonstration to measure beneficiaries' self-reported physical and mental health status, health behaviors and knowledge, quality of care received, and satisfaction with care (see Esposito et al. 2008 for additional description of the survey). The survey was conducted between July and November 2006 for patients who had been enrolled between May and October 2005, such that all respondents had at least 10 months of experience in the demonstration.

There were statistically significant treatment-control differences on several measures that suggested that participants received the intervention. In particular, treatment group patients were more likely to report that a nurse, disease manager, or social worker helped them to arrange care, including assistance with transportation. Treatment group patients reported taking more medications than control group patients (see Appendix B, Table B.1). However, they did not report better adherence to prescribed medication, diet, self-care, and exercise regimens than the control group.

Treatment group patients reported worse outcomes on several health status and health knowledge items, such as impairments in activities of daily living and worse mental health status, and were less likely to report they understood how to eat a healthy diet or the proper way to exercise (Appendix B, Table B.2). In addition, a greater share of treatment group patients with CHF reported worrying about future complications of their disease compared with the control group. However, it is unlikely that these differences represent real program impacts. That is, we would not expect treatment group members to have less knowledge than control group members. Rather, it is more likely that the lower ratings on health status, knowledge, and worries about future complications are either due to chance, or are due to measurement bias arising from treatment group members' new knowledge gained from participating in the LifeMasters disease management program. This bit of acquired knowledge may make treatment group patients more aware of their limited understanding of their condition, more fearful about the condition's consequences, and more cognizant of their shortcomings in adhering to recommended self-care. Treatment group patients may then respond less optimistically when asked subjective questions about their understanding of particular healthy behaviors. In addition, because this was a population-based demonstration and patients did not opt into the program prior to random assignment, treatment group members might be more inclined than control group members to indicate a lack of knowledge about healthy behaviors because they have been chosen by a trusted source, CMS, to participate in this program. That is, the fact that they were "assigned" to the program by CMS may lead them to doubt their self-awareness of healthy behaviors.

II. METHODOLOGY

A. RESEARCH SAMPLES AND SAMPLE SIZES

We evaluated Medicare Part A and Part B utilization and expenditures for all patients over all months enrolled in the demonstration (both active and inactive patients) and for three distinct time periods to understand whether the effect of the LifeMasters program varied with patients' potential exposure to it (Table II.1). These periods included: (1) months 1 to 12 after enrollment for all enrolled patients (51,756 enrollees); (2) months 13 to 24 after enrollment for all patients enrolled on or before January 1, 2006, and who had more than 12 months of enrollment (32,940); and (3) months 25 to 36 after enrollment for all patients who enrolled on or before December 1, 2005, and who had more than 24 months of enrollment (10,820). Over the 36-month demonstration period, approximately 20 percent of patients were eligible for 24 months or more and about 25 percent had 12 or fewer months enrolled (Appendix C, Table C.1). The mean number of follow-up months for enrollees was 17.5.

In addition to analyses of the full study population over the entire demonstration period and by date since enrollment, we estimated impacts on use and expenditures for specific subgroups for which we hypothesized the program may have differential effects. These subgroups included:

- ***Region of Residence at Enrollment.*** Given the well-documented geographic variation in health care utilization and expenditures among Medicare beneficiaries (Fisher et al. 2003a; Fisher et al. 2003b), the intervention may be more effective in regions with beneficiaries who have higher utilization and expenditures compared with regions where beneficiaries have lower use and spending. In addition, Actuarial Research Corporation (ARC) monitoring reports have suggested that the intervention may have had a differential effect in certain Florida counties. For this report, we segregated the state into three regions, given the sizeable differences in expenditures across the areas and the different timing of release of enrollees to the study: Miami-Dade County, Broward and Palm Beach counties, and North Florida.[1]

- ***Eligibility for the Redesign Sample.*** The rationale for this subgroup analysis was to better understand the extent to which the intervention differentially affected patients eligible for the redesign compared with those who were ineligible. Analyses of this population included all patients who met the redesign criteria at any time during the demonstration, not only during the redesign period.

[1] North Florida counties include Alachua, Brevard, Duval, Lake, Marion, Orange, Seminole, and Volusia.

TABLE II.1

LIFEMASTERS RESEARCH SAMPLE SIZES FOR ESTIMATES OF TREATMENT-CONTROL DIFFERENCES

	Treatment Group		Control Group	
	Number	Percentage	Number	Percentage
All Patients Randomized Throughout Entire Demonstration	39,998		15,999	
Patients Who Did Not Meet Eligibility Requirements at Enrollment	3,039		1,202	
Research Sample Members	36,959		14,797	
Research Sample Members Included in Follow-up Measures for:				
Months 1 to 12 after enrollment	36,959	100.0	14,797	100.0
Months 13 to 24 after enrollment	23,545	63.7	9,395	63.5
Months 25 to 36 after enrollment	7,701	20.8	3,119	21.1
All program months	36,959	100.0	14,797	100.0

Sources: MPR Enrollment File, Medicare Enrollment Database, and Medicaid Eligibility data.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

All patients enrolled from January 2005 through September 2006 are included in the analysis of all program months. Analyses for months 1 to 12 and months 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the follow-up measures for months 13 to 24 after enrollment. Sample members with more than 24 months of enrollment are included in the months 25 to 36 analysis.

- ***Target Medical Conditions at Enrollment.*** These analyses were designed to understand whether the intervention had a differential effect on patients with different targeted conditions or combinations of conditions. The rationale for this distinction is the widespread belief in the disease management industry that the length of time required to generate savings is shorter for patients with congestive heart failure (CHF) than for patients with diabetes. In this report, we examine subgroup analyses for patients with CHF, coronary artery disease (CAD), diabetes, as well as two or more of these targeted conditions.

- ***Race/Ethnicity.*** There is a vast literature documenting disparities in health care utilization and quality of care among patients with various diseases and conditions. The rationale for evaluating the effect of the program by race was to understand whether the intervention may have reduced any disparities, leading to improvements in outcomes or quality of care for specific racial or ethnic groups. For this report, we separated research sample members into three groups by race/ethnicity: Latino, Black-non-Latino, and other-non-Latino.

- ***Number of Chronic Medical Conditions.*** Patients with multiple chronic conditions may experience more or less improvement in health status and expenditures. For example, it is possible that patients with multiple conditions respond more favorably to disease management programs due to their greater need for coordination of care. Alternatively, the potentially debilitating effects of having multiple conditions may lessen the effects of disease management programs. In this report, we examined treatment-control differences among beneficiaries with claims for fewer than five versus five or more of 15 chronic medical conditions.[2]

- ***Age.*** There are several reasons why the LifeMasters program may affect patients of varying ages differently. For example, nurses may be better able to reach elderly patients by telephone if they leave their home less frequently than younger patients. However, older patients may have more difficulty hearing or comprehending LifeMasters' nurses on the telephone and may be frailer. Younger patients may be more willing to make the behavioral modifications to monitor their conditions compared to older patients. For this report, we analyzed research sample members by three age groups to test whether there were differential effects by age: younger than 65, 65 to 79, and 80 or older.

[2] Chronic conditions measured included CAD, CHF, stroke, diabetes, cancer, chronic obstructive pulmonary disease, dementia, peripheral vascular disease, HIV/AIDS, depression, asthma, bipolar disorder, schizophrenia, coagulation disorders, and sickle cell anemia.

B. PREENROLLMENT CHARACTERISTICS

Preenrollment characteristics based on Medicare claims and enrollment data demonstrate that the treatment and control groups were well matched, as expected in a random assignment design with a large sample. Comparisons were based on demographic characteristics and health care utilization in the two years before enrollment, including claims for chronic medical conditions, hospitalizations, and average Medicare expenditures per month (Appendix C, Table C.2). We found no statistically significant differences in demographic characteristics between treatment and control groups and only a few significant differences on other characteristics, all of modest size. Specifically, there were slightly fewer treatment group members with a diagnosis for depression in the two years before enrollment (26.4 percent vs. 27.4 percent, $p = 0.024$). Also, compared to control group members, treatment group patients had monthly expenditures that were $5 higher for skilled nursing facility care ($55 versus $50, $p = 0.012$), $19 higher for Part A services ($480 versus $461, $p = 0.036$), and $50 (about 4 percent) higher for total Medicare Part A and Part B services ($1,364 versus $1,314, $p = 0.049$). As noted below in Section D, regression analyses control for these differences in expenditures.

We also compared preenrollment characteristics between treatment and control members who were eligible for the redesign (Appendix C, Table C.3) as well as those who were not eligible (Appendix C, Table C.4). In both samples, there were no statistically significant treatment-control differences in demographic, medical condition, hospitalization, or expenditure variables. Based on the prevalence of comorbid conditions and the rate of hospitalizations, patients eligible for the redesign may have been in worse health than those not eligible for the redesign. In the 24 months before enrollment, average monthly Medicare expenditures for patients eligible for the redesign were $815 greater, or 80 percent more, than for patients ineligible for the redesign.

C. MINIMUM DETECTABLE DIFFERENCES/POWER CALCULATIONS

LifeMasters' very large enrollment provides a high level of statistical precision for analyses of the overall research sample. However, because this is a population-based program and any impacts are likely to be concentrated solely in the sample that received the more intense intervention (those who were mediated), this precision can be misleading. For example, if mediated patients make up roughly one-third of the sample and LifeMasters can reduce their spending by 20 percent compared with the control group (and assuming that LifeMasters does not affect the other two-thirds of the sample), then we would need the power to detect a 6.7 percent effect on the entire sample. However, the sample size needed to detect such an effect is nine times as large as the number needed to detect an effect on only the mediated patients in this example. Thus, if the intervention only had effects for a small proportion of treatment group enrollees, the power to detect an effect would be less than if the intervention affected all treatment group patients.

For the overall research sample, the evaluation has 95 percent power to detect a reduction of $127 in monthly expenditures, which represents the average monthly fee received for the

treatment group over the full demonstration period, or a 6.8 percent reduction in average monthly expenditures (Table II.2). The power to detect the impact needed to cover the monthly fee for specific subgroups is lower, of course, due to smaller sample sizes or smaller percentage reductions in expenditures required to cover program fees. In particular, the power to detect the impact needed to cover fees ranges from 50 percent for patients who resided in the redesign region at enrollment to 98 percent for patients with CAD.

