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Evaluation of Phase I of Medicare Health Support (Formerly Voluntary Chronic Care Improvement) Pilot Program Under Traditional Fee-for-Service Medicare

Report to Congress

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EVALUATION OF PHASE I OF MEDICARE HEALTH SUPPORT (FORMERLY VOLUNTARY CHRONIC CARE IMPROVEMENT) PILOT PROGRAM UNDER TRADITIONAL FEE-FOR-SERVICE MEDICARE

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EXECUTIVE SUMMARY

The purpose of this Report to Congress is to report the results of RTI International's initial evaluation of eight voluntary chronic care improvement pilot programs implemented under Phase I of the "Voluntary Chronic Care Improvement Pilot Program Under Traditional Fee-for-Service Medicare" initiative as authorized by Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Section 721 requires the Secretary of Health and Human Services to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. Prior to program implementation, the name of the initiative was changed to Medicare Health Support, which we refer to as MHS hereafter.

The legislation also mandated four Reports to Congress, the first of which to be provided not later than 2 years after the date of the implementation and to report on the scope of implementation of the programs, the design of the programs, and preliminary cost and quality findings with respect to the programs. This report serves as the first interim report. To meet the congressional timeline, this first Report to Congress presents evaluation findings based on the first 6 months of MHS program operations. This period overlaps completely with the 6-month outreach period for each Medicare Health Support Organization (MHSO); many of the Medicare fee-for-service (FFS) beneficiaries randomized to the intervention group have received very limited exposure to the MHSOs' care management programs and services. Thus, these results should be considered *extremely preliminary*.

A large number of analyses were conducted for this report. In this Executive Summary, we highlight selected key findings that are statistically and/or substantively meaningful. It is important to note that some statistically significant differences are to be expected—even after a randomization process—as a result of the large number of comparisons conducted. At the 5% level of significance, for example, we expect to find statistically significant differences in 1 out of every 20 t-tests performed based on random chance. Furthermore, our sample sizes are extremely large from a statistical power perspective; extremely small differences may be statistically significant. Thus, we refrain from reporting in detail on statistically significant differences if they are not substantively meaningful differences. Lastly, we observe substantial variation in annual total Medicare payments for the study populations. The observed variability can reduce the likelihood of identifying differences as statistically significant. To the extent that we observe differences that are substantively meaningful from an evaluation or pilot program policy perspective, we do report on those differences.

Scope of Implementation of the MHS Program

After a competitive solicitation, the Centers for Medicare & Medicaid Services (CMS) selected nine chronic care improvement programs for award. Eight MHSOs launched their programs between August 1, 2005, and January 16, 2006. A ninth program decided not to go forward with finalizing its agreement. Programs are distributed throughout the United States and serve a variety of populations. Several programs serve urban and suburban populations, while others target metropolitan and rural communities. Among the populations served, there are

significant minority populations of African American, Native American, and Hispanic beneficiaries.

CMS prospectively identified eligible beneficiaries from each area and randomly assigned 30,000 into intervention and comparison groups in a ratio of 2:1 under an intent-to-treat (ITT) evaluation model. Randomization occurred on May 11, 2005. Our analyses reveal that the block (stratified) randomization procedure effectively created equivalent intervention and comparison populations at the time of randomization for each of the eight MHSOs for the variables that were used in randomization (i.e., three Hierarchical Condition Categories [HCC] risk score ranges, Medicaid enrollment, and proportion with heart failure [HF]). We also confirm that the randomization procedure produced similar demographic, disease, and economic burden profiles between the intervention and comparison groups at the time of randomization.

The MHSOs target beneficiaries with the threshold condition of heart failure and/or diabetes from among the diagnoses listed on Medicare claims. The level of co-morbidity and rates of acute care utilization during the year prior to randomization is very high among MHS beneficiaries. Consequently, programs are implementing a holistic approach to care management. The MHS programs have been designed to incorporate relevant features from current private sector disease and case management programs, such as encouraging beneficiaries to adhere to prescribed self-care regimens. Beneficiary participation in the MHS program is voluntary.

Participation rates in the first 6-month period range from 65% to 92%. Mean time-to-agreement to participate for all participants ranges from 37 to 100 days across the MHSOs. This means that the effective intervention start dates (at the beneficiary level) are substantially later than the go-live dates. Thus, this initial evaluation reflects considerably less than 6 months of active care management.

We find that within the intervention group, across MHSOs, the participant populations are statistically and substantively different from the non-participant populations across a broad array of demographic, health status, utilization, and payment characteristics. The MHSOs are engaging significantly healthier beneficiaries from a health status perspective; participants have lower rates of co-morbid conditions than non-participants. Within the first 6 months of operations, MHSOs generally have not been as successful at recruiting either dual eligible (Medicare/Medicaid) or the more costly beneficiaries to participate.

Beneficiary and Provider Satisfaction

RTI conducted a baseline beneficiary satisfaction survey 6 months after launch of each MHSO pilot program. The survey targeted a sample from the entire intervention population (not just participants) and the comparison population for each site. A follow-up survey of beneficiaries, which will be implemented 1 year after the baseline survey, will provide data on change in satisfaction during the MHS program. Beneficiaries were asked to rate their overall experience with their health care team using a 5-point scale anchored by “excellent” and “poor.” Approximately 80% of beneficiaries at each MHSO rated their experience with their health care providers as good, very good, or excellent. The most common response across MHSOs was

"very good." The distribution of responses at only one MHSO was significantly different overall between intervention and comparison groups at baseline.

Within 4 months of implementation, RTI conducted initial site visits at each MHSO and spoke with a small number of randomly selected community-based physicians to gauge their early assessment of their satisfaction with the MHS pilot programs. Universally, the community-based physicians felt that the programs could benefit Medicare FFS beneficiaries with chronic conditions. Not unexpectedly, their exposure had been sufficiently limited that they were unable to provide estimates of their current level of satisfaction with the programs. During Year 2 of each program, RTI will field a mail survey of community-based physicians that will more broadly examine their exposure to and satisfaction with the MHS pilot programs.

Preliminary Quality of Care and Health Outcomes Findings

This initial evaluation reflects considerably less than 6 months of active care management, therefore we would expect to see limited impact on quality-of-care or health outcomes. Consistent with standard HEDIS® quality-of-care measures for persons with heart failure or diabetes, we selected four process-of-care measures for use in our evaluation. Because the process-of-care measures are defined as annual rates of service, we believe that it would be inappropriate to evaluate the performance of the MHSOs now using only 6 months of intervention experience.

We also focus on three utilization measures to capture the intervention's effectiveness in improving the quality of outpatient care, thereby reducing the acute exacerbations of the intervention beneficiaries' chronic diseases that result in acute institutional care. Three sets of intermediate clinical outcome variables are constructed for the principal diagnoses of all-cause, HF, and diabetes: hospitalizations, 30-day readmissions, and emergency room (ER) visits. We observe very few statistical or substantive differences in rates of acute care utilization between the intervention and comparison populations during the first 6 months of program experience.

We do not observe any statistically significant differential change between intervention and comparison populations in mean HCC scores during the first 6-month pilot period as compared with mean HCC scores for the 6-month period just prior to the start of the pilot. We do observe statistically significant differential rates of mortality between intervention and comparison populations during the first 6-month pilot period; however, many of the differences are not substantively meaningful.

Preliminary Cost Findings

In the MHS Phase I pilot, each MHSO receives from CMS a negotiated monthly administrative fee per participant, contingent on improvements in quality, beneficiary and provider satisfaction, and 5% savings on Medicare payments net of management fees at the end of the 3-year pilot. Additionally, the statute requires full recovery of fees paid that exceed program savings (budget neutrality). Monthly fees range from $74 to $159 per beneficiary, or 5.3% to 11.2% of average per-beneficiary-per-month (PBPM) expenditures of the comparison group.

Establishing the equivalence of the intervention versus comparison groups is important under an ITT model. Our analyses at the time of randomization confirm equivalency. However, an unexpected pattern emerges between the time of randomization and the start of the MHS pilots that may have policy implications for CMS's financial reconciliation in Phase I and for Phase II plans for care management in FFS Medicare. Substantive differences between the intervention and comparison populations emerge in the interval between randomization and go-live, most notably, in baseline PBPM payments, when we evaluate these measures for the subset of beneficiaries who are eligible during the first 6 months of the pilot. To a lesser degree, we also observe a growing divergence in prior rates of hospitalizations and ER visits between the time of randomization and the start of the intervention period.

Even though the differences are relatively small, they may affect the MHSOs' abilities to achieve their savings objectives, especially if success is determined by a 1 to 2 percentage point change in Medicare expenditures between the intervention and comparison groups. For example, beneficiaries in one MHSO's intervention group have monthly total Medicare payments that are about 6% higher than the comparison group at the start of their pilot. This amount might seem modest, but it is a substantial portion of the monthly fee the MHSO receives. Six of the MHSOs' intervention populations have higher PBPMs in the year prior to the start of their pilots compared to the comparison populations, ranging from 1% to 6%. While only the difference in one MHSO group's PBPM is statistically significant at 5% or better at the start of the pilot, the financial reconciliation protocols as initially agreed upon do not make adjustments for differences in payments at the start of the pilot. These differences can be actuarially adjusted and further exploration as to the underlying reasons for the divergence should be undertaken. Such divergence may represent the influence of a small number of outliers with extreme medical expenditures for which additional statistical adjustment may be warranted.

We conducted a difference-in-difference analysis of trends in PBPMs for each of the eight MHSOs. Six of the eight MHSOs, relative to their comparison groups, exhibit lower rates of growth in Medicare PBPM payments between the year prior and first 6 months of the pilot program. Yet, only two MHSOs exhibit a statistically significant lower rate of increase in their intervention PBPM versus the comparison group. To achieve statistical significance, the differences-in-trends need to be roughly $70-$80 or more. One MHSO's intervention PBPM growth parallels its comparison group, and another MHSO's intervention PBPM grew faster than its comparison group PBPM.

Average monthly payments and growth trends for participants and non-participants differ systematically within each MHSO. The lack of full, nonrandom, recruitment by the MHSOs results in base year PBPMs of intervention participants averaging 8% to 19% less than those of intervention non-participants across the eight MHSOs. Because the non-participant group is typically one-fifth of the entire intervention group, not impacting these costly beneficiaries will likely hinder the ability of MHSOs to control their intervention group's overall PBPM growth and meet the financial terms of the pilot.

Monthly management fees, as a proportion of comparison group PBPMs, range from a low of 6.5% to a high of 11.2% and average 8% to 9% of monthly expenditures. Consequently, to meet budget neutrality during the first year requires MHSOs to reduce expenditures 8% to 9%, on average, in order to cover all the fees they have received. It should be noted that these

analyses do not apply trims for outliers as will be done in the financial reconciliation nor do they include any adjustment of baseline differences between intervention and comparison PBPMs at the start of the pilot. MHSOs over the first 6 months have had limited success in covering the fees paid out by Medicare. Only one MHSO has recovered as much as one-third of its monthly fee through Medicare expenditure savings after 6 months. However, because this MHSO negotiated the highest fee of all eight programs, it still needs to reduce its intervention PBPM another 12% below its comparison group's PBPM over the next 2½ years of the pilot. Five other MHSOs have recovered (through expenditure savings) between 2.3% and 15% of their fees. However, two MHSOs have not recovered any of the monthly fee paid to them by CMS.

Summary of Key Findings

Although we present a large number of findings in this report, this initial evaluation reflects considerably less than 6 months of active care management. We therefore refrain from drawing any early conclusions with respect to the pilot programs' impact on quality of care or health outcomes. Although preliminary, three key participation and financial findings emerge that have important policy implications for CMS's financial reconciliation in Phase I.

First, although the intervention and comparison groups are similar at randomization, our analyses reveal that an unexpected pattern in PBPM differences between intervention and comparison groups emerges between the time of randomization and the start of the MHS pilots. Second, participating beneficiaries tend to be a healthier and less costly subset of the intervention group. Thus, high participation rates will likely be a factor in the ability of the MHSOs to impact their assigned intervention populations. And, third, fees paid to date far exceed any savings produced. The negotiated MHSO monthly fees are a much higher percentage of the comparison groups' PBPMs than the percentage savings on payments through the first 6-month pilot period. Fees negotiated by the MHSOs with CMS have not been covered by reductions in Medicare expenditures, let alone an additional 5% savings in Medicare payments. Without a substantial reduction in each MHSO's monthly fee, budget neutrality after the first year is questionable.

Given these findings, CMS may wish to consider modifying its financial reconciliation protocol by actuarially adjusting the intervention PBPM for any difference from the comparison group in the 12 months just prior to the start date. Further exploration as to the underlying reasons for the unexpected divergence should be undertaken. Such divergence may represent the influence of a small number of outliers with extreme medical expenditures for which additional statistical adjustment may be warranted. CMS may also wish to consider renegotiating monthly MHS management fees with the MHSOs, if the observed patterns in this initial evaluation continue to hold as longer periods of data are reviewed.

Key Program Developments

Since RTI produced the initial version of this report, some key program developments have occurred. Two organizations requested early termination of their programs. LifeMasters Supported Self Care ended their MHS program December 31, 2006, and McKesson Health Solutions, LLC, will end their MHS operations effective May 31, 2007. CMS has committed to the MHSOs to explore appropriate strategies to adjust for baseline differences in Medicare expenditures between the intervention and comparison populations.

