Medication Therapy Management in a Chronically Ill Population: Interim Report

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EXECUTIVE SUMMARY

Medication therapy management programs (MTM programs) have been a part of the Medicare Part D program since its inception in 2006, though similar programs existed outside of the Medicare context well before then.[1] These programs, targeted at high-risk, high-cost individuals with a variety of chronic medical conditions, represent an effort to optimize therapeutic outcomes and reduce the risk of adverse events through improved medication use. They have been supported by stakeholders, policymakers, and researchers as compelling efforts to improve the quality of chronic care management and to reduce healthcare expenditures.[2,3] Pharmacists and other healthcare professionals working within a Part D MTM program aim to provide patient-centered care by conducting annual one-on-one comprehensive medication reviews (CMRs) and quarterly targeted medication reviews (TMRs), developing personal medication lists and medication-related action plans, and communicating with physicians and other healthcare professionals on behalf of patients to resolve medication-related problems.[2] In this way, they can work with patients individually and over time to help them manage their health conditions and avoid adverse health outcomes. MTM providers working within Part D MTM programs can play a unique role in helping patients manage their drug therapies because they have the ability to consolidate and closely review their patients' drug claims to offer informed recommendations, potentially in a cost-effective way.

Part D MTM programs hold promise to make an impact on Medicare beneficiaries' health outcomes and expenditures through multiple drug-related avenues. First, they may work by halting the use of inadequate or unsafe drug regimens that lead to worse health outcomes and costly health events. Second, they may positively impact drug adherence - several studies[4] suggest that medication non-adherence contributes a substantial human and financial toll in the U.S., with 33 to 69% of all medication-related hospital admissions due to non-adherence. The cost of medication non-adherence is estimated to exceed $177 billion in 2000 in the U.S., with hospital admissions accounting for almost 70% ($121.5 billion) of that amount.[5-7] Mechanisms or interventions that focus on improving medication adherence and other outcomes related to prescription drug use (e.g., drug interactions or use of contraindicated medications for particular health conditions), such as MTM programs,[8,9] may lower healthcare costs by preventing adverse outcomes that lead to hospital admissions. Moreover, MTM providers in MTM programs may identify when the use of particular classes of drugs can be highly beneficial to certain high-cost chronic disease populations – and influencing the administration of these high-quality medications may then positively influence health outcomes. An example of this would be facilitating the use of beta-blockers in patients with a previous acute myocardial infarction.

In 2010, there were 678 active Part D contracts with an approved MTM program (585 Medicare Advantage prescription drug plans [MA-PDs] and 93 fee-for-service plans [PDPs]).

The majority of their MTM programs targeted conditions that align with the most commonly used medications utilized by Medicare Part D beneficiaries, including cardiovascular and metabolic syndrome agents. In 2010, all MTM programs reported that they offered annual CMRs and quarterly TMRs to their enrollees. However, these programs differed in the ways in which they offered these interventions: for example, 81.1% of these programs presented enrollees with a list of medication therapy recommendations, while 29.4% provided enrollees with a reconciled medication list.[10]

This study aimed to identify the impact of 2010 Part D MTM programs on Medicare beneficiaries' adherence, medication use, drug therapies and resource utilization associated with hospital and emergency room (ER) visits, medications, and costs. Although the same Part D MTM programs serve enrollees with a variety of chronic conditions, this study focused on high-cost, high-risk beneficiaries with congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), because these individuals stood to benefit significantly from MTM program interventions, and their health impacts would be expected to be identified in the claims data within a six-month outcome period. Of the 678 different Medicare Part D MTM programs that existed in 2010, 93.7% reported that they targeted CHF, and 52.8% reported that they targeted COPD beneficiaries for MTM. A qualitative follow-up to this report will investigate the impact of different types of MTM interventions on the drug therapy and resource utilization outcomes of interest.

Overview of the Empirical Approach

We used a retrospective cohort study design to investigate how enrollment in a standalone Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD) MTM program with or without receipt of a CMR influenced drug therapy, resource utilization, and costs among beneficiaries with CHF or COPD. The analysis compared outcomes experienced during a 180-day outcome period for beneficiaries with CHF or COPD who were newly enrolled in a MTM program in 2010 against outcomes experienced by a comparison group comprised of Part D beneficiaries who were not eligible for their contract's MTM program (i.e., they failed to meet specific eligibility parameters established by their chosen contract), but who may have been eligible for MTM had they been enrolled in a different contract. Additional sub-population analyses on the impacts of MTM programs associated with specific parent organizations were conducted. These represent small, medium, and large organizations, with varying approaches to CMR implementation (see **Table ES 1**).