We also have over 80 percent power to detect program effects on the annual number of hospitalizations as small as 4.7 percent (Table II.3). For the various subgroup analyses, the minimum detectable difference (MDD) in hospitalizations that we can detect with 80 percent power ranges from 5.5 percent to 11.6 percent. These calculations suggest we have adequate power to detect relatively modest effects on hospitalizations, even on subgroups of the sample; this is reassuring, given the earlier discussion about the relative differences in sample sizes required if the intervention affects only a subset of the treatment group.

D. STATISTICAL METHODOLOGY

We used multivariate regression analyses to estimate program impacts. The coefficient of interest in all models was the one on the binary variable that indicates treatment group status. All models included control variables for patient demographics and preenrollment health status as well as utilization and expenditures in the 24 months prior to enrollment. Table C.5 in Appendix C contains a complete list of variables and their mean values for the treatment and control groups.

The type of regression analysis used depended on the form of the outcome measure of interest. We estimated linear regression models for analyses of Medicare expenditures and average annual utilization measures of hospitalizations, emergency room visits, and Part B services. Expenditure analyses were based on average monthly Medicare expenditures over the relevant time frame. Because expenditure data tend to be right-skewed (that is, relatively few people with very large expenditures, resulting in a mean that is typically much larger than the median), we conducted sensitivity analyses to test whether results of the linear regressions were sensitive to functional form. Specifically, we estimated log-linear regressions models where the dependent variable (expenditures) was the logarithm of expenditures.[3]

Logistic regression models were estimated to test whether there were differences in any health care utilization by category and to test for differences in mortality rates. For analyses of hospital readmissions, we identified index hospitalizations (that is, the first observed hospitalization without a hospitalization within the previous 30, 60, or 90 days) and any associated readmissions (that is, admissions within 30, 60, or 90 days after an index

[3] Because a small number of sample members had zero expenditures, we added $0.50 to each observation to be able to conduct the log-transformation.

TABLE II.2

PRECISION OF ESTIMATES OF PROGRAM EFFECTS ON MEDICARE EXPENDITURES FOR THE ENTIRE SAMPLE AND SELECTED SUBGROUPS, BASED ON ALL PROGRAM MONTHS

Sample Size		Minimum Detectable Difference at 80 Percent Power	**Power to Detect 20 Percent Effect on Cost**	Average Fee Received per Month in Evaluation Sample	Average Control Group Cost	Percentage Savings Needed to Cover Fee	**Power to Detect Impact Needed to Cover Fee**
Treatment	Control						
Entire Sample							
36,959	14,797	$66	0.99+	$127	$1,859	6.8	0.99+
Patients with Diabetes[a]							
21,813	8,656	$91	0.99+	$127	$2,015	6.3	0.97
Patients with CAD[b]							
25,543	10,216	$85	0.99+	$126	$2,030	6.2	0.98
Patients with Two or More Target Medical Conditions[c]							
17,372	6,962	$112	0.99+	$125	$2,320	5.4	0.87
Resides in Redesign Region at Enrollment (with CHF)							
8,364	3,384	$183	0.99+	$120	$2,658	4.5	0.50
Does Not Reside in Redesign Region at Enrollment (with CHF)							
3,913	1,557	$157	0.97	$136	$1,610	8.4	0.70
Race: Black							
8,706	3,530	$134	0.99+	$133	$1,698	7.8	0.80
Race: Latino							
6,729	2,752	$178	0.99+	$123	$2,251	5.5	0.53
Patients with Five or More Chronic Medical Conditions[d]							
14,613	5,812	$134	0.99+	$126	$2,986	4.2	0.75

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: The average fee received is calculated per month of patient enrollment in the demonstration, not per patient-month for which the program was paid. For example, if a patient was enrolled in the program for six months but the program received a fee of only $700 per month over this patient's first three months of enrollment (because the patient chose to opt out by the fourth month), then the average fee per month of enrollment for this patient is $350 [($700 × 3 months) ÷ 6 months].

TABLE II.2 *(continued)*

Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

[a]Patients who had claims for diabetes in the two years before enrollment.

[b]Patients who had claims for CAD in the two years before enrollment.

[c]Patients who had claims for two or more of the demonstration's target medical conditions (CHF, CAD, or diabetes) in the two years before enrollment.

[d]Patients who had claims for five or more chronic medical conditions among those measured: CAD, CHF, stroke, diabetes, cancer, chronic obstructive pulmonary disease, dementia, peripheral vascular disease, ESRD, depression, asthma, bipolar disorder, schizophrenia, coagulation disorders, sickle cell anemia, and HIV/AIDS.

CAD = coronary artery disease; CHF = congestive heart failure.

TABLE II.3

PRECISION OF ESTIMATES OF PROGRAM EFFECTS ON THE ANNUALIZED NUMBER OF HOSPITALIZATIONS FOR THE ENTIRE SAMPLE AND SELECTED SUBGROUPS, BASED ON ALL PROGRAM MONTHS

Sample Size		Minimum Detectable Difference at 80 Percent Power	Power to Detect 10 Percent Effect on Utilization
Treatment	Control		
Entire Sample			
36,959	14,797	4.7%	0.99+
Patients with Diabetes[a]			
21,813	8,656	6.0%	0.99+
Patients with CAD[b]			
25,543	10,216	5.5%	0.99+
Patients with Two or More Targeted Medical Conditions[c]			
17,372	6,962	6.3%	0.99+
Resides in Redesign Region at Enrollment (with CHF)			
8,364	3,384	8.9%	0.87
Does Not Reside in Redesign Region at Enrollment (with CHF)			
3,913	1,557	11.3%	0.71
Race: Black			
8,706	3,530	8.9%	0.88
Race: Latino			
6,729	2,752	11.6%	0.69
Patients with Five or More Chronic Medical Conditions[d]			
14,613	5,812	6.5%	0.99+

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: The average fee received is calculated per month of patient enrollment in the demonstration, not per patient-month for which the program was paid. For example, if a patient was enrolled in the program for six months but the program received a fee of only $700 per month over this patient's first three months of enrollment (because the patient chose to opt out by the fourth month), then the average fee per month of enrollment for this patient is $350 [($700 × 3 months) ÷ 6 months].

TABLE II.3 *(continued)*

Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

[a]Patients who had claims for diabetes in the two years before enrollment.

[b]Patients who had claims for CAD in the two years before enrollment.

[c]Patients who had claims for two or more of the demonstration's targeted medical conditions (CHF, CAD, or diabetes) in the two years before enrollment.

[d]Patients who had claims for five or more chronic medical conditions among those measured: CAD, CHF, stroke, diabetes, cancer, chronic obstructive pulmonary disease, dementia, peripheral vascular disease, ESRD, depression, asthma, bipolar disorder, schizophrenia, coagulation disorders, sickle cell anemia, and HIV/AIDS.

CAD = coronary artery disease; CHF = congestive heart failure.

hospitalization), using a methodology similar to that outlined by Krumholz et al (2007).[4] Under this design, a hospitalization may be either an index hospitalization or a readmission, but not both. We also developed an alternative readmission outcome that indicates whether there is a readmission or death within the 30-, 60- or 90-day time frames; the rationale for the second definition is to account for the possibility that patients who died within the specified time frame may have been more likely to have a readmission. Regression models for readmissions were estimated using generalized linear models that controlled for multiple hospitalizations and readmissions per person and adjusted standard errors accordingly.

For all regression analyses, we report regression-adjusted outcomes for the treatment and control groups. Impacts were estimated by comparing mean predicted values for the treatment and control groups from the regression, which we obtained by holding all covariates at their observed values and alternately setting the treatment variable to one for all enrollees to obtain the predicted value for the treatment group and repeating this procedure with the treatment variable set to zero to get the predicted value for the control group. We then calculated the means for the predicted treatment values and the predicted control values across all sample members. Conclusions about whether the estimated treatment-control differences were true impacts of the program were drawn by conducting two-tailed tests for whether the regression model coefficients on treatment status were significantly different from zero at the 0.05 level.

[4] Krumholz et al. (2007) excluded patients under age 65 and patients with incomplete data from their analyses. Because the LifeMasters population includes dual eligibles, many of whom are under the age of 65, and because patients are required to have full Medicare benefits and Medicare as their primary payer to be eligible for the demonstration, we did not apply these restrictions.

III. PROGRAM EFFECTS ON USE, MEDICARE EXPENDITURES, QUALITY OF CARE, AND MORTALITY

By teaching patients how to better manage their conditions, the LifeMasters Supported SelfCare (LifeMasters) intervention was expected to reduce health care utilization. *A priori*, one might expect that the program would have a greater impact on hospitalizations and emergency room use than Part B services. In particular, improved disease management might lead to fewer hospitalizations and emergency room visits through reductions in acute care episodes and/or early management of disease exacerbations. However, better disease management may lead to more or less use of Part B services. Patients who improve their adherence to recommended medications, diet restrictions, and self-management of their conditions are expected to require fewer physician visits and other Part B services; however, better disease management may lead some patients to obtain more routine preventive care from their physicians than they would have done otherwise, or to see their physicians for problems that a patient might have ignored but the care coordinator thinks warrant physician attention. Figure III.1 presents a model of how the LifeMasters' disease management intervention may impact health care utilization, costs, quality, and mortality.

Reducing hospital and emergency room use is also important in terms of program cost neutrality. To generate cost savings that are equal to or greater than program fees, the greatest opportunity is to reduce patients' need for high-cost services such as hospitalizations. Reducing preventable hospitalizations, readmissions, and the general need for hospitalizations would also likely have positive effects on beneficiaries' well-being and improve their quality of life.