CHAPTER 1
INTRODUCTION

The purpose of this Report to Congress is to report the results of RTI International's initial evaluation of eight voluntary chronic care improvement pilot programs implemented under Phase I of the "Voluntary Chronic Care Improvement (CCI) Pilot Program Under Traditional Fee-for-Service Medicare" initiative as authorized by Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Section 721 requires the Secretary of Health and Human Services to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. Prior to program implementation, the name of the initiative was changed from Chronic Care Improvement Program to Medicare Health Support, which we refer to as MHS hereafter. The principal objectives of this initiative are to test a pay-for-performance contracting model and MHS intervention strategies that may be adapted nationally to improve clinical quality, increase beneficiary and provider satisfaction, and achieve targeted savings for chronically ill Medicare fee-for-service (FFS) beneficiaries. In addition, this initiative provides the opportunity to evaluate the success of the "fee at risk" contracting model, a new pay-for-performance model for the Centers for Medicare & Medicaid Services (CMS). This model provides MHS organizations (MHSOs) with flexibility in their operations and strong incentives to keep evolving toward outreach and intervention strategies that are most effective in improving population outcomes.

Subsection (b)(5) of the legislation states that the evaluation shall include an assessment of the following factors for each program:

- quality improvement measures,
- beneficiary and provider satisfaction,
- health outcomes, and
- financial outcomes.

The legislation also mandated four Reports to Congress, the first of which to be provided not later than 2 years after the date of the implementation and to report on the scope of implementation of the program, the design of the programs, and preliminary cost and quality findings with respect to the programs based on the following measures of the programs: quality improvement measures, such as adherence to evidence-based guidelines and re-hospitalization rates; beneficiary and provider satisfaction; health outcomes; and financial outcomes. This report serves as the first interim report.

To meet the congressional timeline, this first Report to Congress presents evaluation findings based on the first 6 months of MHS program operations. The first 6 months of the intervention period overlap completely with the 6-month outreach period for each MHSO; many of the Medicare FFS beneficiaries randomized to the intervention group had received very limited exposure to the MHSOs' care management programs and services. Thus, these results should be considered *extremely preliminary*. Further, because the programs are designed to be

dynamic, the design features of each MHSO's program presented in this report should also be viewed as preliminary.

1.1 Background on CMS Solicitation and Award

Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), titled the "Voluntary Chronic Care Improvement Under Traditional Fee-for-Service Medicare," required the Secretary of Health and Human Services to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. The legislation envisioned a two-phased approach to the establishment of the chronic care improvement program. Phase I is the development phase and requires the Secretary to enter into agreements with organizations for programs using randomized controlled trials. The first agreement was required to be within 12 months after enactment (by December 8, 2004) and all agreements are to be for a 3-year period. If the Secretary determines that the Phase I programs have improved quality of care and beneficiary satisfaction, and achieved specified spending targets, then the Secretary shall enter into agreements to expand the program or program components to additional geographic areas not covered during Phase I; Phase II may be national expansion and is required to begin no later than 6 months after the completion of Phase I.

CMS issued a competitive solicitation notice in the Federal Register on April 23, 2004, notifying interested parties of an opportunity to apply to implement and operate a chronic care improvement program. Eligible organizations included: (1) disease management organizations, (2) health insurers, (3) integrated delivery systems, (4) physician group practices, (5) a consortium of entities, or (6) any other legal entity that met the requirements of the notice. CMS held a bidders conference on May 13, 2004, highlighting the selection process and requirements. Bidders were required in their proposals to address key features of the program specified by the enabling legislation. Specifically, bidders were asked to identify and provide a rationale for the specific geographic areas within which they would operate and the clinical focus of their targeted population (e.g., heart failure [HF] and diabetes, or chronic obstructive pulmonary disease [COPD]). In addition, bidders were requested to delineate in sufficient detail their proposed chronic care improvement program to allow reviewers to ensure that the proposed programs met the statutory programmatic requirements, such as having a process to screen each targeted beneficiary, development of an individualized, goal-oriented care management plan, etc. Bidders were also required to propose fee amounts and clinical quality and beneficiary and provider satisfaction improvement measures and performance guarantees.

Applications were due August 6, 2004; awards to nine applicants were announced December 8, 2004. The final selections were made after a competitive review that considered among other factors operational feasibility, geographic location, Medicare program priorities, and detailed financial analysis. Once the awards were announced, CMS separately negotiated with each MHSO monthly management fees, "at risk" amounts related to specific quality and satisfaction performance metrics, and performance guarantees. The United HealthCare Services, Inc. – Evercare/Visiting Nurse Services of New York Home Care team decided not to go forward with finalizing their agreement.

1.2 Background on Design of the Phase I MHS Program

The solicitation issued by CMS permitted applicants to propose interventions for populations defined by the threshold conditions of diabetes and/or heart failure or COPD. None of the awardees selected proposed to serve the threshold condition of COPD. Thus, selected MHS programs target populations of beneficiaries with HF and/or diabetes. However, the targeted beneficiaries have myriad other chronic conditions, such as COPD or hypertension. Programs were required by CMS to implement a holistic approach to care management that addresses beneficiary needs, regardless of the threshold condition. CMS is testing programs in eight geographic areas in which roughly 10% of Medicare's national FFS population resides. Only one pilot program has been selected per geographic area, and there is significant variation in the approaches across the selected programs. The MHS programs have been designed to incorporate relevant features from current private sector and Medicare managed care disease management and case management programs, such as supplying physicians with timely, actionable clinical information about their patients; providing clinical decision support for beneficiaries and providers based on evidence-based guidelines; promoting care coordination; and guiding and encouraging beneficiaries to adhere to prescribed care management plans and self-care regimens. The MHS pilot programs differ from earlier CMS disease management demonstrations in that they are population based, large scale, and employ a randomized design with an intent to treat model.

Section 1807(a)(2)(E) of the Social Security Act and subsequent CMS implementation decisions identify Medicare beneficiaries eligible for one of the MHS programs, if the individual is (1) entitled to benefits under Part A and enrolled under Part B but not enrolled in a plan under Part C, (2) has one or more threshold conditions of HF or diabetes, and (3) has a Hierarchical Condition Categories (HCC) risk score of 1.35[1] or greater.[2] Medicare FFS beneficiaries were identified from Medicare claims data as having a threshold condition of diabetes or HF using a combination of two or more evaluation and management visits on separate dates or a hospitalization for HF or diabetes based on 1 year of historical claims data. The data used to identify eligible beneficiaries were from the national claims history file for claims with date-of-service end dates in calendar year 2004.

CMS's financial reconciliation contractor conducted the sampling for each MHSO program and calculated the HCC score for each identified individual and excluded beneficiaries who did not have Medicare as their primary payer, those who were not eligible for Medicare Part A and Part B, and those who were enrolled in any of the following:

- Medicare ESRD program,
- hospice,

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1 The HCC risk score is used in the Medicare program to adjust managed care payments. A beneficiary with an HCC score of 1.35 is predicted to have Medicare payments next year that are 35% greater than estimated payments for the average Medicare fee-for-service beneficiary.

2 The eligibility criterion for one MHSO was modified to include beneficiaries with an HCC score of 1.30 or greater to achieve sufficient population size.

- Medicare Advantage (MA) plan, or
- CMS-sponsored Medicare FFS chronic care demonstration.

The financial reconciliation contractor ensured that identified individuals had their residence of record in the Medicare administrative files in the relevant geographic area. Approximately 20,000 individuals were randomly assigned to each intervention group and approximately 10,000 to each comparison group. Efforts were made to avoid splitting spouse pairs between the intervention and comparison groups by matching claim account numbers. Randomization was based on eligibility as of May 11, 2005. The general approach used was block (stratified) randomization to ensure equal distribution between intervention and comparison groups of individuals with the following characteristics:

- a claims-based diagnosis of HF or not,
- HCC risk scores
  - low: $\geq$1.35 and <2.00[3]
  - medium: $\geq$2.00 and <3.10
  - high: $\geq$3.10, and
- Medicaid eligibility based on the Part B buy-in field in the Medicare Enrollment Data Base (EDB).

Beneficiary names, addresses, available demographic data, available telephone numbers from Social Security Administration records, and Medicare claims from 2003 and 2004 for the intervention group, were provided to each MHSO before the start date of MHS operations. CMS sent eligible beneficiaries in the intervention groups a letter from Medicare introducing the program and provided approximately 2 weeks to opt out of being contacted by the MHSO. MHSOs were then permitted to contact beneficiaries to confirm their willingness to participate in the program and begin providing services.

Medicare beneficiaries chose whether to participate in the MHS program. According to CMS's "Protocol 1 Assignment of Groups," dated March 23, 2005, "confirmation of participation means that the MHSO has reached the beneficiary or caregiver and begun services as described in Section 1807(e)(1) of the Social Security Act." Such confirmation shall be documented in the individual beneficiary file maintained by the MHSO. Participants may drop out of the program at any time and begin participation again at any time as long as they are eligible. Participation ends when a beneficiary becomes ineligible for the program or informs the MHSO or CMS that he or she does not want to receive further services from the program. Non-participants are individuals in the intervention group who decline to be contacted by the MHSO, choose not to participate, drop out of the program, or are not reachable by the MHSO for all

[3] One MHSO has a low range $\geq$ 1.30 and <2.00 to obtain a sufficient sample size for both the intervention and comparison populations.

months in which they are eligible to participate. The MHS pilot program was designed using an intent-to-treat (ITT) model, which means the MHSOs are held accountable for outcomes across the full intervention population and not just those who agree to participate.

Once individuals are randomized to either the intervention or comparison group, they remain in their assigned group for all days in which they meet the inclusion and exclusion criteria. Eligibility for the MHSO program and hence membership in either the intervention or comparison group will be lost for the period(s) that any of the following apply. The beneficiary:

- enrolls in an MA plan,
- loses eligibility for Part A or B of Medicare,
- gets a new primary payer (i.e., Medicare becomes secondary payer),
- dies,
- elects the Medicare hospice benefit, or
- develops ESRD.

The MHSOs were provided with an initial 6-month outreach period during which they were expected to contact their assigned beneficiaries to gain participation in their program. During the outreach period, the MHSOs received monthly MHS fees for all assigned beneficiaries except those who declined participation or were deemed ineligible (e.g., ESRD) based on the Medicare EDB. At the end of the outreach period, MHS monthly payments ceased for any beneficiary who had not agreed to participate in the program. Thus, the MHSOs had a strong incentive to gain the participation of all beneficiaries. The MHSOs may continue to seek beneficiary participation throughout the pilot program. Beneficiaries who decline to participate or later opt out of the program may be re-contacted for participation in the program after a sentinel event, such as a hospitalization, nursing home admission, surgical procedure, or ER visit.

Beneficiary participation in the MHS programs is voluntary and does not change the scope, duration, or amount of Medicare FFS benefits currently received. All Medicare FFS benefits continue to be covered, administered, and paid for by the traditional Medicare FFS program. Beneficiaries do not pay any charge to receive MHS program services. Each MHSO receives from CMS a monthly administrative fee per participant, contingent on improvements in quality, beneficiary and provider satisfaction, and 5% savings net of fees to the Medicare program at the end of the pilot. MHSOs are held at risk for fees based on the performance of the full population of eligible beneficiaries randomized to the intervention group (an ITT model) compared with the comparison group. CMS has developed the MHS initiative with considerable administrative risk as an incentive to reach targeted beneficiaries and their providers and to improve care management. To keep all of its monthly fees, an MHSO must reduce average monthly payments by 5% plus the proportion of the comparison population payments that the fee comprises. The MHSOs must also meet quality and satisfaction improvement thresholds or pay back negotiated percentages of their fees.

1.3 MHS Phase I Pilot Launch

The MHSOs launched their programs between August 1, 2005, and January 16, 2006. The programs are distributed throughout the United States and serve a variety of populations. Several programs serve urban and suburban populations, while others target metropolitan and rural communities. Among the populations served, there are significant minority populations of African American, Native American, and Hispanic beneficiaries. Table 1-1 displays the eight Phase-1 MHSOs, their geographic MHS service areas, and program launch dates.

Table 1-1
Medicare Health Support organizations

MHSO	Target geography	MHSO launch date
Healthways	Maryland and District of Columbia	8/1/2005
LifeMasters Supported SelfCare	Oklahoma	8/1/2005
Health Dialog Services Corporation	Pennsylvania (western region)	8/15/2005
McKesson Health Solutions, LLC	Mississippi	8/22/2005
Aetna Life Insurance Company	Chicago, IL (surrounding area)	9/1/2005
Cigna Health Support	Georgia (northern region)	9/12/2005
Green Ribbon Health	Florida (west-central region)	11/1/2005
XLHealth Corporation	Tennessee (selected counties)	1/16/2006

CHAPTER 2
MHS PROGRAM DESIGN FEATURES AND EARLY IMPLEMENTATION EXPERIENCE

2.1 Overview of the Eight MHS Pilot Programs

The eight selected Medicare Health Support Organizations (MHSOs) are well known in the industry and vary in size, complexity, and organizational focus. Some focus primarily on the provision of care management services, while others provide a broader range of services (including commercial insurance products, information systems, etc.). Although the Medicare Health Support (MHS) interventions vary in a number of important ways (e.g., the presence of on-the-ground nurse support, conduct of nursing home visits, specific programs to support care at the end of life, home monitoring), all programs provide MHS participants with telephonic care management services, including

- nurse-based health advice for the management and monitoring of symptoms,
- health education (via health information, videos, online information),
- health coaching to encourage self-care and management of chronic health conditions,
- medication management, and
- health promotion and disease prevention coaching.

Each MHS program has a nurse-based health coaching and health support program; however, the MHSOs vary in how they implement the various components of their model. While all MHS interventions involve a telephonic nurse component, only five of the MHSOs are actively engaged in serving an institutionally based population. Only a few of the MHS programs have an active end-of-life component offering programs to provide end-of-life support for individuals and their families. All of the MHSOs except one have on-the-ground components of their MHS interventions, ranging from advanced practice nurses to provide intensive case management support to assessment centers where beneficiaries are encouraged to go for in-person interaction. Most of the MHSO programs provide some type of home monitoring or telemonitoring devices at home. Although all MHSOs have tried to obtain information on medications taken by MHS participants, there is considerable variability in the extent to which the MHSOs routinely use this information for medication management. Key features of the MHS programs include the following:

Outreach to Beneficiaries. The MHSOs recruited participants systematically, rather than randomly. Most are using proprietary algorithms to calculate a risk score or risk scores. The scores may be used not only for prioritizing outreach but also to customize interventions to the participants' needs. Initially, most programs prioritize beneficiaries who are at immediate high or moderate risk for adverse events, and then they approach additional beneficiaries who are at lower risk or whose risk level increases. Some MHSOs included demographic modeling to predict the likelihood to participate in their outreach strategy.