Table ES 1: MTM Program Summary for Selected Parent Organizations

Parent Organization	*MTM Enrollment* [a]	*CMR Consultation Mode*	*Written Summary of CMR* [b]	*Percent Receiving CMRs*	*Prescriber Outreach Methods*
Organization A	High*	Phone	Action plan, recommendations	Under 5%	Phone, fax
Organization B	High*	Phone, face to face	Action plan, recommendations, personal medication list	21-40%	Phone, fax, mail
Organization C	Medium**	Phone, face to face	Action plan, recommendations	Under 5%	Phone, fax, mail
Organization D	Medium**	Phone	Personal medication list	81%+	Fax
Organization E	Low***	Phone	Action plan, recommendations, personal medication list	Under 5%	Phone, fax, mail
Organization F	Low***	Phone, face to face	Recommendations, reconciled medication list, education materials	41-60%	Phone, EMRs, e-mail and mail

*High enrollment plans consist of over 100,000 MTM enrollees.
** Medium enrollment plans consist of over 40,000 MTM enrollees and less than 100,000 MTM enrollees.
***Low enrollment plans consist of less than 40,000 MTM enrollees.

Outcomes of interest were divided into two categories: drug therapy and resource utilization. Resource utilization was further subdivided between hospital and ER visits, medications, and costs. These outcomes were assessed over the six-month period following an individual's enrollment in an MTM program. Drug therapy outcomes included the use of and adherence to evidence-based medications for CHF and COPD, the presence of drug-drug interactions in the prescribed regimens, and the use of high-risk or contraindicated medications for CHF patients. Resource utilization was measured by all-cause and disease-specific hospitalizations and emergency room visits, the number of unique medications an individual filled, the individual's ratio of prescription fills for generic medications to fills for all medications that had existing generic options, Part D costs, and all-cause and disease-specific costs related to hospitalization and emergency room visits. Both all-cause and disease-specific outcomes were included because MTM programs, which provide general medication use

[a] This number includes all MTM enrollees, not just enrollees with CHF and COPD.
b This analysis occurred before there was a required standardized format for the CMR action plan and summary. Section 10328 of the Affordable Care Act requires standardized format requirements effective 1/1/2013.

recommendations for beneficiaries with multiple chronic conditions, may impact CHF- and COPD-specific outcomes as well as outcomes related to management of other conditions.

The study relied on a two-step approach to adjust for differences between MTM enrollees and non-MTM enrollees. First, we narrowed the set of non-MTM enrollees in the comparison group to include only beneficiaries who were never enrolled in an MTM program in 2010 but who were potential candidates for MTM enrollment based on 2010 eligibility rules. To this end, we exploited variations in the MTM eligibility rules and implementation policies set by Part D sponsors to identify beneficiaries who were not eligible for MTM in their plan, but who would have been eligible if they had enrolled in another plan within the Medicare system. This first step guaranteed that beneficiaries in the comparison group had chronic conditions and drug utilization levels similar to the MTM enrollees included in our intervention groups. Second, to adjust for remaining differences in demographic and health characteristics between MTM enrollees and the comparison group, we used a regression framework that included health and demographic risk factors observed before enrollment in a MTM program.

All models adjusted for individual-level demographic characteristics including age, gender, race/ethnicity, socioeconomic status, and region. They also adjusted for medical comorbidities and condition severity using Medicare RxHCC flags for 84 combinations of health conditions, the number of chronic condition maintenance drugs, and the number of therapeutic drug categories filled in the six months before the study period. Additionally, we adjusted all model results for intensity of provider care measures as determined by the numbers of prescribers from whom an individual received a prescription and the number of providers an individual visited in the outcome period. The analytic approach took into account individual drug benefit plan enrollment (i.e., cost saving incentives) by using indicators for gap coverage in the regression model. Finally, for each outcome, the model adjusted for the incidence or level of that outcome in the six months preceding each individual's 180-day study period. Significance was assessed at the $p<0.05$ level.