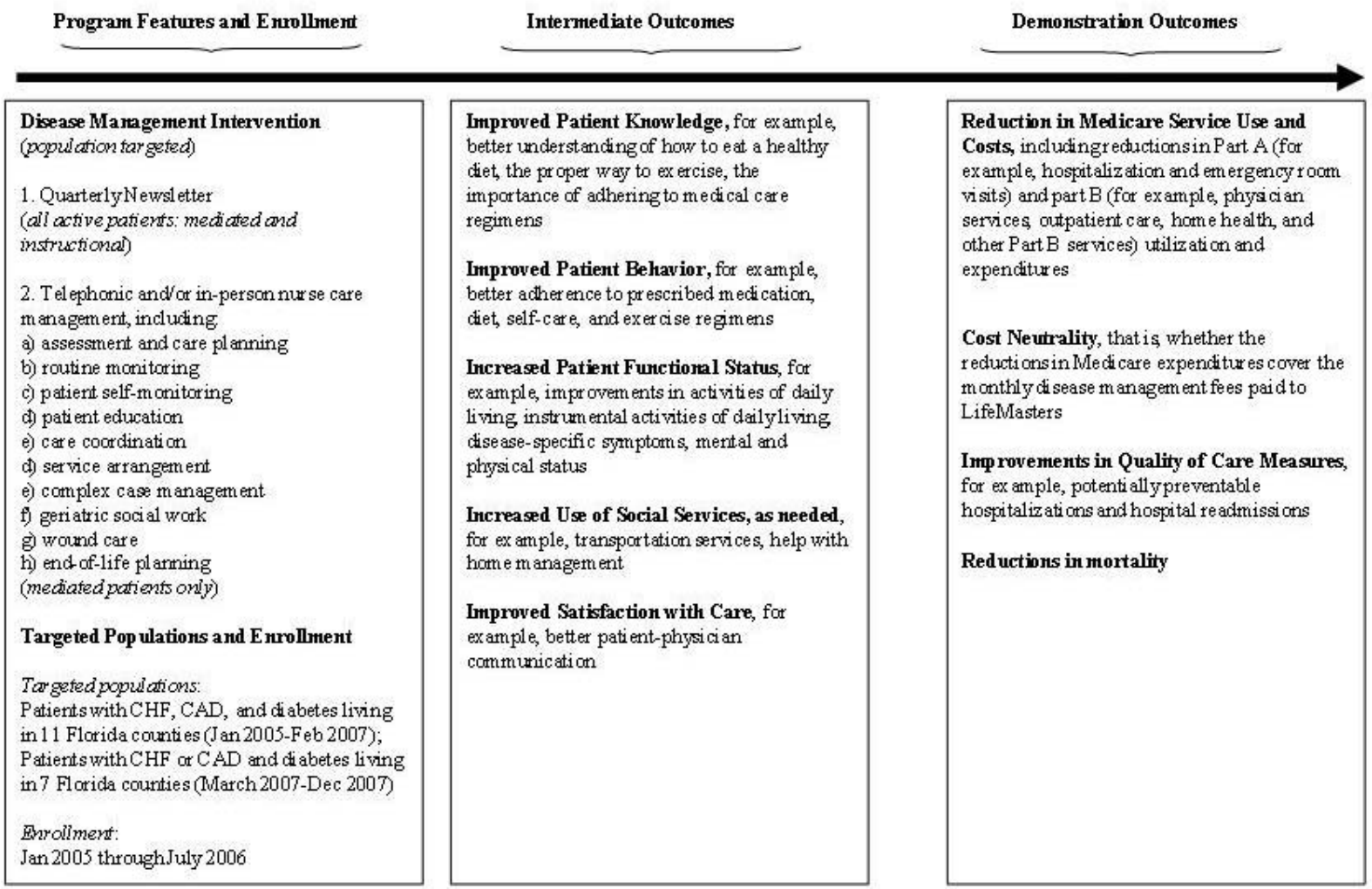
To estimate program impacts on Medicare Part A and Part B utilization and expenditures, we used regression analyses to estimate the treatment-control differences in the means of a number of outcome measures. Analyses were based on an intent-to-treat design, meaning that all *enrolled* months were included, regardless of whether a treatment group patient was active or inactive during that month. We used all data for each research sample member from the time of that member's enrollment to his or her disenrollment or until the end of the demonstration period (December 31, 2007), whichever came first. We also evaluated program effects on various subgroups for which we expected impacts to vary, including subgroups classified by whether patients enrolled relatively early or late in the demonstration, which of the three target conditions the patient had, county of residence, eligibility for the redesign sample, and select demographic characteristics.

A. SERVICE USE

1. Hospitalizations

The intervention had no effect on the likelihood of hospitalization or the average annual number of hospitalizations. The proportion of patients who were ever hospitalized was about 56 percent in both treatment and control groups over the entire study period. Within the various

FIGURE III.1
LOGIC MODEL FOR LIFEMASTERS DISEASE MANAGEMENT PROGRAM OUTCOMES



periods after enrollment (that is, months 1 to 12, 13 to 24, and 25 to 36) the percentage ranged from 35 percent to 39 percent for both groups ($p > 0.10$ for all comparisons, Table III.1). There were also no statistically significant treatment-control differences in the average number or distribution of hospitalizations in any period after enrollment (Appendix C, Table C.6).

2. Emergency Room Use

The intervention did not affect emergency room utilization. Slightly more than half of the control group had at least one emergency room visit over the full study period, with the proportion ranging from 27 to 33 percent within each of the three 12-month follow-up intervals based on time since enrollment. Treatment-control differences were small and not statistically significant. The average annual number of emergency room visits was also similar for treatment and control groups, ranging from approximately 0.6 over the entire study period to 0.44 during months 25 to 36 after enrollment, respectively ($p > 0.05$ for all comparisons, Table III.2). There also were no statistically significant treatment-control differences in the distribution of emergency room visits by time since enrollment (Appendix C, Table C.7).

3. Part B Utilization

There were few scattered treatment-control differences, of modest magnitude, in utilization of various types of Part B services. In particular, the average annualized number of claims for "other part B services" was modestly but significantly lower for the treatment group in months 13 to 24 after enrollment (10.76 versus 11.48; $p = 0.01$), but otherwise not statistically different over all program months or in other follow-up periods (Table III.3). In addition, the adjusted average annualized number of outpatient visits was 8 percent lower for the treatment group in months 25 to 36 after enrollment (6.32 versus 6.87; $p = 0.004$). However, there were no statistically significant differences in outpatient utilization during the other follow-up periods or over all program months. Differences in the use of lab/radiology, physician services, hospice, durable medical equipment (DME), outpatient services, and home health were not statistically different for the treatment and control groups throughout all months of program operations or during any follow-up period after enrollment

B. PROGRAM EFFECTS ON MEDICARE EXPENDITURES

In primary analyses, we estimated the effect of the LifeMasters's intervention on Medicare Part A and Part B expenditures using linear regression models. First, we compared our regression-adjusted estimates of average monthly expenditures for treatment and control groups who qualified for the program redesign over the 36-month demonstration period to the

TABLE III.1

HOSPITAL USE IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 AFTER ENROLLMENT AND ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

Sample Sizes		Any Admission (Percentage)					Average Annualized Number of Admissions per Year				
Treatment Group	Control Group	Treatment Group	Control Group	Treatment-Control Difference	Percentage Change	*p*-Value	Treatment Group	Control Group	Treatment-Control Difference	Percentage Change	*p*-Value
Months 1 to 12 After Enrollment											
36,959	14,797	36.08	36.13	-0.06	-0.15	0.899	0.76	0.76	-0.00	-0.33	0.863
Months 13 to 24 After Enrollment											
23,545	9,395	35.05	35.96	-0.90	-2.51	0.100	0.74	0.76	-0.02	-2.96	0.264
Months 25 to 36 After Enrollment											
7,701	3,119	38.83	38.95	-0.12	-0.31	0.902	0.83	0.83	-0.00	-0.21	0.965
All Months of Program Operations											
36,959	14,797	55.78	56.00	-0.23	-0.42	0.603	0.76	0.77	-0.01	-0.97	0.562

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

All patients enrolled from January 2005 through September 2006 are included in the analysis of all program months. Analyses for months 1 to 12 and months 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the follow-up measures for months 13 to 24 after enrollment. Sample members with more than 24 months of enrollment are included in the months 25 to 36 analysis.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

TABLE III.2

ANY OUTPATIENT EMERGENCY ROOM USE IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 AFTER ENROLLMENT AND ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

Sample Sizes		Any Use (Percentage)					Average Annualized Number of Visits per Year				
Treatment Group	Control Group	Treatment Group	Control Group	Treatment-Control Difference	Percentage Change	*p*-Value	Treatment Group	Control Group	Treatment-Control Difference	Percentage Change	*p*-Value
Months 1 to 12 After Enrollment											
36,959	14,797	31.95	32.62	-0.67	-2.06	0.122	0.61	0.63	-0.02	-3.32	0.169
Months 13 to 24 After Enrollment											
23,545	9,395	29.55	29.87	-0.32	-1.07	0.553	0.53	0.53	-0.00	-0.19	0.957
Months 25 to 36 After Enrollment											
7,701	3,119	27.14	26.62	0.53	1.98	0.567	0.43	0.44	-0.01	-1.87	0.773
All Months of Program Operations											
36,959	14,797	50.51	51.39	-0.88	-1.71	0.060	0.57	0.59	-0.01	-2.22	0.327

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

All patients enrolled from January 2005 through September 2006 are included in the analysis of all program months. Analyses for months 1 to 12 and months 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the follow-up measures for months 13 to 24 after enrollment. Sample members with more than 24 months of enrollment are included in the months 25 to 36 analysis.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed test.