Individualized Assessment. Each of the MHSOs conducts a comprehensive health assessment after the beneficiary agrees to participate. Although the content of the assessments differed somewhat across the MHSOs, nurses generally asked questions to identify presence of primary and comorbid diseases, symptoms, recent health care utilization (e.g., hospitalizations and emergency room visits), self-management knowledge, deficits in activities of daily living, overall self-assessment of health, height/weight, blood pressure, medications, nutritional status including salt intake, fall history, cognitive issues, and current health and social support services. A depression screening is also conducted during the initial health assessment. The information obtained from the individualized assessment is used to help determine the type and level of intervention and to set self-management goals.

Intensive Case Management for High-Cost Beneficiaries. A portion of the intervention populations includes very sick beneficiaries, requiring close monitoring, in-home visits, or end-of-life care. Most of the MHSOs have programs or contractual arrangements for providing additional services to these beneficiaries.

Education and Skills. A key step in improving self-management is educating beneficiaries and their families about their illnesses, how to react to symptoms, and making lifestyle changes. All the MHSOs provide a range of educational resources, including literature, videos, Internet resources, and coaching by a nurse or other care manager via telephone or in person.

Medication Management and Support. All the MHSO programs include efforts to optimize the medication regimens of participating beneficiaries. Interventions range from monitoring compliance and the appropriateness of complex pharmaceutical regimens, to face-to-face meetings with pharmacists.

Monitoring, Feedback, and Follow-Up. Several programs offer ongoing biomonitoring of beneficiaries by placing scales or other equipment in their homes, and several MHSOs ask participants to report their weights, blood sugars, or other measures via e-mail or telephone. When data on preventive services, screenings, or recommended tests are available (e.g., influenza vaccinations), the programs remind beneficiaries and/or their doctors to have them done.

Access to Support Services (i.e., nurses, call lines, e-mail). One feature of several MHSO programs is round-the-clock availability of support services. In these programs, participants may call and speak to a nurse or other provider at any time they are having a problem or would like to ask a question. Other programs have systems in place so participants may leave a message about a problem or question and receive a return call within a certain period of time, varying from 30 minutes to the next business day.

Coordination and Continuity of Care. One hallmark of the disease management model incorporated by the MHSOs is to use data from all available sources and disseminate information to providers and caregivers involved with a beneficiary's care. Some programs conduct discharge planning with beneficiaries, if they are hospitalized. Features include active engagement of physicians or physician practices in their interventions, and data-sharing

arrangements with physician practices. However, only a small portion of physicians who treat the participating beneficiaries have formal relationships with the MHSOs.

Referrals for Provision of Community-Based Ancillary Services. Not all of a participant's needs are provided directly by all MHSOs. Several have recognized the need for transportation or other services typically provided by a community service organization (e.g., social workers, dieticians). The MHSOs have relationships with other service providers and programs and help selected beneficiaries receive these services through their participation in the MHS program.

Information Management Systems. Each MHSO relies heavily on the use of sophisticated information systems that include electronic health records, automated call center operations, and extensive data analysis and storage capabilities and facilities.

Risk Stratification. All of the MHSOs have used at least one method to stratify their populations into various categories of risk for the likelihood of having a high cost event (e.g., hospitalizations, emergency department visits), or deterioration in clinical health status. A number of MHSOs altered their strategy as they analyzed data and considered how to classify MHS beneficiaries who were typically sicker than populations that MHSOs had supported previously. For example, a number of the MHSOs rely on sophisticated predictive models using proprietary logic with more than 100 variables to identify gaps in care, create risk strata scores, and achieve operational efficiency. For two MHS pilot programs, risk is recalculated with every new piece of information obtained on MHS participants. Six of the eight MHSOs use internally developed risk stratification systems to subdivide the MHS population into various risk categories. Where MHSOs found their internal stratification models did not adequately discriminate among different risk groups, they have relied on the Hierarchical Condition Categories scoring system to stratify their MHS populations.

Access to and Use of CMS Data. All MHSOs receive CMS claims data for their intervention group participants on a monthly basis. In addition, comparison group data are provided to the MHSOs, both in quarterly aggregate reports and as deidentified claims data sets annually.. A number of the MHSOs developed creative strategies to enhance their ability to manage MHS operations by obtaining census, Medicare claims, or other administrative data on a more frequent basis. Some of the MHSOs negotiated data sharing agreements with Medicare carriers, fiscal intermediaries, or other major health care partners, while others rely primarily on the data provided from CMS and its MHS contractors. As of the time of the site visits, the MHSOs had not received any Part D prescription data.

2.2 Early Implementation Experience

RTI staff is contracted to conduct two rounds of site visits to each of the MHS programs. The initial set of site visits were conducted approximately 4 months after initial pilot program startup—between November 2005 and May 2006—and the second set between February and August 2007. The first site visit focused on learning about MHS program startup, examining the components of the MHS programs, determining the nature of the MHSOs' relationship with physicians in each community, learning about ways the MHSOs manage costs, quality, and

utilization of beneficiaries, and obtaining information on the types of services that comprise the intervention offered. Key characteristics include:

Outreach to MHS Beneficiaries. All of the MHSOs conducted a range of activities to engage beneficiaries. When contacting potential participants, CMS sent personalized letters, followed by telephone calls inviting individuals to participate in the MHS pilot program. Four of the MHSOs also conducted on-the-ground efforts to secure MHS participation. While all eight of the MHSOs segmented the market to determine who should be contacted in what order, some based their prioritization on health status (i.e., beneficiaries at highest risk for adverse events, such as hospitalization or death, were called first). Others conducted demographic modeling (based primarily on socioeconomic status) as the basis for prioritizing the initial outbound calls, reaching out first to individuals profiled as most likely to consent to participate in the MHS program. One MHSO was unique in providing a $10 gift card incentive for consenting to participate in the MHS program. Several MHSOs changed their participant outreach strategy—and the content of their outreach messages during the 6-month outreach period—from emphasizing the voluntary nature of the program to a more assumptive approach emphasizing how and when to schedule the first MHS intervention call. All the MHSOs were faced with a similar set of challenges, including outreach to beneficiaries during the time when the Medicare Part D Drug Program was beginning, not having telephone numbers for all beneficiaries in their target population, and difficulty reaching beneficiaries who reside in institutional settings.

Outreach to Providers. All MHSOs tried in varying degrees to reach out to providers and engage them early in the process. MHSOs sent personalized welcome letters/packets to physicians serving Medicare beneficiaries in each of their defined geographic areas. Each MHSO identified the "high-volume" providers from CMS claims data and contacted those providers first. Medical offices were visited on site (sometimes the MHS outreach person spoke only with the office manager, while other times, the person was able to speak directly with physicians). The provider outreach coordinator(s) typically was a nurse. MHSO medical directors generally supported provider outreach coordinators, often accompanying them on office visits, and/or working directly with practices having difficulty understanding/embracing the MHS program. All but two of the MHSOs followed this model.

While most community physicians are not directly compensated for their participation in the MHS program, three MHSOs provide incentives to physicians for contact information provided to help MHSOs locate potential MHS participants. These same MHS programs also provide physician compensation for collaborating in patient care management and providing guideline-concordant care or for confirming or providing clinical information on MHS participants. Each MHS program has at least one local medical advisory committee that provides guidance on outreach to physicians and reviews the components of the MHS program on an ongoing basis.

During our initial site visits at each MHSO, we spoke with two to four randomly selected community-based physicians to gauge their early assessment of their satisfaction with the MHS pilot programs. Universally, the community-based physicians felt that the programs could benefit Medicare FFS beneficiaries with chronic conditions. Not unexpectedly, their exposure had been sufficiently limited that they were unable to provide estimates of their current level of satisfaction with the programs. During Year 2 of each program, RTI will field a mail survey of

community-based physicians that will more broadly examine their exposure to and satisfaction with the MHS pilot programs.

Outreach to the Community. Although most of the MHSOs provided some type of outreach to the community, the level and emphasis of this outreach activity varied widely by MHS program. MHSOs consulted with community advisory boards or tribal leaders, worked with local Area Agencies on Aging (AAAs) and local community agencies to help locate potential MHS participants and to gain support for the MHS program, and developed special relationships with Medicare fiscal intermediaries and carriers, social service agencies, and other community service agencies.

Implementation Challenges Reported by the MHSOs. As a result of their early experiences with the MHS program, the MHSOs reported several challenges encountered during program implementation and offered recommendations for potential future rollouts of care management programs by CMS. All the MHSOs were faced with a similar set of outreach challenges, including the initiation of Medicare Part D Drug Program while MHS staff was trying to engage individuals in the MHS pilot program, not having telephone numbers for all beneficiaries in their intervention group, and difficulty locating and reaching institutionalized beneficiaries.

During the site visits, all the MHSOs mentioned problems and suggestions about data. Their concerns address the reporting of their performance data to CMS, the system CMS uses to pay MHSOs and track individual beneficiary eligibility for MHS, getting assistance in using the CMS systems, and the receipt of claims and eligibility data files from CMS. MHSOs found many of CMS's processes very complex, complicated by CMS's large and cumbersome data manuals and changes CMS made to the data transmission protocols following the launch of the MHS program. For the MHS program, CMS utilizes the same system that is used to pay Medicare Advantage plans; effective January 2006, that system was modified to accommodate Part D plan payments. A number of MHSOs relayed problems related to the system modifications as well as concerns that neither the old nor new system is sufficiently tailored to the MHSO program. Specific concerns cited include that the system is difficult to use for financial monitoring of program payments because it does not easily allow the MHSOs to link specific beneficiaries with payments. CMS provides the MHSOs with aggregate payment statements, but individual beneficiary records must be queried to confirm eligibility and payment, including retroactive changes.

In addition, MHSOs have requested that they receive claims data on the intervention and comparison populations more frequently. Some stated they would have preferred that the program had been designed to randomize beneficiaries at the physician practice level rather than at the individual beneficiary level. Although randomization at the beneficiary level was specified in the program solicitation, MHSOs have offered that randomization at the practice level could decrease the potential for contamination between the intervention and comparison group within a given physician's practice and would have been more favorable to practice-level rather than beneficiary-level interventions. Several MHSOs were disappointed that they did not have the opportunity to expand their programs to a larger population, either in the same state or across multiple states; the statute does permit expansion in Phase II.

CHAPTER 3
EARLY FINDINGS RELATED TO BASELINE CHARACTERISTICS OF MHS BENEFICIARIES, LEVEL OF PARTICIPATION, AND CHARACTERISTICS OF PARTICIPANTS AND NON-PARTICIPANTS

3.1 Introduction

The Medicare Health Support (MHS) programs target Medicare fee-for-service (FFS) beneficiaries with the clinical conditions of heart failure (HF) and/or diabetes and a Hierarchical Condition Categories (HCC) score of 1.35 or greater. To provide a contextual overview of the population eligible for participation, we paint a statistical portrait of the demographic, clinical, and financial characteristics of beneficiaries randomized to the MHS pilot program. Further, we confirm that the block (stratified) randomization procedure produced similar demographic, disease, and economic burden profiles between the intervention and comparison groups at the time of randomization.

We also examine whether there are any systematic baseline differences in the disease burden and prior medical utilization patterns between the intervention and comparison group beneficiaries assessed at the start of the pilot programs because of the lag between randomization and the start of each pilot program. Randomization occurred based on eligibility criteria as of May 11, 2005, with start dates of the Medicare Health Support Organization (MHSO) pilot programs ranging from August 1, 2005, to January 16, 2006. This examination allows us to determine if there are meaningful differences between the intervention and comparison groups present at the start of each pilot.

Our initial analysis is designed to critically evaluate the level of initial engagement by the MHSOs in this novel, population-based program and to identify any characteristics that systematically vary between participants and non-participants within the intervention groups. The analyses are designed to answer the broad policy question about the depth and breadth of the reach into the community—i.e., how well do the MHSOs engage their intended audiences? Subsequent years of the evaluation will focus on retention rates during the full course of the pilot program, changes in characteristics of active participants and non-participants for the intervention group, and a comparison of changes in characteristics between the intervention and comparison groups.

3.2 Characteristics of MHS Beneficiaries at the Time of Randomization

This section describes the MHS populations and contrasts differences across the geographic areas. No statistical testing is conducted across MHSOs as our primary evaluation is comparing differences between the intervention and comparison groups within each MHSO pilot program. Table 3-1 displays selected demographic characteristics of Medicare FFS beneficiaries randomized to the MHS pilot program. The proportion of beneficiaries who aged in to the Medicare program (as opposed to being eligible based on disability) ranges from 79% to 91%. There are also substantive differences in the rate of Medicare/Medicaid dual enrollment across the MHSOs, ranging from a low of 14% to a high of 43%. Racial distributions also differ considerably across the MHSOs, reflecting the diversity of the geographic areas and levels of urbanicity of the selected sites. These findings are consistent with the Centers for Medicare &

Medicaid Services' (CMS's) interest in piloting the program in diverse populations and diverse geographies.

Table 3-1
Selected demographic characteristics of Medicare beneficiaries randomized to the Medicare health support pilot program

MHSO	Aged in to Medicare (%)	Medicaid participation (%)	White (versus Black or other) (%)
1	91	14	91
2	88	17	93
3	80	34	78
4	79	43	64
5	91	16	77
6	84	25	76
7	89	16	68
8	86	21	84

The distribution of beneficiaries in the threshold disease groups of HF and diabetes across the MHSOs typically follow a similar pattern whereby about half of the beneficiaries have the threshold condition of diabetes only, and about one-quarter each have HF only and HF with diabetes. Mean HCC scores range modestly from 2.3 to 2.6, with fairly similar distributions across the three randomization levels of HCC scores.