Summary of Results

In 2010, 3,506,350 individuals enrolled in Part D were identified within the risk adjustment data as having CHF; 3,973,578 were identified with COPD (11.8% and 13.4%, respectively). From these patients, 8.3% with CHF and 8.7% with COPD participated in an MTM program. Of these MTM enrollees, 10.4% to 11.5% received an annual CMR. The key findings from our analysis of the impact of MTM on these individuals, in relation to the comparison groups, are summarized as follows:

MTM programs effectively targeted high-risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment. In the CHF and COPD cohorts, individuals who had problems in their drug therapy regimens in the six months preceding MTM enrollment were more likely to be targeted for inclusion in MTM programs. For example, 37.1% of individuals in PDPs who had COPD and enrolled in a MTM program used a high risk medication in the six months prior to MTM enrollment, while only 33.2% of individuals in the comparison group used a high risk medication during that time period. This difference at baseline shows that out of individuals with CHF, those who had an issue in their drug therapy regimen were more likely to be targeted for enrollment in a MTM program in 2010. MTM programs also targeted individuals with CHF and COPD who used contraindicated medications and/or had drug-drug interactions in their treatment regimens.

MTM programs were also effective in targeting individuals who had experienced a recent hospitalization or ER visit. In the CHF cohort, for example, the proportion of individuals experiencing a hospitalization due to any cause in the six months preceding the outcome period ranged from 31.0% (comparison group) to 34.7% (MTM without CMR) for those in PDPs, and 24.1% (comparison group) to 30.3% (MTM without CMR) for those in MA-PDs. Individuals in the MTM without CMR groups also had higher absolute all-cause and CHF-related costs relative to the comparison group. For example, those who enrolled in PDP MTM programs who did not receive CMRs incurred about $1,034 more in inpatient costs than those in the comparison group, in the six-month period before they received any MTM services. These findings were similar across the COPD cohort as well.

In comparison to Medicare beneficiaries with CHF or COPD who did not receive any MTM services in 2010, those who were enrolled in MTM programs – particularly those who received annual CMRs – experienced significant improvements in the quality of their drug regimens.

Improvements in drug therapy outcomes included increased take up of and adherence to evidence-based medications for individuals' chronic conditions, and discontinuation of high-risk medications. As shown in **Table ES 2** and **Table ES 3**, those who received CMRs as part of

their MTM program were more likely to experience such positive effects, suggesting that the annual CMR may be one of the more crucial components of the MTM program. For example, relative to the comparison groups, beneficiaries with CHF who enrolled in an MTM program had higher odds of being adherent to their evidence-based medications; further, the magnitude of this impact was greater for those who received a CMR compared to those who did not (PDP: OR = 1.036 without CMR and 1.141 with CMR; MA-PD: OR = 1.032 [not significant] without CMR and 1.239 with CMR). Results diverged, however, in terms of impacts on other indicators for quality of drug therapy, including use of high-risk and contraindicated medications. Such findings were similar for individuals included in the COPD cohort.

Table ES 2: Risk-Adjusted Drug Therapy Outcomes for Individuals with CHF (OR with 95% CI)

	Comparison or Intervention Group Assignment	*N*	*Take Up of Evidence-Based Medication for CHF*	*Adherent to Any Evidence-Based Medications for CHF*	*Remove Drug-Drug Interaction*	*Discontinue Use of High Risk Medications*	*Discontinue use of Medication Contraindicated for CHF*
Beneficiaries Only Enrolled in PDPs	Comparison	208,850	---	---	---	---	---
	MTM without CMR	136,305	1.198* (1.123, 1.277)	1.036* (1.009, 1.064)	1.050 (.988, 1.117)	1.041* (1.014, 1.069)	.879* (.847, .912)
	With CMR	14,858	1.100 (.928, 1.303)	1.141* (1.065, 1.222)	0.952 (.819, 1.106)	1.039 (.970, 1.113)	0.643* (.596, .693)
Beneficiaries Only Enrolled in MA-PDs	Comparison	62,119	---	---	---	---	---
	MTM without CMR	81,353	1.377* (1.253, 1.513)	1.032 (.990, 1.075)	1.137* (1.022, 1.265)	0.954* (.914, .995)	1.105* (1.038, 1.178)
	With CMR	10,349	1.302* (1.057, 1.604)	1.239* (1.135, 1.352)	1.117 (.917, 1.360)	1.177* (1.077, 1.287)	1.140 (.997, 1.304)

* Indicates significance at the 5% level.