TABLE III.3

PART B UTILIZATION IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 AFTER ENROLLMENT AND ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

	Sample Sizes		Any Use (Percentage)					Average Annualized Number of Claims per Year				
	Treatment Group	Control Group	Treatment Group	Control Group	Treatment-Control Difference	Percentage Change	*p*-Value	Treatment Group	Control Group	Treatment-Control Difference	Percentage Change	*p*-Value
Months 1 to 12 After Enrollment												
Lab/Radiology	36,959	14,797	94.82	94.92	-0.11	-0.11	0.613	14.68	14.64	0.04	0.29	0.765
Other[a]			76.41	76.63	-0.22	-0.29	0.566	9.60	9.60	-0.01	-0.06	0.974
Home Health			28.06	28.23	-0.17	-0.59	0.674	28.88	28.53	0.35	1.21	0.596
Outpatient[b]			75.52	75.30	0.22	0.28	0.592	5.02	5.02	-0.00	-0.04	0.976
Physician Services			97.61	97.52	0.09	0.09	0.536	26.92	26.57	0.35	1.30	0.340
Months 13 to 24 After Enrollment												
Lab/Radiology	23,545	9,395	94.18	94.11	0.07	0.07	0.813	16.65	16.88	-0.24	-1.40	0.281
Other[a]			78.67	78.35	0.32	0.40	0.506	10.76	11.48	-0.71	-6.22	0.001***
Home Health			35.36	35.68	-0.32	-0.90	0.546	43.27	44.11	-0.84	-1.90	0.428
Outpatient[b]			74.89	75.43	-0.54	-0.71	0.291	5.35	5.50	-0.14	-2.60	0.118
Physician Services			97.32	97.27	0.05	0.05	0.809	29.01	29.32	-0.31	-1.06	0.549
Months 25 to 36 After Enrollment												
Lab/Radiology	7,701	3,119	94.60	94.71	-0.11	-0.11	0.823	17.44	17.60	-0.17	-0.95	0.672
Other[a]			83.08	83.06	0.02	0.02	0.983	10.46	10.83	-0.37	-3.41	0.318
Home Health			54.26	55.87	-1.60	-2.87	0.099	76.55	80.78	-4.23	-5.24	0.079
Outpatient[b]			76.40	75.98	0.42	0.55	0.636	6.32	6.87	-0.56	-8.09	0.004***
Physician Services			97.32	97.50	-0.18	-0.18	0.602	32.02	33.56	-1.54	-4.58	0.167
All Months of Program Operations												
Lab/Radiology	36,959	14,797	97.81	97.77	0.04	0.04	0.772	15.45	15.50	-0.05	-0.31	0.715
Other[a]			88.65	88.58	0.06	0.07	0.831	9.96	10.18	-0.22	-2.18	0.123
Home Health			47.05	46.94	0.11	0.23	0.802	36.56	36.86	-0.30	-0.81	0.658
Outpatient[b]			87.76	87.60	0.15	0.18	0.620	5.20	5.28	-0.08	-1.50	0.190
Physician Services			98.94	98.87	0.07	0.07	0.477	27.86	27.86	0.00	0.01	0.993

TABLE III.3 *(continued)*

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

All patients enrolled from January 2005 through September 2006 are included in the analysis of all program months. Analyses for months 1 to 12 and months 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the follow-up measures for months 13 to 24 after enrollment. Sample members with more than 24 months of enrollment are included in the months 25 to 36 analysis.

Use of hospice services and durable medical equipment were excluded from this table because very few patients used these services.

[a]Other use and costs include claims for hospice and other Part B services.
[b]Outpatient use and costs include all outpatient claims, outpatient care provided in a hospital, renal dialysis facility, clinic, ambulatory surgical center, or health center.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed test.

unadjusted estimates from Actuarial Research Corporation's (ARC's) most recent monitoring report, and found the estimates were similar (Appendix C, Table C.8).[1] We then compared Medicare expenditures between treatment and control groups over the full 36-month demonstration period as well as during 12-month intervals after enrollment and for subgroups defined by redesign eligibility and region of residence, health status, and demographic characteristics.

In sensitivity analyses, we used log-linear regression models to confirm whether any statistically significant results from the linear models remained significant once the expenditure data were log-transformed. Log-linear models are commonly used for health care spending analyses, as these models generally predict a higher proportion of the variance in the dependent variable and yield parameter estimates with smaller variances than linear models when the distribution of expenditures is skewed. The log transformation creates a more bell-shaped distribution of the expenditure data, which more closely matches the assumption of constant variance across observations implicit in linear regression models.

1. Overall Research Sample

Medicare expenditures for Part A services were not significantly different between the treatment and control groups, but there may have been modest reductions in Part B expenditures. Table III.4 shows no statistically significant differences in average monthly Part A expenditures or total average monthly expenditures over the 36-month demonstration period. Average monthly Part B expenditures for the treatment group were $31 (2.6 percent) lower than the control group's ($1,165 versus $1,196; $p = 0.026$).[2] However, average cumulative monthly Medicare expenditures throughout the program were also similar for treatment and control groups (Table III.5), with only one month relatively early in program operations (month 9) showing statistically significant differences ($1,866 versus $1,991; $p = 0.011$). This one statistically significant difference in total expenditures was more likely due to chance than to a program impact.

[1] Our unadjusted estimates are not identical to ARC's for the first three years because our data included only 36 months of data while ARC's included 37 months. There were also sample size differences due to differences in Medicare Enrollment Database (EDB) data used in the two analyses. Although ARC used the most recently available EDB data for its monitoring report in May 2008, we used the most recent EDB data available to us at the time we conducted analyses in July 2008. We also constructed measures of inpatient psychiatric use and organ transplant data using all the claims data available to us, while ARC did not adjust for these eligibility criteria in its 37-month report (but will in its final reconciliation).

[2] When we truncated Medicare expenditures at the 99th percentile, we found that average Medicare expenditures were $22 smaller ($p = 0.268$) for the treatment group compared with the control group (Appendix C, Table C.9). The treatment-control difference in Part B expenditures fell to -$21 and was no longer statistically significant ($p = 0.075$).

TABLE III.4

AVERAGE MEDICARE EXPENDITURES PER MEMBER PER MONTH ENROLLED,
THROUGH ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Average Medicare Payments per Month in Fee for Service				
Part A	$680	$671	$9	0.558
Part B	$1,165	$1,196	-$31	0.026**
Total	$1,846	$1,867	-$22	0.332
Sample Size	**36,959**	**14,797**		

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the 36-month follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

Includes all patients enrolled from January 2005 through September 2006.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

TABLE III.5

AVERAGE CUMULATIVE MONTHLY MEDICARE EXPENDITURES AMONG ALL PROGRAM ENROLLEES, THROUGH ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

	Sample Sizes		Average Monthly Medicare Expenditures			
	Treatment Group	Control Group	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Month 3	5,297	2,135	$2,158	$2,220	-$62	0.666
Month 6	10,150	4,091	$2,150	$2,246	-$96	0.247
Month 9	17,255	6,940	$1,866	$1,991	-$126	0.011**
Month 12	26,341	10,562	$1,641	$1,712	-$71	0.087
Month 15	33,647	13,462	$1,602	$1,645	-$42	0.135
Month 18	35,240	14,105	$1,652	$1,690	-$38	0.137
Month 21	36,959	14,797	$1,730	$1,752	-$22	0.371
Month 24	36,959	14,797	$1,769	$1,797	-$28	0.236
Month 27	36,959	14,797	$1,803	$1,830	-$26	0.249
Month 30	36,959	14,797	$1,824	$1,852	-$28	0.223
Month 33	36,959	14,797	$1,840	$1,866	-$26	0.256
Month 36	36,959	14,797	$1,846	$1,867	-$22	0.332

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Includes all patients enrolled from January 2005 through September 2006 and eligible for the demonstration in their first month of enrollment.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

In addition to the above analyses, we also evaluated whether the unadjusted distribution of average monthly Medicare Part A and Part B costs was different for the treatment and control groups. The rationale for this analysis was to examine whether LifeMasters may have identified underserved patients as well as patients for whom they could lower expenditures through improved disease management. If so, we would expect to see more treatment group patients in the middle of the expenditure distribution compared to control patients, and fewer at the upper and lower ends. However, in actuality, treatment group members were slightly more likely to have expenditures among the top 30 percent of all research sample members (30.3 percent versus 29.2 percent, $p = 0.027$), so this hypothesis was rejected (Appendix C, Table C.10).

The intervention may take several years to produce cost-savings, if at all. Analyses suggest there were no statistically significant differences in average monthly expenditures for Part A or Part B expenditures during months 1 to 12 after enrollment (Table III.6). In months 13 to 24 after enrollment, there were no differences in average monthly Part A expenditures, but Part B expenditures were significantly lower (by 3.4 percent) for the treatment group compared with the control group ($1,358 versus $1,405; $p = 0.018$).

In months 25 to 36 after enrollment (predominantly patients eligible for the redesign), average monthly expenditures were 6.2 percent lower for the treatment group compared with the control group ($p = 0.012$). This difference was due primarily to a 7.5 percent ($156, $p < 0.01$) difference in Part B expenditures. The difference in total expenditures in months 25 to 36 was large enough to cover the average fee of $68 per month enrolled paid to LifeMasters over this period, suggesting that the program generated net savings during enrollees' third year after enrollment. There were no statistically significant treatment-control differences in Part A expenditures.

Reductions in Part B expenditures in months 13 to 24 and 25 to 36 after enrollment, were generally consistent with reductions in Part B utilization during these time frames. We compared treatment-control differences in Part B expenditures by time since enrollment and type of service, and found that reductions in these expenditures during months 13 to 24 after enrollment were concentrated in "other Part B" services, including lab and radiology (Appendix C, Table C.11), consistent with reductions in "other Part B" service use shown in Table III.5. In addition, Part B expenditures for home health and outpatient services were significantly lower for treatment group patients in the 25 to 36 months after enrollment (Appendix C, Table C.11). The differences are generally consistent with estimated changes in Part B services use, although the treatment-control difference in home health utilization was not statistically significant.