The level of comorbidity is very high among both the intervention and comparison populations during the year prior to randomization. Almost half of all beneficiaries have diagnoses of coronary artery disease. Twenty-five to 35% of beneficiaries have diagnoses related to cardiac dysrhythmias and conduction disorders. Almost one third of beneficiaries have diagnoses related to respiratory diseases, such as chronic obstructive pulmonary disease. Fifteen to 20% of beneficiaries have evidence of acute or chronic renal disease, while roughly 10% of beneficiaries have diagnoses related to valve disorders, cardiomyopathy, peripheral vascular disease, and renal failure. Five percent or fewer of beneficiaries have prior claims-based diagnoses of stroke or dementias.

We also observe high rates of acute care utilization during the year prior to randomization. Rates of all cause hospitalizations range from 83 to 116 per 100 beneficiaries. However, only a small fraction of the hospitalizations are for the principal reason of HF or diabetes; 15% or fewer are for HF and 5% or fewer are for diabetes. This likely reflects the myriad of comorbid conditions present in the MHS population. Rates of all cause emergency room (ER) visits range from 51 to 106 per 100 beneficiaries. As with acute hospitalizations, very few ER visits are principally for HF or diabetes.

Average per-beneficiary-per-month (PBPM) total Medicare payments range from $1,214 to $1,671 in the year prior to randomization. The pattern of variation is consistent with previously observed geographic variation in average Medicare payments. Acute hospital

payments account for the largest component of the PBPM followed by physician payments, outpatient department payments, skilled nursing facility payments, and home health payments.

3.3 Characteristics of Intervention and Comparison MHS Populations at Randomization and Start of Pilot

We compare the intervention and comparison populations within each MHSO at the time of randomization across a large number of demographic, health status, utilization, and payment characteristics. Our analyses reveal that the block (stratified) randomization scheme effectively created equivalent intervention and comparison populations at the time of randomization for each of the eight MHSOs for the variables that were used in randomization (i.e., three HCC score ranges, Medicaid enrollment, and proportion with HF). We also confirm that the block (stratified) randomization procedure produced similar demographic, disease, and economic burden profiles between the intervention and comparison groups at the time of randomization. We find limited statistical and no substantive differences between intervention and comparison groups within MHSOs in demographic characteristics including mean age, distribution of age groups, percentage male, percentage urban, percentage white or black, percentage aged-in versus disabled, or percentage Medicaid. In addition, we find limited statistical and no substantive differences between intervention and comparison groups in health status as measured by mean HCC score based on score at time of randomization (Table 3-2), the distribution of HCC scores based on score at time of randomization, or the Charlson co-morbidity index.

Table 3-2
Mean HCC scores of intervention and comparison populations at time of randomization[1]

	Intervention	Comparison[2]
1	2.6	2.6
2	2.6	2.6
3	2.5	2.5
4	2.3	2.3
5	2.6	2.6
6	2.4	2.5
7	2.6	2.6
8	2.4	2.4

[1] Calculated using Medicare Part A and B claims for the 12-month period prior to randomization.

[2] There are no statistically significant differences at the 5% level or better.

We find virtually no statistical or substantive differences between the intervention and comparison populations in rates of several chronic conditions and prior rates of hospitalizations and emergency room visits. Table 3-3 displays rates of all cause, heart failure, and diabetes hospitalizations per 100 Medicare FFS beneficiaries. It is important to note that some statistically significant differences are to be expected—even after a randomization process—as a result of the large number of comparisons conducted. At the 5% level of significance, for example, we expect

to find statistically significant differences in 1 out of every 20 t-tests performed based on random chance. Furthermore, our sample sizes are extremely large from a statistical power perspective; thus, extremely small differences may be statistically significant.

Table 3-3
Comparison of rates of all cause, heart failure, and diabetes hospitalizations per 100 Medicare beneficiaries between Intervention and Comparison populations at time of randomization[1]

MHSO	All cause		Heart failure		Diabetes	
	Intervention	Comparison[2]	Intervention	Comparison[2]	Intervention	Comparison[2]
1	83	83	12	13**	2.6	2.9
2	100	102	15	15	3.8	3.5
3	90	92	12	13	4.0	4.1
4	96	98	13	14	5.3	5.5
5	116	114	17	16	5.1	5.2
6	83	84	11	11	3.7	3.7
7	93	90*	12	11	4.0	3.6
8	99	98	13	12	3.7	3.8

[1] Calculated using Medicare Part A and B claims for the 12-month period prior to randomization.

[2] * indicates difference is statistically significant at the 5% level.

** indicates difference is statistically significant at the 1% level.

Table 3-4 displays PBPM total Medicare payments for the year prior to randomization for intervention and comparison populations within each MHSO. These PBPMs are calculated using Medicare claims data for the year prior to randomization and are weighted by months of eligibility in Medicare Part A for the 12-month period. No trimming of outliers has been applied as is currently specified in the financial reconciliation protocol. Also, these average PBPMs differ modestly from those presented in Chapter 6 related to key financial findings as those PBPMs are calculated for only beneficiaries who are eligible during the pilot period. We observe no statistically significant differences in PBPMs between the intervention and comparison groups at the time of randomization. Although not statistically significant, we note that the average PBPM for MHSO 3's intervention group is 3% lower than its comparison group. Three MHSOs have intervention PBPMs that are 1% lower than their respective comparison group, and one MHSO has an intervention group PBPM that is 1% higher than its comparison group's PBPM. This topic is explored in more detail in Chapter 6.

Establishing the equivalence of the intervention versus comparison groups is important under an intent-to-treat model. Our analyses at the time of randomization confirm equivalency. However, an unexpected pattern emerges between the time of randomization and the start of the MHS pilots that may have policy implications for CMS's financial reconciliation in Phase I and for Phase II plans for disease management in FFS Medicare. Substantive differences between the intervention and comparison populations emerge in the interval between randomization and go-

live, most notably, in baseline PBPM payments, when we evaluate these measures for only those beneficiaries who are eligible during the pilot. To a lesser degree, we observe a growing divergence in prior rates of hospitalizations and ER visits.

Table 3-4
Mean per-beneficiary-per-month (PBPM) total Medicare payments[1] of Intervention and Comparison populations at time of randomization[2]

MHSO	Intervention PBPM ($)	Comparison PBPM ($)[3]
1	$1,327	$1,311
2	1,352	1,368
3	1,292	1,327
4	1,288	1,297
5	1,671	1,658
6	1,214	1,226
7	1,496	1,494
8	1,368	1,368

[1] PBPM Medicare payments are weighted by months of eligibility for Medicare Part A. The numbers in Table 3-4 vary slightly from those presented in Chapter 6 due to differences in the weighting of the data and the reference period.

[2] Calculated using Medicare Part A and B claims for the 12-month period prior to randomization.

[3] There are no statistically significant differences at the 5% level or better.

Even though the differences are relatively small, they may affect the MHSOs' abilities to achieve their objectives, especially if financial success is determined by a 1 to 2 percentage point change in Medicare expenditures between the intervention and comparison groups. For example, beneficiaries in one MHSO's intervention group have monthly total Medicare payments that are about 6% higher than the comparison group at the start of its pilot. This amount might seem modest, but it is a substantial portion of the monthly fee the MHSO receives. Six of the MHSOs' intervention populations have higher PBPMs in the year prior to the start of their pilots compared to the comparison populations, ranging from 1% to 6% (data shown in Table 6-1). While only the difference in one MHSO group's PBPM is statistically significant at the 5% level or better at the start of the pilot, the financial reconciliation protocols as initially agreed upon do not make adjustments for differences in payments at the start of the pilot. These differences can be actuarially adjusted and further exploration as to the underlying reasons for the divergence should be undertaken. Such divergence may represent the influence of a small number of outliers with extreme medical expenditures for which additional statistical adjustment may be warranted.

3.4 Participation Rates During the First 6-month Pilot Programs

Table 3-5 displays the participation rates during the first 6 months of the MHS pilot programs. An eligible beneficiary is considered a participant if he or she was contacted by the MHSO and verbally consented to participation. Thus, intervention group beneficiaries are either participants or non-participants. Future analyses will capture length of participation by individual beneficiaries.

Participation rates in the first 6-month period range from a high of 92% for MHSO 2 to a low of 65% for MHSO 3. Mean time-to-agreement to participate for all participants ranges from 37 to 100 days across the MHSOs. This means that the effective intervention start dates (at the beneficiary level) are substantially later than the go-live dates. Thus, this initial evaluation reflects considerably less than 6 months of active care management.

Table 3-5
Participation rates during the first 6 months of the MHS program, by MHSO

MHSO	First 6-month pilot participation rate (%)
1	70.0%
2	92.3
3	65.0
4	83.6
5	80.3
6	83.2
7	82.6
8	75.6

3.5 Characteristics of Participants and Non-participants

Once the pilot programs began operation, a second pattern emerged whereby the participating beneficiaries tend to be considerably healthier and less costly in the prior year compared to the non-participants. We define a participant as an intervention beneficiary who consented to participate at any point during the initial 6-month pilot. This descriptive analysis includes the full intervention and comparison populations, including those who lost eligibility between randomization and the start date, to fully capture the differences between the randomized population and the population engaged by the MHSOs. We find that the participant populations are different from the non-participant populations across the majority of demographic, health status, utilization, and payment characteristics reviewed. In all pilot programs except one, the proportion of beneficiaries with Medicaid enrollment is about 5% lower for participants than for non-participants, meaning that most MHSOs have not been as successful at recruiting dual eligible (Medicare/Medicaid) beneficiaries to participate. Participants have mean HCC scores calculated for the 1-year period prior to going live that are substantially lower than non-participants (Table 3-6) indicating that the MHSOs are engaging significantly healthier beneficiaries from a health status perspective.

Table 3-6
Mean HCC scores of participants and non-participants one year prior to go-live[1]

MHSO	Participants	Non-participants[2]
1	2.4	3.3**
2	2.5	3.7**
3	2.3	2.6**
4	2.2	2.7**
5	2.4	3.2**
6	2.3	2.9**
7	2.5	3.1**
8	2.3	2.7**

[1] Calculated using Medicare Part A and B claims for the 12-month period prior to the start of each MHSO pilot program. Includes all randomized beneficiaries.

[2] ** indicates difference is statistically significant at the 1% level.

We also observe that participants have lower rates of comorbid conditions than non-participants. As one example, Table 3-7 displays rates of acute and chronic renal disease for participants and non-participants. Between 13% and 17% of participants have a claims-based diagnosis of renal disease. In contrast, between 16% and 28% of non-participants have a diagnosis of renal disease. Within each MHSO, participants are more likely to have received three of the four recommended tests representing receipt of guideline concordant care. There were no observed substantive differences in rate of urine protein screening between participants and non-participants.

Table 3-7
Prevalence per 100 beneficiaries of acute and chronic renal disease for participants and non-participants 1 year prior to go-live[1]

MHSO	Participant	Non-participants[2]
1	15	22**
2	16	28**
3	16	20**
4	13	18**
5	16	24
6	17	22
7	15	20**
8	13	16**

[1] Calculated using Medicare Part A and B claims for the 12-month period prior to the start of each MHSO pilot program. Includes all randomized beneficiaries.

[2] ** indicates difference is statistically significant at the 1% level.

Table 3-8 displays rates of all cause, heart failure, and diabetes hospitalizations per 100 MHS beneficiaries. All cause hospitalizations rates range from 67 to 96 per 100 participating beneficiaries. In contrast, all cause hospitalization rates range from 122 to 196 per 100 nonparticipating beneficiaries. Within each of the MHSOs the differences are quite profound, with the difference ranging from 37 to 102 more hospitalizations per 100 nonparticipating beneficiaries and observed for participating beneficiaries. A similar pattern is observed for heart failure and diabetes hospitalizations.

Table 3-8
Comparison of rates of all cause, heart failure, and diabetes hospitalizations per 100 MHS beneficiaries between participants and non-participants 1 year prior to go-live[1]

	All cause		Heart failure		Diabetes	
MHSO	Participants	Non-participants[2]	Participants	Non-participants[2]	Participants	Non-participants[2]
1	67	137**	7	20**	2.2	4.5**
2	94	196**	13	35*	3.4	7.4
3	68	123**	7	16**	2.5	4.9**
4	84	131**	11	20**	4.2	7.3**
5	96	172**	13	27**	3.8	7.8*
6	75	134**	9	20**	2.8	6.3*
7	81	140**	9	20**	3.3	6.1
8	85	122**	10	16*	3.0	4.9

[1] Calculated using Medicare Part A and B claims for the 12-month period prior to the start of each MHSO pilot program. Includes all randomized beneficiaries.

[2] * indicates difference is statistically significant at the 5% level;
** indicates difference is statistically significant at the 1% level.

Participants in all eight pilot programs have markedly lower total Medicare PBPM payments than non-participants in the year prior to the start dates (Table 3-9). Mean participant payments range from $477 to $1,329 per month lower than non-participant PBPMs. Thus, the MHSOs are engaging considerably less expensive intervention beneficiaries and not engaging the sicker, more costly beneficiaries.

Table 3-9
Mean per-beneficiary-per-month (PBPM) total Medicare payments[1] of participants and non-participants 1 year prior to go-live[2]

MHSO	Participant	Non-participants[3]
1	1,170	2,028**
2	1,286	2,615**
3	1,064	1,754**
4	1,167	1,771**
5	1,432	2,494**
6	1,158	1,865**
7	1,333	2,270**
8	1,214	1,691**

[1] PBPM Medicare payments are weighted by months of eligibility for Medicare Part A. Includes all randomized beneficiaries. The numbers in Table 3-9 vary slightly from those presented in Chapter 6 due to differences in the weighting of the data.