Table ES 3: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD (OR with 95% CI)

	Comparison or Intervention Group Assignment	*N*	*Adherent to LABA-Only Regimen*	*Adherent to LAAC-Only Regimen*	*Adherent to Combination Regimen*	*Remove Drug-Drug Interaction*	*Discontinue Use of High Risk Medications*
Beneficiaries Only Enrolled in PDPs	Comparison	250,593	---	---	---	---	---
	MTM without CMR	141,324	1.080 * (1.030 , 1.133)	1.019 (.949 , 1.095)	1.119 * (1.059 , 1.183)	1.055 (.981 , 1.134)	1.049 * (1.021 , 1.078)
	With CMR	19,149	1.166 * (1.059 , 1.284)	1.19 (.989 , 1.432)	1.296 * (1.160 , 1.449)	0.97 (.821 , 1.146)	1.049 (.982 , 1.121)
Beneficiaries Only Enrolled in MA-PDs	Comparison	86,725	---	---	---	---	---
	MTM without CMR	82,953	1.029 (.960 , 1.103)	1.021 (.922 , 1.130)	1.05 (.965 , 1.144)	1.023 (.904 , 1.157)	.954 * (.914 , .995)
	With CMR	9,862	1.095 (.948 , 1.264)	1.062 (.869 , 1.298)	0.965 (.809 , 1.152)	1.043 (.823 , 1.323)	1.122 * (1.023 , 1.232)

* Indicates significance at the 5% level.

Among individuals with CHF, MTM enrollment was not consistently correlated with improvements in resource utilization.

Beneficiaries with CHF had slightly lower risks of hospitalization and emergency room visits if they were enrolled in an MTM program, particularly among beneficiaries enrolled in PDPs (see **Table ES 4**); however, cost-savings associated with the slight reduction in these adverse events were not consistently significant (see **Table ES 5**). Individuals enrolled in PDPs who received CMRs, for example, had lower odds of experiencing a hospitalization due to any cause and accrued $490 less in all-cause hospitalization costs than the comparison group, but these results were not the result of lower CHF-specific hospitalizations.

While MTM aims to reduce the IP and OP-ER costs associated with poor medication adherence, some Part D cost savings may also be possible. This is because MTM programs promote the use of the cost-effective medications, such as generics, and also identify duplication of treatment. In the Part D setting, estimates suggested that individuals who received MTM services cost approximately $4-$5 less per month in total prescription drug costs (excluding CHF-specific medications, an adjustment made to exclude costs related to beneficiaries' potential improved adherence to CHF medications) relative to those in the comparison group.

Table ES 4: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital and ER Visits (OR with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Any (All-Cause) Hospitalization*	*Any CHF-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any CHF-Related ER Visit*
Beneficiaries Only Enrolled in PDPs	Comparison	208,850	---	---	---	---
	MTM without CMR	136,305	0.987 (.970, 1.005)	1.037* (1.015, 1.060)	.960* (.943, .978)	1.030* (1.000, 1.061)
	With CMR	14,858	.879* (.840, .919)	926* (.877, .978)	.907* (.867, .949)	.930* (.866, .999)
Beneficiaries Only Enrolled in MA-PDs	Comparison	62,119	---	---	---	---
	MTM without CMR	81,353	1.032* (1.002, 1.063)	1.128* (1.087, 1.169)	---	---
	With CMR	10,349	0.993 (.937, 1.052)	1.077* (1.007, 1.153)	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

Table ES 5: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Medications and Costs (OLS Estimate with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-CHF Drugs*	*All-Cause Hospitalization Costs*	*CHF-Related Hospitalization Costs*	*All-Cause ER Costs*	*CHF-Related ER Costs*
Beneficiaries Only Enrolled in PDPs	Comparison	208,850	---	---	---	---	---	---	---
	MTM without CMR	136,305	-.138 * (-.154 , -.122)	0 (-.001 , .000)	-$21.15 * (-35.95 , -6.36)	$11.99 (-105.36 , 129.33)	$94.02 (-2.37 , 190.41)	-$5.06 (-10.56 , .45)	$0.45 (-3.22 , 4.12)
	With CMR	14,858	-.049 * (-.091 , -.007)	0 (-.002 , .002)	-$30.22 (-67.89 , 7.46)	-$490.15* (-764.66 , -215.64)	-$211.87 (-429.23 , 5.5)	-$15.6* (-28.6 , -2.6)	-$6.47 (-13.66 , .72)
Beneficiaries Only Enrolled in MA-PDs	Comparison	62,119	---	---	---	---	---	---	---
	MTM without CMR	81,353	-.285 * (-.308 , -.262)	-.002 * (-.003 , -.000)	-$30.75 * (-52.55 , -8.95)	---	---	---	---
	With CMR	10,349	-.274 * (-.319 , -.229)	-.006 * (-.009 , -.004)	-$31.326 (-74.07 , 11.42)	---	---	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

Among individuals with COPD, MTM enrollment was not consistently correlated with improvements in resource utilization.