2. Program Impacts Within Selected Subgroups

a. Redesign Population

Expenditures for Part B services and total expenditures for treatment group enrollees eligible for the redesign were significantly lower over all months of program operations and in months 13 to 24 and 25 to 36 after enrollment. Among those eligible for the redesign, average

TABLE III.6

AVERAGE MEDICARE EXPENDITURES PER MEMBER PER MONTH ENROLLED
IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 AFTER ENROLLMENT
(Regression Adjusted)

	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Months 1 to 12 After Enrollment				
Average Medicare Payments per Month in Fee for Service				
Part A	$659	$644	$15	0.401
Part B	$994	$1,005	-$11	0.470
Total	$1,653	$1,649	$4	0.871
Sample Size	**36,959**	**14,797**		
Months 13 to 24 After Enrollment				
Average Medicare Payments per Month in Fee for Service				
Part A	$685	$683	$2	0.932
Part B	$1,358	$1,405	-$47	0.018**
Total	$2,043	$2,088	-$45	0.203
Sample Size	**23,545**	**9,395**		
Months 25 to 36 After Enrollment				
Average Medicare Payments per Month in Fee for Service				
Part A	$820	$847	-$27	0.593
Part B	$1,927	$2,082	-$156	0.001***
Total	$2,747	$2,929	-$182	0.012**
Sample Size	**7,701**	**3,119**		

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

All patients enrolled from January 2005 through September 2006 are included in the analysis of all program months. Analyses for months 1 to 12 and months 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the follow-up measures for months 13 to 24 after enrollment. Sample members with more than 24 months of enrollment are included in the months 25 to 36 analysis.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

monthly expenditures for the treatment group were 4.3 percent lower ($p = 0.010$) than for the control group over all program months (Table III.7). [3]Similar to the entire research sample, treatment-control differences for the redesign sample were due primarily to lower Part B expenditures, which were almost 5 percent lower for the treatment group ($p = 0.004$). As shown in Table III.8, treatment-control differences for the redesign sample first materialize in months 13 to 24 after enrollment (-$133, $p = 0.036$) and become even larger in months 25 to 36 after enrollment (-$182, $p = 0.024$). In both of these follow-up periods, treatment-control differences in total average monthly expenditures were driven by differences in Part B expenditures. However, no single component of Part B expenditures was significantly lower for treatment group patients in months 13 to 24 after enrollment, although almost all point estimates were negative and overall Part B costs were significantly lower ($2,462 versus $2,595; $p < 0.05$) during this follow-up period (Table C.13). In months 25 to 36 after enrollment, treatment group costs were significantly lower for home health care ($1,023 versus $1,112; $p < 0.05$), outpatient services ($254 versus $297; $p < 0.01$), and total Part B expenditures ($2,798 versus $2,980; $p < 0.05$) among sample members eligible for the program redesign. Among patients eligible for the redesign, treatment-control differences were large and statistically significant as early as the sixth month of program operation (Table III.9). However, the difference shrank consistently until stabilizing in the -$107 to -$132 range beginning in Month 18.

Treatment-control differences in utilization and expenditures for the redesign population were consistent with analyses of the entire research sample. The program had no effects on hospitalizations, readmissions, or emergency room use for sample members who were eligible for the redesign (Appendix C, Tables C.14 to C.18). There were some limited, significant treatment-control differences in the estimated average annual number of Part B claims among the redesign sample (Appendix C, Table C.19). For example, treatment group claims for other Part B services were 7.3 percent lower than the control group in months 13 to 24 after enrollment ($p = 0.011$). The use of outpatient services was 6.1 percent lower ($p = 0.021$) in months 13 to 24 after enrollment and 8.8 percent lower ($p = 0.004$) for the treatment group compared with the control group. Over all program months, only the average annual number of other Part B claims were significantly lower (5 percent, $p = 0.013$) for treatment group compared with the control group among redesign patients.

These findings suggest that the few observed treatment-control differences in utilization and expenditures in the full population were driven by reductions in utilization and expenditures in the redesign population. In particular, when we compare differences in expenditures over all program months between the full sample of enrollees and the redesign sub-population, the cost differences are much greater for the redesign sample (-$107 for the redesign versus -$22 for the entire population), consistent with the intervention having an impact on this population but not on others. In addition, treatment-control differences in Part B and total expenditures in months 25 to 36 after enrollment are similar between the redesign subpopulation and the full population (-$157 versus -$156 for Part B and -$187 versus -$182 for total

[3] The percent treatment-control difference was essentially the same (4.2 percent) when we truncated costs at the 99th percentile (Table C.12).

TABLE III.7

AVERAGE MEDICARE EXPENDITURES PER MEMBER PER MONTH ENROLLED, THROUGH ALL MONTHS OF PROGRAM OPERATIONS, AMONG THE REDESIGN POPULATION
(Regression Adjusted)

	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Average Medicare Payments per Month in Fee for Service				
Part A	845	874	-29	0.289
Part B	1,526	1,604	-78	0.004***
Total	2,372	2,479	-107	0.010**
Sample Size	**13,090**	**5,253**		

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix B for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the 36-month follow-up period the sample member meets the Centers for Medicare & Medicaid Services' demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations in the group.

Includes all patients who were enrolled from January 2005 through September 2006 who were eligible for the demonstration in their first month of enrollment, and eligible for the LifeMasters redesign. Patients were eligible for the redesign if they had claims for CHF or claims for at least two of the three target conditions and if they resided in Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, or Volusia counties.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

TABLE III.8

AVERAGE MEDICARE EXPENDITURES PER MEMBER PER MONTH ENROLLED IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 AFTER ENROLLMENT, AMONG THE REDESIGN POPULATION
(Regression Adjusted)

	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Months 1 to 12 After Enrollment				
Average Medicare Payments per Month in Fee for Service				
Part A	843	880	-37	0.275
Part B	1,389	1,438	-48	0.112
Total	2,233	2,318	-85	0.080
Sample Size	**13090**	**5253**		
Months 13 to 24 After Enrollment				
Average Medicare Payments per Month in Fee for Service				
Part A	854	883	-29	0.517
Part B	1,607	1,711	-104	0.005***
Total	2,462	2,595	-133	0.036**
Sample Size	**8452**	**3388**		
Months 25 to 36 After Enrollment				
Average Medicare Payments per Month in Fee-for-Service				
Part A	846	871	-25	0.650
Part B	1,953	2,109	-157	0.002***
Total	2,798	2,980	-182	0.024**
Sample Size	**6,164**	**2,503**		

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix B for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Patients were eligible for the redesign if they had claims for CHF or claims for at least two of the three target conditions and if they resided in Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, or Volusia counties.

Observations are weighted according to the proportion of the 12- or 24-month follow-up period the sample member meets the Centers for Medicare & Medicaid Services' demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations in the group.

The analyses of months 1 to 12 and 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the analysis of months 13 to 24 after enrollment. Months 25 to 36 after enrollment include sample members with more than 24 months of enrollment.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

TABLE III.9

AVERAGE CUMULATIVE MONTHLY MEDICARE EXPENDITURES AMONG ALL RESDESIGN ENROLLEES, THROUGH ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

	Sample Sizes		Average Monthly Medicare Expenditures			
	Treatment Group	Control Group	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Month 3	2,553	1,035	$2,466	$2,587	-$120	0.572
Month 6	4,873	1,980	$2,389	$2,731	-$342	0.004***
Month 9	7,036	2,853	$2,262	$2,514	-$252	0.003***
Month 12	9,098	3,670	$2,080	$2,256	-$177	0.004***
Month 15	11,344	4,554	$2,009	$2,158	-$149	0.002***
Month 18	11,798	4,734	$2,073	$2,205	-$132	0.005***
Month 21	13,090	5,253	$2,177	$2,291	-$113	0.016***
Month 24	13,090	5,253	$2,223	$2,347	-$124	0.004***
Month 27	13,090	5,253	$2,278	$2,395	-$117	0.006***
Month 30	13,090	5,253	$2,324	$2,443	-$120	0.005***
Month 33	13,090	5,253	$2,360	$2,476	-$116	0.006***
Month 36	13,090	5,253	$2,372	$2,479	-$107	0.01**

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Includes all patients enrolled from January 2005 through September 2006 and eligible for the redesign in their first month of enrollment. Patients were eligible for the redesign if they had claims for CHF or claims for at least two of the three target conditions and if they resided in Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, or Volusia counties.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

expenditures). This is also consistent with the fact that most patients included in the months 25 to 36 analyses were those living in Miami-Dade, most of whom were eligible for the redesign. In addition, the observed reductions in total expenditures among the redesign population in months 13 to 24 and 25 to 36 after enrollment (that is, $133 and $182, respectively) were large enough to cover average fees paid for this group during each of those periods (that is, $89 and $75, respectively).

Both disease status and region of residence were important for the redesign population in demonstrating impacts in the redesign population. Table III.10 shows average Medicare expenditures throughout the full demonstration period by residence at enrollment and diagnosis. Treatment group patients with congestive heart failure (CHF) and those patients with coronary artery disease (CAD) and diabetes who resided in the redesign region at enrollment had 6.6 percent ($p = 0.027$) and 7.8 percent ($p = 0.028$) lower expenditures per month, respectively, than control group members. LifeMasters had no impact on other patients who resided in the redesign region at enrollment (those with diabetes only or CAD only). There were also no effects on any patients who did not reside in the redesign region at enrollment. These findings suggest that both geography and disease status were driving program effects.

To understand whether disenrolling patients who were ineligible for the redesign prevented LifeMasters from demonstrating long-term impacts, we also estimated average monthly expenditures for patients ineligible for the redesign in the 12 months before and the 10 months after the redesign (Appendix C, Table C.20).[4] Treatment-control differences in average monthly spending in the 12 months prior to the redesign were small and not statistically significant. During the redesign period, average monthly Part A expenditures were borderline significantly lower for the treatment group compared with the control group ($547 versus $592, $p = 0.046$), but there were no significant treatment-control differences in Part B or total expenditures. Given the lack of effects on Part A utilization and expenditures among the full sample, the borderline significant result is likely a statistical anomaly.

b. Region of Florida

In the first 24 months after enrollment, treatment-control differences in Medicare expenditures among research sample members who resided in Miami-Dade County at enrollment were large and statistically significant. Specifically, treatment group patients residing in Miami-Dade County had significantly lower expenditures overall compared with the control group ($2,428 versus $2,545; $p = 0.017$), driven by slightly lower laboratory and radiology costs ($215 versus $232; $p = 0.001$) and residual other part B costs ($336 versus $381; $p = 0.038$, Appendix C, Table C.21). There were no significant treatment-control differences in expenditures in the first 24 months since enrollment for enrollees residing in Broward and Palm Beach counties. Expenditures for treatment patients in the North Florida region generally tended to be higher than expenditures for the control group, but most differences were not statistically significant; average monthly expenditures for skilled nursing care among North Florida treatment group members were significantly higher ($120 versus $103; $p = 0.035$).

[4] The redesign period began on March 1, 2007. Patients ere ineligible for the redesign if they only had claims for diabetes or CAD, or if they did not reside in Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, or Volusia counties.