[2] Calculated using Medicare Part A and B claims for the 12-month period prior to the start of each MHSO pilot program.

[3] ** indicates difference is statistically significant at the 1% level.

CHAPTER 4
BASELINE FINDINGS FROM MHS BENEFICIARY SURVEY

The primary purpose of the Medicare Health Support (MHS) beneficiary survey is to determine the impact of the MHS interventions on beneficiary satisfaction. Secondary objectives of the MHS beneficiary survey are to provide beneficiary characteristics and behaviors not available through administrative data, which will enable us to determine the impact of the MHS program on behavioral change, physical functioning, and emotional well-being. To ensure that the survey questions are also relevant to individuals who are not participating in an MHS program, both those who declined as well as the comparison population, the beneficiary survey contains questions about services provided by a beneficiary's health care team, with no questions directly related to the MHS pilot program.

The purpose of this chapter is to report on baseline survey characteristics of beneficiaries in the intervention and comparison groups in each of the pilot programs. A follow-up survey of beneficiaries, which will be implemented 1 year after the baseline survey, will provide data on change in satisfaction resulting from the MHS program. Baseline characteristics of survey samples are presented, as well as differences between beneficiaries in the intervention and comparison groups by Medicare Health Support Organization (MHSO). Since beneficiaries randomized to the intervention group had limited exposure to the MHS programs at the time of this survey, we expect that the baseline survey results for the intervention and comparison groups will be similar.

4.1 Survey Methodology

Individual beneficiaries for the survey were randomly sampled from the larger intervention and comparison populations assigned to each MHSO. We randomly selected 755 intervention beneficiaries and 863 comparison beneficiaries from each site for the baseline survey mailing. We surveyed beneficiaries by mail with a telephone follow-up of nonrespondents.

Satisfaction is measured by four items that tap assessments of the quality of interactions with the beneficiary's health care team, as well as an overall evaluation item. The selected items have been adapted from similar questions in the Consumer Assessment of Health Plans Survey (CAHPS) ambulatory care instrument. These items allow us to measure satisfaction with health care that can be impacted by the MHS program but is not specific to the MHS program. These items apply to all members of an individual's health care team so that we may compare satisfaction among individuals in the intervention group with those in the control group, who are not receiving the MHS intervention.

A series of statistical analyses was conducted to evaluate the quality and comparability of the self-reported beneficiary data from the MHS baseline survey. The first analysis examined the likelihood of responding to the survey. The overall response rate was 70%. The response propensity analysis revealed that older beneficiaries and those in poorer health were less likely to complete surveys than other beneficiaries. This is consistent with response patterns for most mixed-mode surveys of the Medicare population. Beneficiaries with high Hierarchical Condition Categories (HCC) risk scores tend to have higher mortality rates, so that a portion of the baseline

nonrespondents would not be alive at the time of a follow-up survey. Beneficiaries assigned to intervention groups had a slightly lower response rate than comparison group beneficiaries. The characteristics of survey respondents were also compared to those for all approximately 30,000 beneficiaries in each MHSO's intervention and comparison population. These comparisons yielded similar findings to those for the multivariate analyses.

4.2 Baseline Characteristics of MHS Beneficiaries

MHS intervention effects on the major study outcomes are to be estimated from a follow-up survey of the baseline respondents. It is therefore important that the intervention and comparison groups of respondents be comparable at the beginning of the evaluation period so that any changes over time in the comparison group may be used as the benchmark for inferring changes attributable to intervention activities. Group equivalence was tested in two ways: We first looked to see if there were certain characteristics that were associated with who was likely to be in the intervention versus comparison group. We did this by using a multivariate analysis which showed that beneficiary characteristics such as risk score, disease category, or demographic characteristics were not associated with the likelihood of a beneficiary being in the intervention versus comparison group. In addition, we compared the intervention and comparison group values within MHSOs for each of the baseline survey variables. The number of statistically significant differences emerging from this large set of comparisons was roughly what would be expected by chance. Several of the significant differences were the result of small cell sizes in some tables. Most of the differences that were found were scattered across the individual programs.

Health status, both physical and mental, was measured in several ways. While there were no significant differences noted between the intervention and comparison groups, there were some differences among MHSOs. Of note is the finding that the population as a whole is quite frail. Functioning was measured by items from the VR-12, the Department of Veterans Affairs' version of the SF-12. This instrument produces both a physical component score (PCS) and a mental component score (MCS). The six standard activities of daily living (ADL) tasks are included as an additional measure of physical functioning. We also included the questions that compose the Patient Health Questionnaire-2 to serve as a screening tool for depression.

We found that mean scores for VR-12 PCS ranged from 27 to 33 at individual MHSOs, reflecting a frail and sick population manifesting the severe physical impact of HF, diabetes, and other comorbidities in this population. The ADL measure, which reports on difficulty with everyday activities such as bathing, dressing, eating, getting out of a chair, walking, and toileting, was also indicative of frailty; for example, between 55% and 69% of respondents reported some difficulty with walking and between 22% and 32% of respondents reported difficulty with dressing. This compares with a national survey of Medicare fee-for-service (FFS) beneficiaries that found that approximately 23% of all fee-for-service beneficiaries report some difficulty performing at least one of these activities (West et al., 2005). Reports of difficulty with walking are more than double the findings for the general FFS population.

The MCS scores ranged between 42 and 49, which is modestly lower than the general population mean of 50. Only one MHSO showed any differences on mental health scores between its intervention and comparison population. However, we do observe very high levels of

depression risk from the two-item screening tool among both the intervention and comparison cohorts. The prevalence rates for depression risk varied across MHSOs, ranging from 29% to nearly half of all beneficiaries.

There was some evidence that the MHSOs that started the earliest had already begun delivering some components of their programs by the time the baseline surveys were completed. In half of the MHSOs, more intervention group beneficiaries reported that they had received one-on-one educational or counseling sessions or print or video materials than those in the comparison groups. In some sites, intervention beneficiaries also reported they checked their feet or weighed themselves more often during the past week. Like many studies involving self-efficacy, many beneficiaries were confident that they could perform the required types of self-care behaviors. This was especially true for medication use and foot surveillance on the part of diabetics. The two behaviors were already being performed an average of 5 days per week. Given the already high compliance rates, there is little room for further improvement in these rates.

Overall, our analysis of the baseline survey data revealed that the intervention and comparison groups at each MHSO were very similar, as expected. A small number of minor differences are noted below; however, these statistical differences are not unexpected when conducting the large number of statistical tests needed to examine the information provided by beneficiaries at eight MHSOs. Further, some differences observed were due to small numbers of beneficiaries in the groups being compared for each characteristic and, therefore, do not represent meaningful population differences.

4.3 Baseline Beneficiary Satisfaction with Health Care

Beneficiaries were asked to rate their overall experience with their health care team using a 5-point scale anchored by “excellent” and “poor.” Approximately 80% of beneficiaries at each MHSO rated their experience with their health care providers as good, very good, or excellent. The most common response across MHSOs was “very good.” The distribution of responses at only one MHSO was statistically significantly different overall between intervention and comparison groups at baseline.

The survey contained four questions that make a composite item, taken from the Ambulatory CAHPS Survey, related to the quality of communication between beneficiaries and their providers. Communication is an important component of patients’ experience and satisfaction with their health care. Specifically, beneficiaries were asked whether their health care team did the following:

- Explain things in a way that was easy to understand.
- Listen carefully to you.
- Give you clear instructions about what to do when health problems came up.
- Spend enough time with you.

Respondents indicated whether each aspect of communication was conducted always, usually, sometimes, or never. Overall, beneficiaries were satisfied with provider communication, as evidenced by the fact that the most common response across all of the questions was “always,” and at least 70% of beneficiaries at each MHSO rated each item as “always” or “usually.”

In summary, we found considerable frailty and risk of depression, but no major baseline differences between the intervention and comparison groups. In the follow-up survey analysis, we will look for differences between the intervention and control that may result from the intervention, however, there are some outcomes where there is already a high level of behavior leaving little room for improvement. For example, medication adherence and foot surveillance on the part of diabetics: for these two behaviors beneficiaries are already reporting that they are being performed an average of 5 days per week. Given the already high compliance rates, there is little room for further improvement in these rates. In the follow-up analysis, for outcomes where some decline may be seen resulting from natural progression of disease, we will examine whether the decline is less in the intervention versus the control groups.

CHAPTER 5
PRELIMINARY FINDINGS RELATED TO QUALITY IMPROVEMENT AND HEALTH OUTCOMES

5.1 Methodology

We define quality of care as adherence to evidence-based guideline-concordant care, and selected four measures related to the threshold conditions of heart failure (HF) and diabetes as the focus of our evaluation for this report: rate of annual HbA1c testing (diabetes); rate of dilated retinal eye examination (diabetes), rate of low-density lipoprotein cholesterol (LDL-C) testing (diabetes and/or HF), and rate of urine protein screening (diabetes). Medicare claims data are used to assess adherence to guideline-concordant care through the development of a set of process measures that we believe are reliably calculated from Medicare claims data. National Quality Forum (NQF)-endorsed National Voluntary Consensus Standards for Physician-Focused Ambulatory Care specifications are used to create the four process-of-care measures that we report.

We construct baseline rates of receipt of these process measures for two 1-year periods prior to each MHSO go-live date. We also create process-of-care measures for the 6-month period immediately prior to each MHSO's go-live date and for the first 6-month pilot period. Because the process-of-care measures that we study are defined as annual rates of service, we believe that it would be inappropriate to evaluate the performance of the MHSOs using only 6 months of intervention experience; however, we wanted an early indicator of status at the 6-month point. Therefore, we report the percentage of intervention and comparison beneficiaries who did not receive the service in the 6-month period prior to the pilot but received the service during the 6-month intervention period. These numbers provide a snapshot of the degree to which the MHSOs are reaching beneficiaries with no prior receipt of the service and effecting change. No statistical comparisons are made here for the process-of-care measures.

In this report, we focus on three utilization measures to capture the intervention's effectiveness in improving the quality of outpatient care, thereby reducing the acute exacerbations of the intervention beneficiaries' chronic diseases that result in acute institutional care. Three sets of intermediate clinical outcome variables are constructed for the principal diagnoses of all-cause, HF, and diabetes: hospitalizations; 30-day readmissions; and emergency room (ER) visits, including observational bed stays. We construct utilization rates for the first 6-month intervention period and for a comparable 6-month period during the year prior to each MHSO's go-live date. The comparable 6-month period in the prior year was selected to remove the seasonality influence on these measures. Changes in utilization rates are assessed for both the intervention and comparison groups, and are reported separately for three patient populations: those with both diabetes and HF, HF only, and diabetes only.

We assess changes in health outcomes by analyzing changes in a claims-based measure of health status, using the concurrent Hierarchical Condition Categories (HCC) model calculated by RTI for the first 6 months of the intervention period, as well as the 6-month period prior to the start of each pilot. In contrast to the predictive HCC model, which uses a prior year's worth of claims data to generate a risk score indicative of the next year's Medicare costs, the concurrent model produces an HCC score based on the current period's claims experience. Thus, we have a

measure of health status that is contemporaneous with our period of observation. Lastly, we report mortality rates during the first 6-month intervention period.

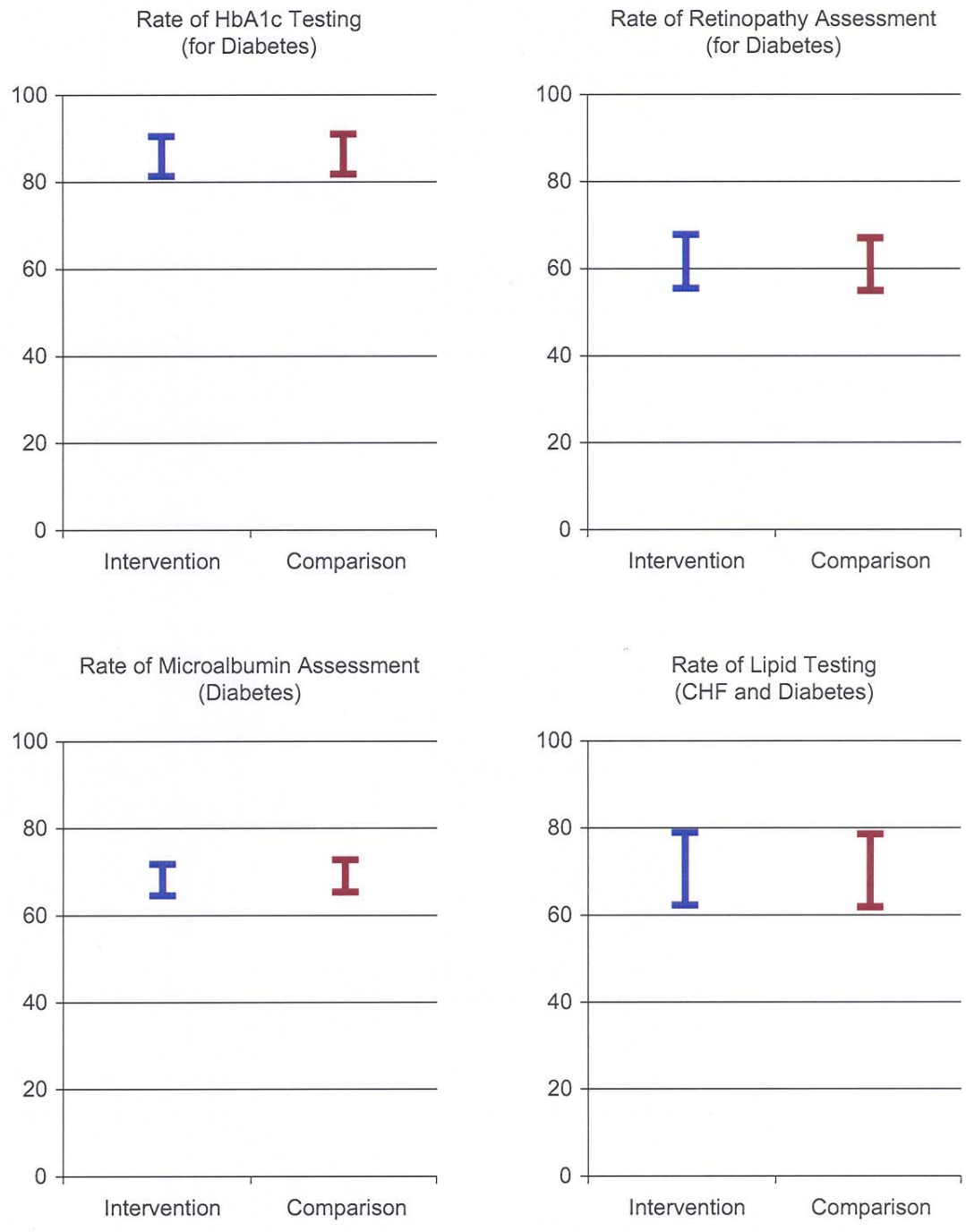
5.2 Results

Adherence to guideline-concordant care, consistent with standard HEDIS® quality-of-care measures for persons with heart failure or diabetes, varies considerably across the MHSOs during the year prior to the start of the pilot. Rates of annual HbA1c testing are universally high—above 75% in both the intervention and comparison populations across all the MHSOs. Annual rates of retinal eye examinations, urine protein screening, and lipid testing are lower than those observed for HbA1c testing; retinal eye examination rates range from 55% to 67%; urine protein screening rates range from 66% to 74%; and lipid testing rates range from 60% to 79%.