TABLE III.10

ANALYSIS OF MEDICARE EXPENDITURES AND HOSPITAL ADMISSIONS CUMULATIVE THROUGH ALL MONTHS OF PROGRAM OPERATIONS, BY RESIDENCE AT ENROLLMENT AND TARGET DISEASE STATUS
(Regression Adjusted)

	Resides in Redesign Region at Enrollment[a]			Does Not Reside in Redesign Region at Enrollment		
	With CHF	With CAD and Diabetes	Other Patients	With CHF	With CAD and Diabetes	Other Patients
Sample Size						
Treatment	8,364	4,726	1,2433	3,913	2,059	5,464
Control	3,384	1,869	4,974	1,557	829	2,184
Average Medicare Payments per Month in Fee for Service						
Treatment	$1,975	$1,946	$1,758	$1,971	$1,916	$1,805
Control	$2,114	$2,111	$1,793	$1,997	$1,970	$1,742
Percentage difference	-6.56	-7.83	-1.93	-1.32	-2.74	3.61
p-Value	0.027**	0.028**	0.549	0.799	0.671	0.357
Average Annualized Number of Hospital Admissions per Year						
Treatment	0.94	0.80	0.78	0.99	0.82	0.65
Control	0.95	0.85	0.77	0.99	0.87	0.65
Percentage difference	-1.38	-5.84	0.46	-0.03	-6.12	-0.00
p-Value	0.710	0.246	0.914	0.997	0.459	0.999

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: The seven counties remaining in the demonstration are Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, and Volusia. Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Table A.5 for a complete list of independent variables used in this regression specification. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

Patients were eligible for the redesign if they had claims for CHF or claims for at least two of the three target conditions and if they resided in Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, or Volusia counties.

[a]County of residence is determined at the time of enrollment.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

Treatment-control differences in Miami-Dade County were driven by reductions in expenditures in months 25 to 36 after enrollment. When we compared differences in average monthly Medicare expenditures by region and time since enrollment, we only found statistically significant lower expenditures for treatment group patients living in Miami-Dade County in months 25 to 36 after enrollment ($2,875 versus $3,102; $p < 0.01$) (Appendix C, Tables C.22, C.23, and C.24).

c. Chronic Medical Conditions

There was limited evidence that the program had differential effects on patients with different diseases and conditions. Intervention impacts on expenditures across subgroups of treatment group patients defined by number of targeted conditions (two or more and only one) were significantly different from one another ($p = 0.046$). Among patients with two or more target conditions, treatment group members had lower average monthly Medicare expenditures compared with the control group ($1,976 versus $2,041; $p = 0.039$, Appendix C, Table C.25). However, there were no effects on the rate of hospitalization for this subgroup. There were no significant treatment-control differences for average monthly expenditures or hospitalizations among patients with diabetes or CAD (Table C.25). Intervention impacts on expenditures across subgroups defined by the total number of chronic conditions (five or more and fewer than five) were significantly different ($p < 0.01$). Treatment group patients with five or more chronic conditions had significantly lower costs than control group patients with five or more conditions ($2,053 versus $2,151; $p = 0.004$) over the full three-year demonstration period (Appendix C, Table C.26). We found no differences between treatment and control group expenditures or hospitalizations for patients with fewer than five chronic conditions.

d. Demographic Characteristics: Race/Ethnicity and Age

The intervention showed a significant impact on Latino patients, but not on Black patients or patients of other races. Compared to Black and other race patients in the treatment group, Latino treatment group patients had significantly lower average monthly Medicare expenditures ($p = 0.004$). Among Latino patients, treatment group enrollees had significantly lower average monthly costs through all months of the demonstration compared with control group patients ($1,771 versus $1,924; $p = 0.003$, Table C.27), although there was no difference in hospitalization rates. Black patients had the highest average monthly costs of the three groups. There were no treatment-control differences for black patients or patients of other races. The intervention had no differential effect on expenditures or hospitalizations across the age subgroups examined for this report—younger than 65, ages 65 to 79, and 80 and older (Table C.28).

3. Cost-Neutrality

The intervention was not cost neutral over the full 36-month demonstration period. Over all months of the demonstration combined, average monthly Medicare expenditures for the treatment group, including monthly fees paid for active months, were $98 higher than for the control group ($p < 0.01$), essentially because there were no savings in Medicare expenditures, so the disease management fees paid represented a net increase in costs to Medicare (Table III.11).

Favorable effects on costs emerge only after enrollees' first 24 months in the program. In months 1 to 12 after enrollment, average total monthly expenditures were $147 higher for treatment than control patients ($p < 0.01$). During months 13 to 24 after enrollment, average monthly expenditures, including monthly fees paid, were not significantly different between the treatment and control groups. The treatment-control difference in total spending was about -$112 ($p = 0.122$) in months 25 to 36 after enrollment. Thus, we cannot conclude that the program definitely reduced *net* costs in this 25 to 36 month interval, because the estimate was not statistically significant. However, it did reduce *gross* costs in this period and the estimated size of the decrease was more than sufficient to offset the program fees paid.

The intervention appears to be cost neutral among patients eligible for the redesign. Specifically, when we compare treatment-control differences in expenditures, including fees, we find no statistically significant differences in expenditures over all program months or during months 1 to 12, 13 to 24, or 25 to 36 after enrollment (Table III.12). Point estimates for treatment-control differences were positive in months 1 to 12 after enrollment ($56) and over all program months ($5), although they were negative in months 13 to 24 and 25 to 36 after enrollment (-$45 and -$110, respectively); these figures suggest the program may have been cost saving in the later periods of the demonstration.

4. Sensitivity Analyses

Table C.29 in Appendix C compares the results of all statistically significant results from linear regression models to results from log-linear models. With the exception of the model for "other Part B" costs during the first 24 months after enrollment for patients living in Miami-Dade County, none of the significant results from the linear models remained significant in log-linear models. The log-linear model of other Part B costs among Miami-Dade patients was only borderline significant ($p = 0.049$). In addition to rendering treatment-control differences nonsignificant, the log-linear models also predicted smaller differences in treatment-control adjusted expenditures. We also tested several nonsignificant linear models using the log-linear specifications, and all statistically insignificant treatment-control differences from these models remained statistically insignificant when reestimated under the log-linear specification. Finally, we tested expenditure models of the redesign population with log-linear models. With the exception of the log-linear model for Part B expenditures over all program months, the log-linear treatment effect estimates for this subpopulation were also not significant (Appendix C, Table C.30).

TABLE III.11

COST NEUTRALITY IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 MONTHS AFTER ENROLLMENT, AND ALL MONTHS OF PROGRAM OPERATIONS

Sample Size					
Treatment Group	Control Group	Average Monthly Disease Management Fee	Treatment-Control Expenditure Difference Without Disease Management Fee[a]	Treatment-Control Expenditure Difference with Disease Management Fee[a]	p-Value
Months 1 to 12 After Enrollment					
36,959	14,797	$144	$4	$147***	< 0.01
Months 13 to 24 After Enrollment					
23,545	9,395	$82	-$45	$40	0.257
Months 25 to 36 After Enrollment					
7,701	3,119	$68	-$182**	-$112	0.122
All Months of Program Operations					
36,959	14,797	$127	-$22	$98***	<0.01

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

All patients enrolled from January 2005 through September 2006 are included in the analysis of all program months. Analyses for months 1 to 12 and months 13 to 24 after enrollment include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the follow-up measures for months 13 to 24 after enrollment. Sample members with more than 24 months of enrollment are included in the months 25 to 36 analysis.

[a]Regression adjusted differences.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

TABLE III.12

COST NEUTRALITY IN MONTHS 1 TO 12, 13 TO 24, AND 25 TO 36 MONTHS AFTER ENROLLMENT, AND ALL MONTHS OF PROGRAM OPERATIONS, AMONG THE REDESIGN POPULATION

Sample Size		Average Monthly Disease Management Fee	Treatment-Control Difference Without Fee[a]	Treatment-Control Difference with Fee[a]
Treatment Group	Control Group			
Months 1 to 12 After Enrollment				
13,090	5,253	$144	-85	56
Months 13 to 24 After Enrollment				
8,452	3,388	$89	-133**	-45
Months 25 to 36 After Enrollment				
6,614	2,503	$75	-182**	-110
All Program Months				
13,090	5,253	$120	-107**	5

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix B for a complete set of diagnostic eligibility criteria specified by LifeMasters.

The "all months of program operations" results include all patients enrolled from January 2005 through September 2006 and eligible for the demonstration in their first month of enrollment. Other analyses include sample members enrolled early enough in program operations to potentially be observed for 12 or 24 months. For example, only patients enrolled in the demonstration on or before January 2006 were included in the first 24 months results.

Patients were eligible for the redesign if they had claims for CHF or claims for at least two of the three target conditions and if they resided in Alachua, Broward, Marion, Miami-Dade, Orange, Palm Beach, Seminole, or Volusia counties.

[a]Regression adjusted differences.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed t-test.

These sensitivity analyses suggest that results are sensitive to the functional form of the expenditure data, and that the significant results obtained using linear regression models are not robust. Thus, any statistically significant treatment-control differences, including those pertaining to the cost neutrality of the program, that were estimated using linear regression models must be interpreted with caution. These results contrast with the more typical findings from such comparisons, in which the lower variance from log-linear models leads to some previously insignificant differences becoming statistically significant.

IV. EFFECTS ON QUALITY OF CARE AND MORTALITY

A. QUALITY OF CARE

1. Readmissions

We found no significant differences between the treatment and control groups in the rate of hospital readmission, regardless of the follow-up period used to identify readmissions (30, 60, or 90 days after discharge) or the definition of readmission used (Table IV.1). Among treatment and control group members with a qualifying hospital discharge, about 22 percent of hospital discharges resulted in a readmission within 30 days, 30.5 percent within 60 days, and almost 36 percent within 90 days.

2. Claims-based Quality of Care Measures

Although a few measures of quality of care showed improvement, these effects were generally small in magnitude and not apparent until months 13 to 24 after enrollment. In the first year after enrollment, there were no significant treatment-control differences in claims-based quality-of-care outcomes (Table IV.2). In months 13 to 24 after enrollment, treatment group patients were significantly less likely to have any potentially preventable hospitalizations (13.0 percent versus 13.9 percent; $p = 0.026$), and patients with diabetes in the treatment group were significantly more likely to have any claims for blood glucose self-monitoring supplies (66.6 percent versus 65.0 percent; $p = 0.038$).[1] The few observed improvements in quality-of-care measures during the second year after enrollment were consistent with utilization and expenditure analyses, which showed only modest program effects in months 13 to 24 and 25 to 36 after enrollment.

Intervention impacts on quality-of-care measures appeared to vary by geography. For example, slightly more treatment group than control group patients with diabetes in the nonredesign subgroup in the first year after enrollment had one or more claims for several quality indicators, including blood glucose monitoring supplies (56.6 percent versus 54.9 percent; $p = 0.036$); podiatry visits (62.1 percent versus 60.3 percent; $p = 0.023$); blood tests for cholesterol or lipids (79.4 percent versus 77.9 percent; $p = 0.024$); tests for HbA1c (68.5 percent versus 66.6 percent; $p = 0.018$); and urine tests for protein (24.4 percent versus 22.8 percent; $p = 0.018$). However, there were no effects on preventable hospitalizations for this subgroup of patients. (Appendix C, Table C.31). This is in contrast to patients with diabetes living in the redesign region during this period, who had significantly fewer potentially preventable

[1] We limited quality-of-care analyses to months 1 to 12 and 13 to 24 after enrollment, as patients with more than 24 months of enrollment were primarily those in the redesign (and who mostly lived in South Florida). Various studies have shown geographic variation in quality of care; to keep the comparisons comparable over time, we limited these analyses to patients in their first and second years after enrollment.

TABLE IV.1

INPATIENT READMISSIONS WITHIN 30, 60, AND 90 DAYS OF A HOSPITAL DISCHARGE
THROUGH ALL MONTHS OF PROGRAM OPERATIONS
(Regression Adjusted)

	Number of Patients with a Hospital Discharge		Number of Discharges		Percentage of Discharges			
	Treatment Group	Control Group	Treatment Group	Control Group	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Hospital Discharges Resulting in Readmission								
30 Days	14,377	5,723	26,909	10,876	22.25	22.12	0.13	0.802
60 Days	13,551	5,412	22,363	9,057	30.50	30.50	-0.00	0.970
90 Days	12,740	5,112	19,216	7,755	35.51	35.89	-0.38	0.502
Hospital Discharges Resulting in Readmission or with Followup Truncated by Death								
30 Days	14,601	5,826	27,440	11,108	23.87	23.90	-0.03	0.990
60 Days	13,958	5,576	23,143	9,372	32.94	32.98	-0.04	0.927
90 Days	13,304	5,321	20,157	8,127	38.66	38.98	-0.32	0.632

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

††Treatment and control group distributions are significantly different from 0 at the 0.05 level, chi-squared test.
†††Treatment and control group distributions are significantly different from 0 at the 0.01 level, chi-squared test.

TABLE IV.2

CLAIMS-BASED QUALITY-OF-CARE MEASURES IN MONTHS 1 TO 12 AND 13 TO 24 AFTER ENROLLMENT
(Regression Adjusted)

	Months 1 to 12				Months 13 to 24			
	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
All Enrolled Patients								
Number of patients	36,959	14,797			23,545	9,395		
Any potentially preventable hospitalization[a]	10.8	11.1	-0.3	0.299	13.0	13.9	-0.9	0.026**
Preventive care								
Colon cancer screening[b]	7.6	7.6	0.0	0.886	9.6	9.5	0.1	0.788
Screening mammography for females[c]	19.2	19.5	-0.3	0.477	11.1	10.3	0.8	0.083
Patients with Diabetes								
Number of patients	21,813	8,656			13,609	5,432		
Potentially preventable hospitalizations and complications								
Any cardiac hospitalization[d]	4.3	4.5	-0.3	0.317	5.6	5.7	-0.1	0.691
Average number per 100 patients	5.2	5.8	-0.6	0.141	7.0	7.1	-0.2	0.840
Any diabetes hospitalization[e]	2.8	3.2	-0.4	0.068	3.7	4.0	-0.3	0.268
Average number per 100 patients	3.8	4.4	-0.6	0.124	4.9	6.4	-1.5	0.105
Any peripheral vascular or extremity complication[f]	27.9	27.1	0.9	0.114	36.5	36.8	-0.3	0.694
Average number per 100 patients	38.8	37.6	1.2	0.268	55.2	54.6	0.5	0.783
Any microvascular complication[g]	17.7	17.9	-0.1	0.763	23.2	24.0	-0.8	0.224
Preventive care								
Any diabetes education[h]	3.3	3.0	0.3	0.177	4.7	5.2	-0.5	0.131
Average number of diabetes education visits	0.2	0.2	0.0	0.138	0.4	0.4	0.0	0.932
Any claims for blood glucose self-monitoring supplies	55.4	54.3	1.1	0.068	66.6	65.0	1.5	0.038**
Any therapeutic shoes	12.1	11.9	0.2	0.686	16.6	16.0	0.6	0.277
Any eye examination	59.3	59.7	-0.4	0.545	67.7	68.0	-0.3	0.690
Any podiatry visit	60.6	59.5	1.1	0.078	56.7	55.5	1.2	0.117
Average number of podiatry visits	1.7	1.7	0.0	0.364	2.5	2.4	0.1	0.438
Any blood test for cholesterol or lipids	78.8	78.1	0.8	0.137	84.9	84.7	0.2	0.718
Any blood test for hemoglobin A1c (HbA1c)	68.4	67.4	1.0	0.095	76.9	76.4	0.5	0.469
Any urine test for protein	23.4	22.8	0.6	0.259	31.8	31.0	0.8	0.271
Patients with Congestive Heart Failure								
Number of patients	12,277	4,941			6,611	2,681		
Potentially preventable hospitalizations and complications								
Any hospitalization for fluid/electrolyte problems[i]	0.6	0.5	0.1	0.574	0.6	0.5	0.0	0.776
Any congestive heart failure hospitalization	8.4	8.7	-0.2	0.624	9.9	10.5	-0.5	0.429
Preventive care								
Any assessment of left ventricular function	57.8	57.7	0.1	0.903	63.1	63.0	0.1	0.913

Table IV.2 *(continued)*

	Months 1 to 12				Months 13 to 24			
	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value	Treatment Group	Control Group	Treatment-Control Difference	*p*-Value
Patients with Coronary Artery Disease								
Number of patients	25,543	10,216			16,425	6,541		
Any cardiac hospitalizations	4.8	5.0	-0.2	0.403	5.6	5.8	-0.3	0.452
Average number of cardiac hospitalizations per 100 patients	5.8	6.2	-0.5	0.220	7.0	7.5	-0.5	0.550
Preventive care								
Any blood test for cholesterol or lipids	76.4	76.5	0.0	0.937	82.8	83.1	-0.2	0.658

Sources: Medicare Enrollment Database, National Claims History File, and Standard Analytic File.

Notes: The 1 to 12 month analysis includes sample members enrolled early enough in program operations to potentially be observed for 12 months while the 13 to 24 month analysis includes those members enrolled early enough to be observed for 24 months and who have more than 12 months' enrollment. Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

Observations are weighted according to the proportion of the follow-up period the sample member meets CMS's demonstration-wide requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations.

[a]Any hospitalizations for any of the conditions for which we search.

[b]Fecal occult blood testing, screening colonoscopy, sigmoidoscopy, or barium enema.

[c]Females only: in the first 12-month sample, there were 9,797 control group members and 24,475 treatment group members. In the second 12-month sample, there were 6,134 control group members and 15,408 treatment group members.

[d]Any hospitalizations for acute myocardial infarction, coronary artery bypass graft surgery, percutaneous transluminal angioplasty, or coronary artery stenting.

[e]Any hospitalizations for diabetes with hyperosmolarity, diabetes with ketoacidosis, diabetes with other (nonhyperosmolar and non-ketotic) complications, diabetes with other (non-hyperosmolar and non-ketotic) coma, or diabetes without mention of complications.

[f]Any hospitalizations or other services for femoral-bypass procedure, peripheral circulatory disorders, lower-limb amputation, incision and drainage of bone cortex, skin and subcutaneous debridement for gangrene, cutaneous gangrene, leg cellulitis, diabetic arthropathy or neurological disorders, osteomyelitis, or incision and drainage below fascia.

[g]Any hospitalizations, claims, or change in enrollment status for diabetic eye disease, laser treatment for diabetic eye disease, nephropathy, or new ESRD.

[h]Any claims for individual or group diabetes outpatient self-management training services, or for education/training services, including diabetes diet training.

[i]Any hospitalizations for hyperkalemia, hypernatremia, hypokalemia, hyponatremia, or other fluid/electrolyte problems.

**Difference between the treatment and control groups significantly different from 0 at the 0.05 level, 2-tailed t-test.
***Difference between the treatment and control groups significantly different from 0 at the 0.01 level, 2-tailed t-test.

hospitalizations than control group patients (10.3 percent versus 11.1 percent; $p = 0.048$). However, there were no treatment-control differences in the preventive care measures for which we found significant differences in the nonredesign population. Similarly, in the redesign subgroup, patients with diabetes were significantly less likely to be hospitalized for cardiac care (4.0 percent versus 4.9 percent; $p = 0.008$), and patients with CAD were significantly less likely to have any cardiac hospitalizations (4.8 percent versus 5.7 percent; $p = 0.018$). No such differences were observed for the nonredesign population. Previous discussions with LifeMasters staff suggested that patients in the nonredesign regions may have been medically underserved, and this differential pattern could be viewed as evidence that the program is improving care in both underserved and overserved areas, but in different ways. Preventive care for patients with diabetes in underserved areas increased, while hospitalizations declined for these patients in areas where fee-for-service patients have ample access to hospital care. However, the impacts in all cases were small.

B. IMPACTS ON MORTALITY

No differences in mortality rates were detected. There were no treatment-control differences in mortality rates within the first year after enrollment (6.2 percent of patients in both treatment and control groups died during this timeframe), nor during the first 18 months after enrollment (10.1 percent mortality for the treatment group versus 9.8 percent for the control group; $p = 0.425$), nor during the first 24 months after enrollment (14.1 percent versus 14.3 percent; $p = 0.988$) (Table IV.3).

TABLE IV.3

MORTALITY RATE AMONG PROGRAM ENROLLEES IN THE 12, 18, OR 24 MONTHS SINCE ENROLLMENT
(Regression Adjusted)

Sample Size		Mortality Rate			
Treatment	Control	Treatment	Control	Difference	*p*-Value
12 Months Since Enrollment					
36,959	14,797	6.2	6.2	0.0	0.950
18 Months Since Enrollment					
35,240	14,105	10.1	9.8	0.2	0.425
24 Months Since Enrollment					
29,345	11,759	14.1	14.2	0.0	0.988

Source: Medicare Enrollment Database.