During the first 6-month pilot period, we observe no differential pattern of adherence to care between the intervention and comparison groups for the four selected measures; however, as noted earlier we do not conduct statistical testing. Figure 5-1 displays the range of rates per 100 MHS beneficiaries across the MHSOs during the first 6-month period for the intervention and comparison groups. The rate of HbA1c testing is generally very high across all the MHSOs, providing limited opportunity for quality improvement; however, 50% or fewer intervention beneficiaries who did not receive an HbA1c test in the 6-month period prior to the initiation of the pilot receive a test during the first 6-month intervention period. The rates of LDL-C testing, urine protein screening, and retinal eye examinations all have lower baseline rates of receipt than the rates observed for HbA1c testing. For each of these three process-of-care measures, there is considerable improvement opportunity for the MHS pilot programs. However, only about one-third of all intervention beneficiaries with no prior receipt of an LDL-C screening receive the test during the first 6 months of the pilot. Similarly, only about one-third of intervention beneficiaries with diabetes who had no prior receipt of a urine protein screening receive the test during the first 6 months of the pilot. The greatest opportunity for the MHSOs appears to be related to retinal eye examination. Only one-quarter of beneficiaries with diabetes who had not previously received a retinal eye examination receive one during the first 6 months of the intervention period.

Consistent with the data presented in Chapter 3 for the year prior to randomization, 6-month rates of hospitalization and ER visits for HF or diabetes remain a small fraction of all-cause hospitalization or ER visits. Across the MHSOs and for beneficiaries with HF, the rates of hospitalizations with a principal diagnosis of heart failure are typically one-fifth of the all cause hospitalization rates. For beneficiaries with diabetes, the rates of hospitalizations with a principal diagnosis of diabetes are typically one-tenth of the all cause hospitalization rates. This reinforces the notion that MHS beneficiaries have a significant amount of other clinical comorbid conditions that result in the use of acute care. A review of the frequency of principal diagnoses for nondiabetes or HF acute events reveals that many are related to pneumonia or other respiratory diseases and coronary artery disease. Clearly, the MHSOs must focus on reducing these types of acute utilization events to achieve cost savings among the MHSO beneficiaries.

Figure 5-1
Range of rate of guideline-concordant care per 100 Medicare health support intervention and comparison populations during the first 6-month MHS pilot period



For beneficiaries with the threshold condition of HF (with or without diabetes), the general pattern is one whereby rates of hospitalization, 30-day readmission, and ER visits generally decline during the first 6-month intervention period relative to a comparable 6-month period in the prior year. The decline is observed for both the intervention and comparison populations. However, there are very few statistical or substantive differences in rates of acute care utilization between the intervention and comparison groups. The observed declining trend may reflect regression-to-the-mean or random volatility of the clinical condition of heart failure. In contrast, utilization rates tend to show small increases during the first 6-month pilot period across all MHSOs for both the intervention and comparison populations for beneficiaries with diabetes. This may reflect a steady worsening of the diabetes clinical state or random volatility. Once again, few of the differences are statistically or substantively different.

Across all three threshold condition populations, we do not observe any statistically significant differential change between intervention and comparison populations in mean HCC scores during the first 6-month pilot period as compared with mean HCC scores for the 6-month period just prior to the start of the pilot. We do observe statistically significant differential rates of mortality between intervention and comparison populations during the first 6-month pilot period (Table 5-1); however, many of the differences are not substantively meaningful. Among beneficiaries with HF only, we observe that four MHSOs have statistically significant differences between their intervention and comparison populations during the first 6-month intervention period; the intervention population rates are higher than those of their comparison populations. Among beneficiaries with both HF and diabetes, two MHSOs' intervention populations have higher rates of death during the first 6-month intervention period than do their comparison populations. One MHSO has a lower death rate among its intervention beneficiaries with both HF and diabetes. In contrast, death rates among beneficiaries with the threshold condition of only diabetes are lower among the intervention populations for four MHSOs. There is only one MHSO whose intervention population death rate among beneficiaries with diabetes only is higher than its comparison population. As observed in the participation analysis, beneficiaries who consented to participate are generally a healthier population than non-participants. Across all eight MHSOs, the death rates for participants (1.4 to 4.2 per 100) are dramatically lower than death rates for non-participants (6.4 to 16.2 per 100).

Table 5-1
Comparison of intervention and comparison group mortality rates during the first 6-month MHS pilot period, by MHS threshold condition

	HF Only			HF and Diabetes			Diabetes Only		
	I	C		I	C		I	C	
MHSO	(%)	(%)	P value	(%)	(%)	P value	(%)	(%)	P value
1	9.7	9.8		7.3	7.8		3.9	3.8	
2	8.7	8.3		7.8	7.7		3.8	3.1	***
3	7.0	5.9	***	5.6	5.5		2.9	3.1	**
4	8.2	7.6	**	6.4	5.4	***	3.2	3.8	***
5	8.1	8.4		6.0	5.8		3.5	3.8	***
6	9.7	8.1	***	7.5	8.5	***	3.4	3.5	
7	8.0	8.0		6.3	5.2	***	2.8	3.3	***
8	8.5	7.9	**	7.2	7.3		3.7	3.8	

NOTES: C = comparison population; I = intervention population.
** denotes statistical significance at the 5% level.
*** denotes statistical significance at the 1% level.

CHAPTER 6
FINANCIAL OUTCOMES: PRELIMINARY FINDINGS

In this chapter, we present *preliminary* evaluation findings on levels and trends in Medicare payments for the year prior to the start date and over the first 6 months of the Medicare Health Support (MHS) pilot programs. Although it is premature to draw definitive conclusions about financial success of the MHS pilot programs on just the first 6 months, it is valuable to summarize the preliminary findings to date and draw a few implications for MHS's success over the subsequent 2½ years of Phase I of the pilot program.

6.1 MHS Pilot Payment Arrangements

In the MHS pilot, each MHSO receives from CMS a negotiated monthly administrative fee per participant. Fees are at risk for performance, including:

- improvements in quality, beneficiary, and provider satisfaction; and
- 5% savings on Medicare payments net of fees.

Reconciliation on these measures will take place at the end of the 3-year pilot. While a fraction of the fees are at risk for the clinical and satisfaction measures, up to 100% of fees are at risk to comply with the statutory requirement of budget neutrality. Monthly fees range from $74 to $159 per beneficiary, or 5.3% to 11.2% of average per-beneficiary-per-month (PBPM) payments of the comparison group.

During the first 6 months, or pilot outreach period, the MHSOs receive a monthly management fee for each beneficiary in their assigned intervention group until such time that the beneficiary becomes ineligible or declines to participate. Beyond the outreach period, management fees are paid only for confirmed participants.

MHSOs are held at risk for fees based on the performance of the full population of beneficiaries randomized to the intervention group (an intent-to-treat [ITT] model) compared with the comparison group. MHSOs, to keep all their management fees, not only must reduce Medicare payments for the intervention group by the amount of fees collected, they must further reduce the intervention group's Medicare payments by an additional 5%. To the extent that the MHSOs do not fully engage their assigned population, the percentage savings on those that they do actively manage (the participants) must be even greater for them to be financially successful assuming no savings among the non-participants. CMS designed the MHS initiative with considerable administrative risk to MHSOs as an incentive for them to maximize overall participation across the full spectrum of eligible beneficiaries and to improve the care they receive.

CMS also required each MHS organization to select a minimum of four performance measures at financial risk: three clinical measures (one diabetes specific, one heart failure (HF) specific, and one preventive service) and one patient satisfaction measure. Risk arrangements were negotiated on a case-by-case basis with each MHS organization, subject to final approval by CMS. The funds at risk for clinical quality performance measures vary by MHSO, but typically range from 3% to 10% of fees paid. The financial analysis presented in this chapter

does not assess performance on these quality and satisfaction measures because of the short intervention period.

It is also important to emphasize that the payment analyses presented in this chapter do not represent the official results of MHSO savings during the pilot. CMS's financial reconciliation contractor is responsible for official comparisons on an interim (first-year) and final (3-year) period basis. These reconciliations will compare differences in Medicare program payments on a PBPM basis for the full intervention and comparison groups using claims for the first 12 and 36 months, respectively. The protocols for the financial reconciliation methodology differ slightly from the one used in this report.

6.2 Financial Analysis Data and Methods

The data used in the analysis of PBPMs are Medicare claims extracted for all eligible beneficiaries in the eight MHSOs. Medicare payments are based on claims for services during the 6-month pilot period and for 12 months prior to each MHSO's start date. The prior year's claim file has a longer "run-out," and therefore is more complete than the 6-month pilot period. RTI estimates that the 6-month PBPM estimates may be 10% lower than actual PBPMs based on a full run-out period; however we expect this to equally impact both the intervention and comparison groups.

In *evaluating* performance we not only compared overall intervention and comparison group payment during the pilot, we also conduct statistical tests of hypotheses regarding levels and trends in beneficiary payments. This requires calculating PBPMs at the beneficiary level in the base year and pilot periods in order to generate weighted standard errors and PBPM confidence intervals. The weights are each beneficiary's eligible fraction of days or months for the analytic period. Statistical significance between baseline and pilot periods is determined using a paired t-test using 6-month beneficiary eligible fractions as weights. Furthermore, in this chapter we restrict analyses to beneficiaries who had at least one day of eligibility during the first 6 months of the pilot. Hence, the sample of patients used in calculating the base year PBPMs excludes those who die prior to the MHSO start date and those who have no periods of eligibility during the first 6 months of the pilot.

The intervention group's PBPM may vary relative to the comparison group depending on (a) how costly intervention and comparison groups are at randomization; (b) the impact of ineligibles on payment differences between randomization and the MHSO's start date; (c) the percentage of intervention eligibles that the MHSOs engage; and (d) what happens to the rate of growth in participant, non-participant, and comparison group PBPMs between the base year and the 6-month periods. We begin by presenting PBPMs for the intervention and comparison groups at the start of each pilot based on utilization for the 12-month period prior to start. Historical PBPMs for those eligible during the initial 6 months of the program reflect any financial (dis)advantages at the time of randomization and the additional impact of any inequalities that develop between the intervention and comparison groups after randomization and before the start date. Next, we present the change in the intervention PBPMs between the base year and the first 6 months of the pilot relative to the change in the comparison PBPMs using a difference-in-difference analytic method. We then compare pilot period PBPMs for participants and non-participants, separately, with the entire comparison group. A panel of healthier, less costly,

participants (relative to non-participants) may limit an MHSO's ability to achieve the level of savings required across its entire intervention group.

Budget neutrality after 1 year requires that the PBPM of the comparison group exceed that of the intervention group by at least the monthly fee. In a final analysis, we express this criterion as a percentage of each MHSO's comparison group PBPM to adjust for differences in MHSO average expenditure levels. For example, if an MHSO exhibits an intervention PBPM after 6 months that is 1% lower than its comparison group's PBPM, and its monthly fee is 7% of the comparison group's PBPM, then it is roughly one-seventh of the way to meeting its Year 1 budget neutrality.

6.3 Results

Intervention Payment Savings. PBPMs between intervention and comparison groups differ to varying degrees in the year prior to the start date. Table 6-1 and Figure 6-1 display the prior base year PBPM differences at the start of the pilot for beneficiaries who had any period of eligibility during the first 6 months. Four of the eight MHSOs begin with intervention beneficiaries who are 2% to 6% more costly than in their comparison group. For these MHSOs, this inequality at baseline requires PBPM savings of 7% to 11%, instead of the contractual 5%, before they may retain any of their management fees.

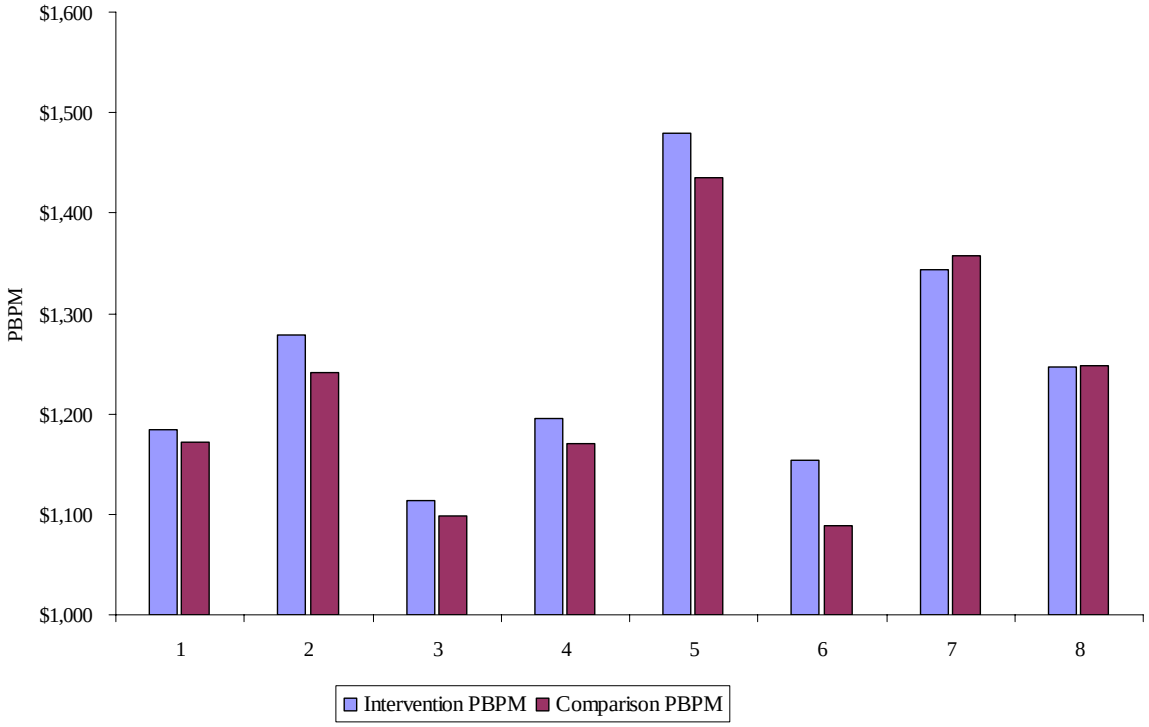
Table 6-1
Medicare per-beneficiary-per-month (PBPM) payment differences[1] between Intervention and Comparison Beneficiaries for the year prior to the start of each pilot, by MHSO

MHSO	Intervention Mean	Comparison Mean	Percent Difference
1	$1184	$1172	1.0%
2	1278	1241	3.0
3	1113	1099	1.3
4	1196	1170	2.2
5	1479	1435	3.1
6	1154	1088	6.1
7	1343	1358	-1.1
8	1246	1248	0.2

NOTES: MHSO = Medicare Health Support Organization.

[1] Differences = Medicare intervention minus comparison group per beneficiary per month (PBPM) payments in the 12 months prior to the MHSO's start date. Differences weighted by beneficiary's eligible fraction of days in the 6-month pilot period. This analysis includes only beneficiaries who were eligible for at least one day during the first 6-month period.

Figure 6-1
Prior year PBPMs: Intervention and comparison group, by MHSO



NOTE: Prior year PBPM = 12 months prior to MHSO start date.

SOURCE: Medicare 2004-2006 Part A & B claims. No adjustments for outliers have been made.

In Table 6-2 and Figure 6-2, we present a difference-in-difference analysis of trends in PBPMs for each of the eight MHSOs. For example, MHSO 1's intervention group PBPM increased by $208 between the baseline year and the first 6-month period. Over the same period, MHSO 1's comparison group PBPM increases $231, implying $23 per beneficiary Medicare payment savings. This difference-in-trends is not statistically significant at conventional levels, however. To achieve statistical significance, the differences-in-trends need to be roughly $70-$80 or more. Six of the eight MHSOs, relative to their comparison groups, exhibit lower rates of growth in Medicare PBPM payments between the year prior and first 6 months of the pilot program. Yet, only MHSO 3 and MHSO 6 exhibit a statistically significant ($p<.05$) *lower rate of increase* in their intervention PBPM versus the comparison group. MHSO 4 and MHSO 5 have intervention increases that also are roughly $45-$47 less than their comparison group, but the differences are not statistically significant. MHSO 1 and 2 exhibit more marginal differences of -$23 and -$17, respectively, in their intervention and comparison group PBPM growth trends. MHSO 7's intervention PBPM parallels its comparison group. By contrast, MHSO 8's intervention PBPM grew faster than its comparison group PBPM (which increases only $63, the lowest of any group).

Table 6-2
Medicare per-beneficiary-per-month (PBPM) payment differences[1] between 6-month pilot and prior year period, by MHSO

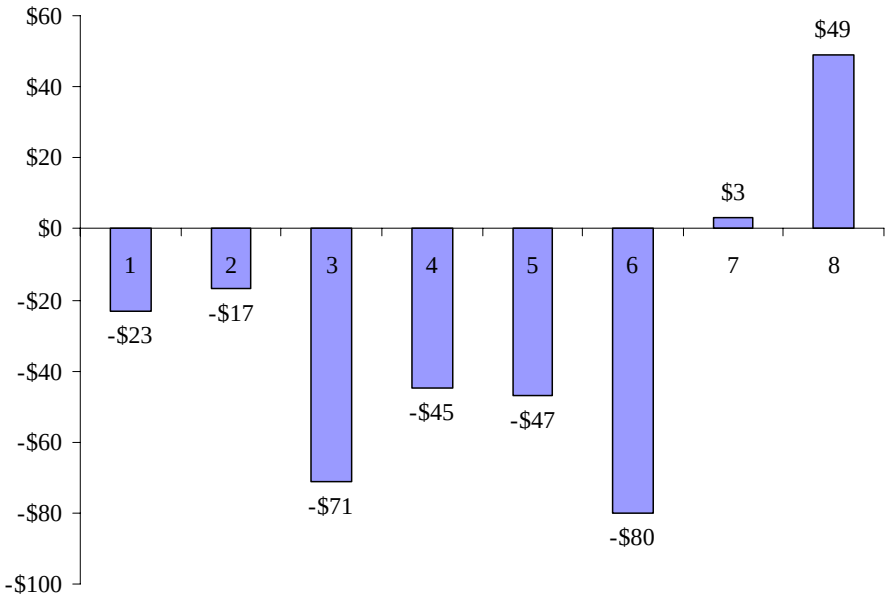
MHSO	Intervention Mean	Comparison Mean	Difference-in-difference[2]
1	$208	$231	-$23
2	121	138	-17
3	247	318	-71**
4	85	130	-45
5	220	267	-47
6	97	177	-80***
7	252	249	+3
8	112	63	49

NOTE: MHSO = Medicare Health Support Organization.

[1] Differences = Medicare program per beneficiary per month (PBPM) payments in first 6 pilot months minus payments for same patients in 12 months prior to MHSO's start date. Differences weighted by beneficiary's eligible fraction of days in the 6-month pilot period. This analysis includes only beneficiaries who were eligible for at least one day during the first 6-month period.

[2] Difference-in-difference pairwise t-test p-value between intervention and comparison group shown by asterisks: *** p<.01; ** p<.05.

Figure 6-2
Differences in intervention and comparison growth in Medicare payment PBPMs from base year through first 6 pilot months, by MHSO

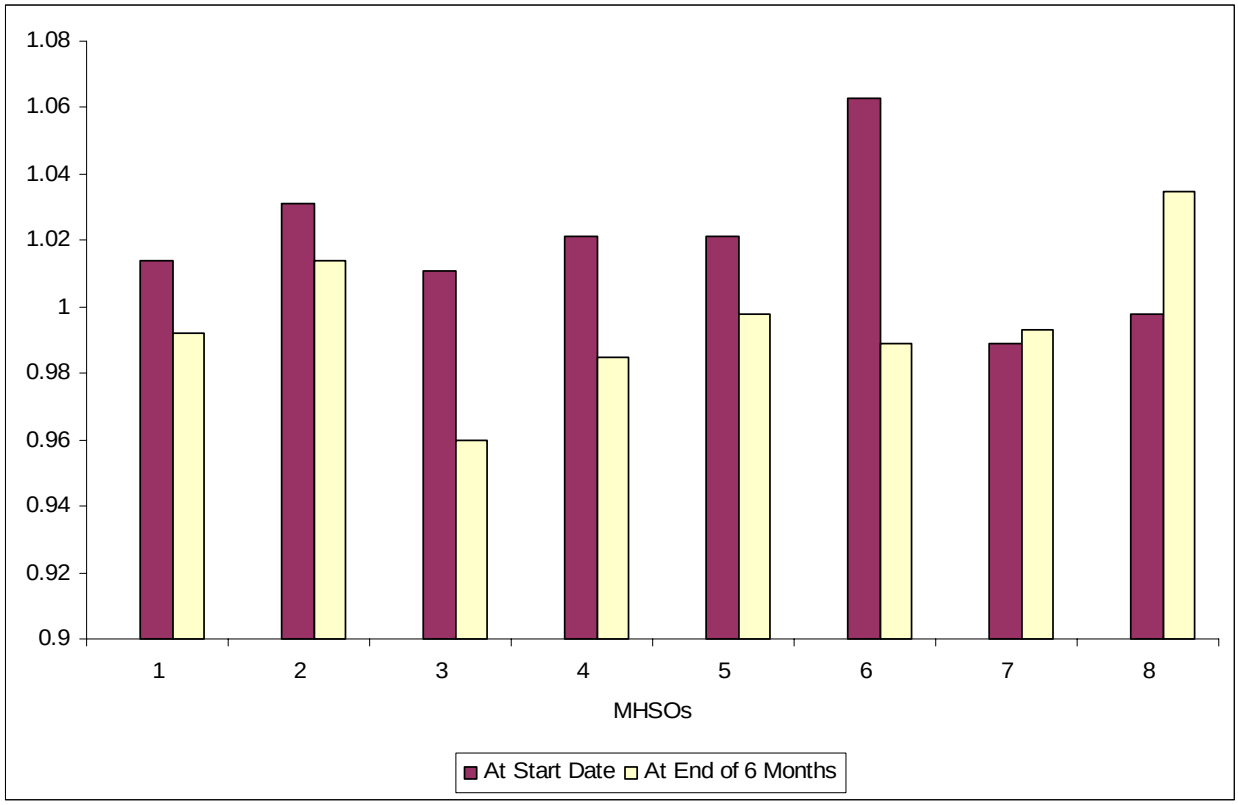


NOTES: Base year = 12 months prior to MHSO start date. Negative values signify slower growth in intervention versus comparison group PBPMs.

SOURCE: Medicare 2004-2006 Part A & B claims.

Figure 6-3 shows the progression of MHSO PBPMs from the start date through the first 6-month pilot period for only those beneficiaries who were eligible during the first 6-month pilot period. The light bars represent the ratio of the intervention to the comparison group PBPM during the first 6-month period. The shorter the light colored bar, the more successful was the MHSO in controlling Medicare payments in the initial pilot period. Bars below 1.0 imply actual Medicare claims savings relative to the comparison group. MHSOs 3 and 4 perform best on this. The dark bar is the ratio of intervention-to-comparison group PBPMs for the year prior to the start date. The difference between the dark bar and the light bar shows the improvement in PBPMs during the pilot period relative to the year prior to the start date. MHSO 6, in particular, along with MHSO 3, stand out as experiencing the most change.

Figure 6-3
Ratio of PBPMs for intervention vs. comparison groups at randomization, start date, and after 6 months



NOTES: Figure reflects Medicare claims costs and does not include fees paid to MHSOs. No adjustments for outliers have been made. Only Medicare FFS beneficiaries that are eligible during the first 6 months of the pilot are included in the PBPM estimates in this figure.

We next stratified trends in MHSO PBPMs by the three threshold disease groups: (1) HF only, (2) Diabetes only, and (3) HF and Diabetes. No pattern of success was found within any of the three groups among the eight MHSOs that might imply targeting of intervention efforts.

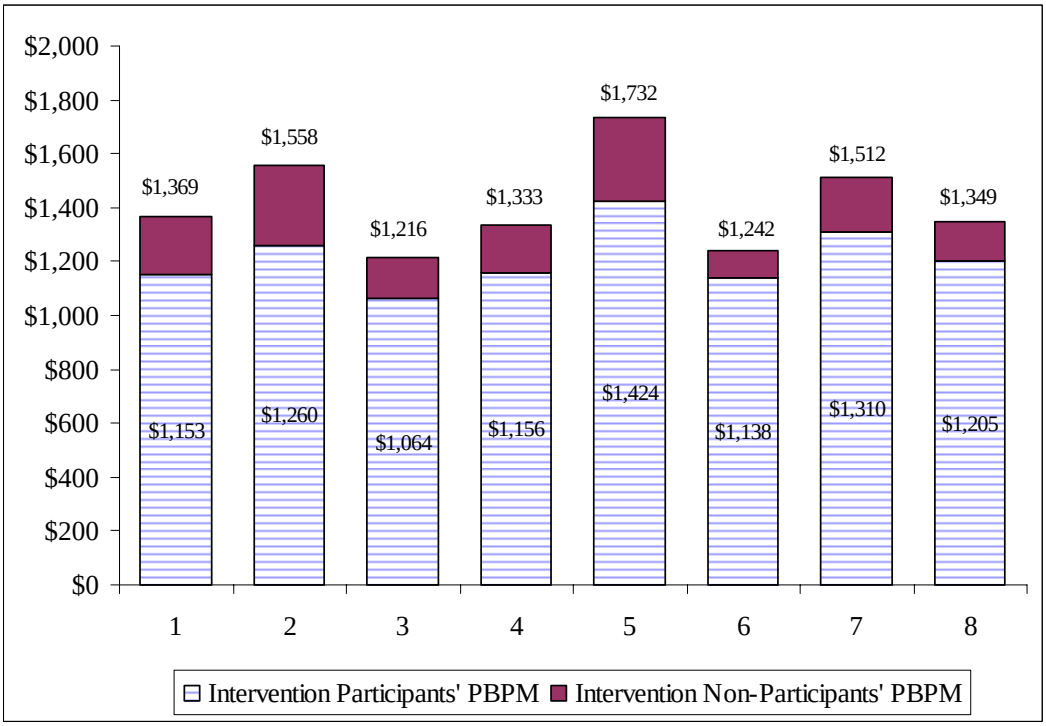
Intervention Payment Differences between Participants and Non-participants. Average monthly payments and growth trends for participants and non-participants differ systematically within each MHSO. Table 6-3 displays PBPMs for intervention participants and non-participants and comparison beneficiaries during the base year prior to the start of the pilot. This allows one to observe the pure selection effects from the MHSOs not fully engaging their intervention population. Base year PBPMs of participants average 8% to 19% less than those of non-participants across the eight MHSOs. In Figure 6-4, the dark areas show how much more costly non-participants were prior to program start relative to participants. Because the non-participant group is typically one-fifth of the entire intervention group, not impacting these costly beneficiaries will likely hinder the ability of MHSOs to control their intervention group's overall PBPM growth and meet the financial terms of the pilot program.