Notes: For each follow-up period, mortality rates are calculated for all those enrolled early enough to have the potential to be observed through April 2008. For example, mortality rates for the first 12 months since enrollment are calculated for everyone with at least 12 months of potential experience since their enrollment date to April 2008.

Beneficiaries' first month of enrollment is the second calendar month after the month of randomization. Demonstration-wide eligibility requirements at the time of enrollment included (1) enrolled in fee-for-service Medicare, (2) enrolled in Part A and Part B Medicare, (3) Medicare is primary payer, (4) received full Medicaid benefits, (5) not in hospice care, and (6) not classified as having end-stage renal disease (ESRD). In addition, in the 12 months before enrollment, patients cannot have (1) had an inpatient psychiatric admission of more than 14 consecutive days, (2) been long-term nursing home residents, or (3) had an organ transplant. During the follow-up period, patient observations are truncated when they fail to meet any of these eligibility criteria (with the exception of Part A coverage or being classified as an ESRD patient) or move from the program's service area. See Appendix A for a complete set of diagnostic eligibility criteria specified by LifeMasters.

**Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed test.
***Difference between the treatment and control groups is significantly different from 0 at the 0.01 level, 2-tailed test.

V. SUMMARY OF FINDINGS AND CONCLUSIONS

A. SUMMARY OF FINDINGS

Program impacts on health care use, quality of care, and Medicare Part A and Part B expenditures were very limited. Throughout the entire 36-month demonstration period, the LifeMasters Supported SelfCare (LifeMasters) disease management program did not reduce total average monthly Medicare expenditures (Part A and Part B) among all treatment group patients compared with the randomly assigned control group. However, the program did reduce utilization and expenditures for various Part B components during months 13 to 24 and months 25 to 36 after enrollment, although these differences were not enough to cover the average fee over the full demonstration period ($127 per member per month). In months 13 to 24 after enrollment, the primary driver of treatment-control differences in Part B expenditures was "other Part B services," including laboratory and radiology services, but these differences did not persist in months 25 to 36 after enrollment, suggesting they may have been spurious. In months 25 to 36 after enrollment, there were Part B expenditure reductions for home health and outpatient services. These differences may have been the result of increased in-person contact with program nurses who visit treatment group members in their homes, reducing the need for some home health and outpatient services. However, the sustainability of savings from these sources is questionable.

LifeMasters did not reduce the rate or number of hospitalizations among treatment group members for either the entire research sample or any subgroup. While Medicare Part A costs accounted for only 36 percent of total expenditures among treatment and control group members, conventional wisdom about the potential effects of disease management programs suggests that reducing the rate of hospitalization is the most effective way to reduce expenditures. However, the inability of the LifeMasters program to demonstrate an impact on the use and cost of Part A services casts serious doubt on its ability to reduce Medicare expenditures.

Program impacts were favorable for some beneficiary subgroups, particularly those who met program redesign criteria. Although there were no impacts for the treatment group in the first 12 months after enrollment, this subpopulation's expenditures for Part A and B services in months 13 to 24 and 25 to 36 after enrollment were about 5 to 6 percent lower than the control group's. The absolute dollar value of these differences ($133 and $182) was large enough to cover program fees and generate modest net savings, although these net savings were not statistically significant. Effects for the redesign sample appear to be driven by geography and/or greater levels of comorbidity, as both patients with congestive heart failure (CHF) and those with combined coronary artery disease (CAD) and diabetes showed favorable trends in the redesign sample, but those effects were not evident for the overall population.

Most favorable program impacts did not hold up in sensitivity analyses. Among all the impacts for the entire research sample and all subgroup analyses, only one was robust to a log-linear regression specification (which typically provides more precise impact estimates than linear regression), casting doubt on the ability of the program to achieve its stated goals. On the

other hand, if these were only chance impacts, we would expect to find just as many statistically significant treatment-control differences in the "wrong" direction (that is, larger than the control group) as in the expected direction. However, we found only one statistically significant difference in the wrong direction throughout all of the analyses. Thus, it appears that the program had some small, real effects on Medicare use and costs, though not for the overall population and not for the anticipated Medicare services, such as hospitalizations.

LifeMasters did not achieve cost neutrality overall, but came close for certain periods near the end of the demonstration. Because the overall impact estimate for the full demonstration period without the disease management fee was very small (-$22), the program was far from cost neutral. In months 13 to 24 after enrollment, the treatment-control difference in expenditures with fee was not statistically different from zero, although the point estimate was slightly more than zero ($40, or 2.1 percent of the control group mean). Among sample members who had 25 to 36 months of enrollment (primarily those eligible for the redesign), the treatment-control difference in expenditures with fee was large and negative (-$112) but not statistically significant. This suggests that, with proper intervention targeting and patient participation, it can take up to a year before an intervention is cost neutral and possibly more than three years before it demonstrates cost savings.

A stronger intervention, with greater patient participation, using evidence-based methods may have demonstrated more consistent results. The low rate of mediation was likely an important contributor to the lack of program impacts, particularly for hospitalizations. The proportion of treatment group members mediated was below 30 percent for much of the demonstration and did not remain steadily above that point until the last six months of operations. Without greater participation by patients, a population-based disease management program for dual-eligible beneficiaries will have a difficult time achieving cost savings and cost neutrality. Moreover, there is little evidence that the program used evidence-based methods to reduce hospitalizations and readmissions (Naylor et al. 1999; Lorig et al. 1999; Coleman et al. 2006). Effective programs are generally smaller in scale and involve more patient-nurse interaction, particularly at "teachable" moments. They also invest in relationships with primary care providers and hospitals to better track and manage patients. While LifeMasters improved its patient engagement late in the demonstration and began communicating more with providers as the redesign began, the lack of these elements is likely a primary reason for the small program effects exhibited over the 36-month demonstration period.

B. CONCLUSIONS

The findings from the demonstration offer little encouragement that a population-based disease management intervention for Medicare beneficiaries is likely to generate net savings for Medicare. To simply cover the average fees of approximately $127 per member per month (pmpm), a program serving a population such as that in this demonstration (which had average Medicare expenditures of approximately $2,000 pmpm) would require a reduction in costs of about 6.4 percent. Such a reduction could be obtained by reducing hospitalizations by about 10 percent—a result that would improve the lives of beneficiaries as well. However, the results show no evidence of a reduction in hospital use, emergency room use, or readmissions, or of a downward trend in these outcomes as enrollees' exposure to the program grows. The absence of

effects on hospital use even by the second year after enrollment and later suggests that inadequate length of followup is not the reason that no effects were observed.

The general absence of favorable effects on the quality of care received by beneficiaries is also disappointing. When coupled with the negative findings to date for the Medicare Health Support population-based disease management program for Medicare beneficiaries publicly reported by the Centers for Medicare & Medicaid Services (CMS) in early 2008, the findings cast serious doubts about whether such programs can be counted on to help Medicare improve care and lower costs (CMS 2008). Moreover, relatively new evidence suggests that care coordination interventions are more likely to reduce hospitalizations if they have the following features: (1) fairly frequent in-person contact with patients (about one contact per month); (2) a relationship with area hospitals that ensures they notify the program when a patient has been admitted so the program can conduct transitional care planning; (3) colocation of care coordinators with patients' primary care physicians or, at least, the opportunity for frequent in-person interaction; and (4) teaching patients about how to take their medications (Peikes et al. 2008). LifeMasters lacked the first three of these features, and could only educate about taking medications to the 30 percent or less of patients who were mediated.

The results do suggest that there may be sufficient savings to cover program fees during patients' second and third years after enrollment (that is, not including expenditures during the first year and the first and second year from calculations, respectively) among the subgroup of beneficiaries who had CHF and resided in very high-cost areas (average monthly Medicare expenditures of about $2,700 per beneficiary). However, even for this subgroup, savings were limited to "other" Part B services in the second year after enrollment, and home health and outpatient services in the third year of enrollment. The program did not reduce Part A expenditures or hospital use for this subgroup of beneficiaries. These results raise questions about how such savings were generated and whether they are sustainable. Even if they are sustainable, without impacts on expensive services such as hospitalizations, disease management programs are unlikely to realize their potential of generating sizable net savings for Medicare.

The lack of overall savings and improvements in quality of care is not surprising when coupled with the result that only about 30 percent of the population was ever fully engaged (that is, classified as mediated) by LifeMasters. Effects for this group would have to be quite large in order to offset program fees, if, as LifeMasters did, the program continued to receive fees for most of those who were not mediated. To generate net savings, disease management programs must engage a higher proportion of their populations than LifeMasters did, and quickly inactivate (that is, stop taking fees for) those patients they cannot engage meaningfully. Other factors may have contributed to LifeMasters' inability to generate savings, such as poor contact information and inability to routinely establish a close relationship with patients' primary care providers. However, unless disease management firms can find ways to address these and other factors that limit their programs' effectiveness, disease management programs cannot be viewed as part of the solution to Medicare's problem of controlling cost growth.

LifeMasters has substantially enhanced its outreach to increase patient engagement, resulting in an increase in the proportion of enrolled patients who are mediated from 25 percent in July 2006 to 30 percent in December 2007. It continues to operate under a three-year extension granted by CMS to serve the redesigned population (made up of beneficiaries enrolled

during its first three years and newly assigned patients as of 2008) where it has been most successful, conditional on continued findings of cost neutrality for this group. Average health care utilization of beneficiaries in the redesign region differed considerably from those residing in the North Florida counties dropped from the demonstration. In North Florida, average monthly costs per beneficiary were lower than in South Florida and LifeMasters staff reported that enrollees residing in North Florida appeared to be underserved. Even with a much larger mediation rate, generating savings in these counties would prove challenging. On the other hand, health care use in South Florida counties (those in the redesign) was high and some of it was likely unnecessary, creating an opportunity for LifeMasters to achieve its goals as long as it can continue to engage treatment group members to actively participate. However, although focusing on increasing its mediation rate and inactivating patients who do not engage is clearly critical, to achieve sizeable net savings that are likely to be sustainable over an extended period, LifeMasters must also focus on ways to reduce hospitalizations and the expensive post-acute services that often follow inpatient care.

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