Table 6-3
Medicare per-beneficiary-per-month (PBPM) payments for intervention participants and non-participants and comparison beneficiaries during the base year prior to the pilot, by MHSO

MHSO	Intervention participants' PBPM mean	Intervention non-participants' PBPM mean	Comparison PBPM mean	Participant to non-participant PBPM ratio	First 6-month pilot participation rate (%)
1	$1,153	$1,369	$1,172	.84	70.0%
2	1,260	1,558	1,241	.81	92.3
3	1,064	1,216	1,099	.88	65.0
4	1,156	1,333	1,170	.87	83.6
5	1,424	1,732	1,435	.82	80.3
6	1,138	1,242	1,088	.92	83.2
7	1,310	1,512	1,358	.87	82.6
8	1,205	1,349	1,248	.89	75.6

NOTES: MHSO=Medicare Health Support Organization. PBPMs weighted by beneficiary's eligible fraction of days in the 6-month pilot period. This analysis includes only beneficiaries who were eligible for at least one day during the first 6-month period.

Figure 6-4
Intervention non-participant to participant of base year PBPMs, by MHSO



NOTE: Base year = 12 months prior to MHSO start date.

SOURCE: Medicare 2004-2006 Part A & B claims.

Monthly Fee Budget Neutrality. Lastly, Table 6-4 and Figure 6-5 show each MHSO's success in meeting its Year 1 budget neutrality requirement of covering all fees paid by CMS. The first column gives the 6-month payment savings as a percentage of its comparison group's PBPM. For example, MHSO 3's Medicare claims costs for the intervention group were 4% lower than for the comparison group during the first 6 months of the program. Column 2 reports each MHSO's monthly fee as a percentage of its comparison group's PBPM. Column 3 shows the sum of the two percentages, which may be interpreted as the monthly fee cost to Medicare, net of savings on payments after 6 months. The last column shows the percentage of the monthly fee that has been "recovered" halfway through Year 1. Positive percentages in the last column indicate some fee recovery while negative percentages imply that an MHSO is even further behind in covering the fees it has received.

The bars in Figure 6-5 indicate the percentage that the MHSO must reduce Medicare expenditures relative to the monthly Medicare payments of its comparison group, and include both the 5% payment savings reduction requirement plus the MHSO's monthly management fee. For example, MHSO 1's fee of 5.3% of Medicare payments plus the required 5% savings means MHSO 1 needs to save a total of 10.3%. To date, it has achieved 0.8% savings, so to be budget neutral by the end of the first year, it needs to save enough in months 7-12 to recoup its fee for that period, plus close the 4.5% shortfall from the initial 6 months.

Table 6-4
Percentage of monthly management fee recovered through Medicare savings: 6 months

MHSO	% difference intervention/ comparison[1]	% monthly fee[2] of comparison PBPM	% monthly fee net of savings[3]	% of fee recovered[4]
1	-0.8	5.3	4.5	15.1
2	1.4	8.7	10.1	-15.9
3	-4.0	11.2	7.2	35.9
4	-1.5	10.1	8.6	14.5
5	-0.2	7.8	7.6	2.3
6	-1.1	9.2	8.0	12.1
7	-0.8	6.5	5.8	10.7
8	3.5	7.0	10.5	-50.1

NOTE: MHSO = Medicare Health Support Organization.

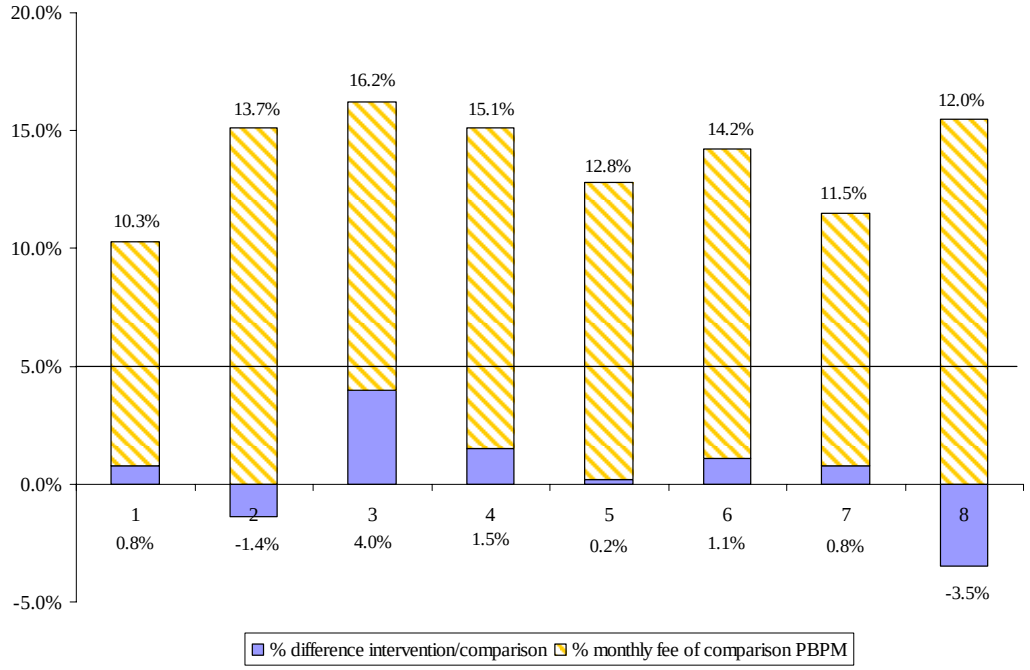
[1] Intervention minus comparison group PBPM, as percentage of comparison PBPM, during first 6 months of pilot.

[2] Monthly fees taken from MHSO cooperative agreement terms and conditions, protocol 6.0. Simple average fees calculated when two fees were negotiated. Comparison PBPM taken from 6-month PBPMs.

[3] Column 2 plus column 1.

[4] Equals column 3 divided by column 2 minus 1.0 times 100.

Figure 6-5
Proportion of total net savings[a] achieved through pilot's first 6 months, by MHSO



[a] Includes both 5% Medicare claims savings plus fee percentage of comparison PBPM.

SOURCE: Medicare 2004-2006 Part A & B claims; MHSO protocol 6.0, terms and conditions.

Column 1 of Table 6-4 and the dark portions of bars in Figure 6-5 shows that savings on Medicare payments have been generated in six of eight MHSOs. These savings, as a percentage of comparison group monthly PBPMs, range from two-tenths of one percent to 4.0%. Even though MHSO 6 achieves a statistically lower rate of PBPM *growth* than its comparison group in Table 6-2, it has not achieved a statistically lower PBPM after 6 months because its intervention PBPM is 6.1% higher than its comparison group PBPM at its start date (see Figure 6-3). Two MHSOs show higher Medicare expenditures for the comparison group, indicated by positive percentages in the first column of Table 6-4, although MHSO 2 overcomes nearly one-half of its higher base year intervention start-date PBPM during the first 6 pilot months.

Monthly management fees in column 2, as a proportion of comparison group PBPMs, range from a low of 5.3% (MHSO 1) to a high of 11.2% (MHSO 3) and average 8% to 9% of monthly payments. Consequently, to meet Year 1 budget neutrality requires MHSOs to reduce payments 8% to 9%, on average, in order to cover all of the fees they have received. It should be noted that these analyses exclude any adjustment of baseline differences between intervention and comparison PBPMs at the start of the pilot.

Column 3 indicates that MHSOs over the first 6 months have had limited success in covering the fees paid out by Medicare, as evidenced by sizable monthly fees still "uncovered" by savings on Medicare payments. The last column of the table indicates that only MHSO 3 has recovered as much as one-third (35.9%) of its monthly fee through Medicare payment savings after 6 months. However, because MHSO 3 negotiated the highest fee of all eight programs, it still needs to reduce its intervention PBPM another 12% below its comparison group's PBPM over the next 2½ years of the pilot. MHSOs 1 and 4 have recovered (through payment savings) about 15% of their fees, MHSO 6 has recovered 12%, MHSO 7, 10.7%, and MHSO 5, just 2.3%. Both MHSO 2 and MHSO 8 have diverged even further in their attempt to recover the monthly fee paid to them by CMS.

CHAPTER 7
PHASE I KEY FINDINGS

Although we present a large number of findings in this report, this initial evaluation reflects considerably less than 6 months of active care management. Therefore we refrain from drawing any early conclusions with respect to the pilot programs' impact on quality of care or health outcomes. Although preliminary, three key participation and financial findings emerge that have important policy implications for the Centers for Medicare & Medicaid Services' (CMS's) financial reconciliation in Phase I.

It should be kept in mind that RTI has analyzed only the first 6 months of the pilot period and cost savings, which may not be indicative of long-run, or even one-year, savings. That said, CMS may wish to consider changes in the Medicare Health Support (MHS) contract terms and conditions in light of the facts that we presented in this report and in the review of the financial reconciliations based on the first 12 months of program operations.

Key Finding: PBPMs are unequal between intervention and comparison group at start date

We find that the block (stratified) randomization procedure employed effectively created equivalent intervention and comparison populations within each Medicare Health Support Organization (MHSO) at the time of randomization for each of the variables used in the randomization (i.e., three Hierarchical Condition Categories score ranges, Medicaid enrollment, and proportion with heart failure [HF]). We also confirm that the block (stratified) randomization procedure produced similar demographic, disease, and economic burden profiles between the intervention and comparison groups at the time of randomization.

However, unexpected inequalities in per-beneficiary-per-month (PBPM) emerge between randomization and the start date of some MHSOs when one restricts the calculation of the PBPMs to only those beneficiaries who are eligible during the pilot. Thus, during the necessary lag time between the randomization and the pilot go-live dates unintended imbalances in payments for some MHSOs appear. Thus, most MHSOs have higher base-year PBPMs before the start date, relative to their comparison group.

CMS may wish to consider modifying its financial reconciliation protocol by actuarially adjusting the intervention PBPM for any difference from the comparison group in the 12 months just prior to their start date. A complete actuarial analysis should be conducted on base year and program period performance in order to determine appropriate adjustments to make and to better understand the observed dynamics in PBPMs. These differences can be actuarially adjusted and further exploration as to the underlying reasons for the unexpected divergence should be undertaken. Such divergence may represent the influence of a small number of outliers with extreme medical expenditures for which additional statistical adjustment may be warranted.

Key Finding: MHSOs did not engage the most costly beneficiaries

The second key finding from our early implementation evaluation is that, once the pilot programs began, the participating beneficiaries tend to be a healthier subset of the intervention group. We find that the participant populations are substantively different from both the non-participants and the comparison populations across the majority of demographic, health status,

utilization, and payment characteristics reviewed. Non-participants are more costly to Medicare in the 6-month period of the pilot than either participants or the comparison group. Thus, the range of participation rates observed across the MHSOs will likely be a factor in the ability of the MHSOs to impact their assigned intervention populations.

CMS may wish to explore specific subpopulations of non-participants, such as those that the MHSOs had the most difficulty locating (i.e., those in nursing homes or other institutional settings), those who were in a health facility for more than 2 weeks during the first 3 months of the pilot, or beneficiaries who died very early in the intervention period. Additional analyses with longer periods of observation may identify beneficiaries for whom care management is less appropriate. More in-depth analyses of these subpopulations may suggest potential design changes for Phase II.

Key Finding: Fees paid to date far exceed savings produced

The negotiated MHSO monthly fees are a far higher percentage of the comparison groups' PBPMs than the percentage savings on Medicare expenditures through the first 6-month pilot period. Further, MHSO monthly fees are a higher percentage of the comparison groups' PBPMs than the required 5% savings on payments. Fees negotiated by the MHSOs with CMS have not been covered by reductions in costs, let alone an additional 5% savings in Medicare payments. The fee liability accrued during the first 6 months of operations requires savings for the remaining 30 months be even greater in order to achieve the overall financial targets by the end of Phase I.

We also believe that the MHSOs may have substantially overestimated the impact of their intervention on their ability to reduce the stream of beneficiary utilization (particularly inpatient hospital admissions) relative to a comparison group. The MHSOs universally experience at least three non-HF or nondiabetes admissions for every one HF or diabetes admissions. Thus, unless the MHSOs' programs are able to target and prevent hospitalizations for causes other than HF and diabetes, projected cost savings related to reduced hospitalizations are unlikely to materialize. We observe no substantive differences in rates of admissions or readmissions between the intervention and comparison populations during the first 6-month period.

CMS may wish to consider substantial reduction in each MHSO's monthly fee if the Medicare expenditure patterns do not show claims savings for the intervention population soon in order to achieve budget neutrality. A revised fee would need to be constructed to reflect future savings projections, but also factor in fees already paid for which no net savings have occurred in order to achieve the cumulative program savings targets by the end of Year3.

REFERENCES

West, N., Bernard, S., and Eicheldinger, C. (2005). “What do the disabled report about their satisfaction and experience with Medicare?” Presented at the AcademyHealth 2005 Annual Research Meeting. Boston MA June 26-28.