During the outcome period, beneficiaries with COPD generally had slightly lower risks of all-cause and COPD-related hospitalizations and ER visits if they were enrolled in MTM programs (see **Table ES 6**), and this effect was more pronounced if they received CMRs. Enrollees in some parent organizations (results not shown in the Executive Summary) had particularly low risks of COPD-related hospitalizations relative to the comparison groups. However, reductions in the risks of adverse events were not consistently linked to cost savings (see **Table ES 7**).

At the overall PDP level, individuals who received MTM services with CMRs saved approximately $370 over six months on hospitalizations related to any cause, equivalent to about $62 per member per month. However, these results were not replicated for COPD-specific hospitalizations. In the Part D setting, individuals with COPD in MTM programs with CMRs cost $6 less per month.

The impact of specific parent organizations' MTM programs was also inconsistent across resource utilization outcomes. For example, those enrolled in a large organization that provided CMR to a very small percent of their MTM enrollees, saved an average over $2,000 in all-cause hospital costs, and $1,400 in COPD-related hospital costs. Because a small number of beneficiaries enrolled in this organization received a CMR, this result may need to be approached cautiously. Additionally, individuals in other parent organizations' MTM programs accrued significantly higher inpatient costs than the comparison group.

Table ES 6: Risk-Adjusted Resource Utilization for Individuals with COPD: Hospital and ER Visits (OR with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Any (All-Cause) Hospitalization*	*Any COPD-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any COPD-Related ER Visit*
Beneficiaries Only Enrolled in PDPs	Comparison	250,593	---	---	---	---
	MTM without CMR	141,324	.976 * (.959 , .994)	1.006 (.986 , 1.026)	.965 * (.948 , .982)	1.016 (.992 , 1.041)
	With CMR	19,149	.856 * (.822 , .892)	0.963 (.919 , 1.008)	.882 * (.847 , .918)	1.034 (.980 , 1.091)
Beneficiaries Only Enrolled in MA-PDs	Comparison	86,725	---	---	---	---
	MTM without CMR	82,953	1.053 * (1.023 , 1.083)	1.031 (.998 , 1.066)	---	---
	With CMR	9,862	0.964 (.908 , 1.023)	.904 * (.843 , .969)	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

Table ES 7: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Medications and Costs (OLS Estimate with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-COPD Drugs*	*All-Cause Hospitalization Costs*	*COPD-Related Hospitalization Costs*	*All-Cause ER Costs*	*COPD-Related ER Costs*
Beneficiaries Only Enrolled in PDPs	Comparison	250,593	---	---	---	---	---	---	---
	MTM without CMR	141,324	-.126 * (-.142 , -.110)	.002 * (.001 , .004)	-$42.18 * (-56.19 , -28.16)	$61.9 (-45.17 , 168.97)	$35.15 (-38.09 , 108.4)	-$5.60* (-10.89 , -.3)	-$1.23 (-4.96 , 2.49)
	With CMR	19,149	-.079 * (-.117 , -.042)	.004 * (.001 , .006)	-$34.62 * (-67.50 , -1.73)	-$369.55* (-592.31 , -146.78)	-$50.55 (-218.72 , 117.62)	-$20.3* (-31.8 , -8.80)	$2.13 (-5.9 , 10.17)
Beneficiaries Only Enrolled in MA-PDs	Comparison	86,725	---	---	---	---	---	---	---
	MTM without CMR	82,953	-.143 * (-.164 , -.122)	.006 * (.004 , .007)	-$17.39 (-36.52 , 1.73)	---	---	---	---
	With CMR	9,862	-.050 * (-.095 , -.006)	.006 * (.002 , .009)	-$10.62 (-50.29 , 29.05)	---	---	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

Comments

MTM programs within the Medicare setting consistently helped enrollees with CHF and COPD improve adherence to their evidence-based regimens and discontinue the use of high-risk medications while demonstrating less consistent impact on other drug therapy outcomes, hospital and ER visits, and other resource utilization including costs. CMRs appear to be strongly associated with positive outcomes, as beneficiaries who received CMRs were more likely to benefit from MTM program participation across almost all outcomes relative to those in MTM programs who did not receive CMRs.

MTM programs impacted all-cause and disease-specific (e.g., CHF-specific and COPD-specific) cost savings inconsistently across individuals included in our study cohorts. At the overall PDP and MA-PD levels, for example, there were significant cost savings associated with all-cause hospitalizations but not with disease-specific (e.g., CHF-specific or COPD-specific) hospitalizations. Because MTM programs are general interventions that aim to improve medication therapy across all of an enrollee's chronic conditions, it is possible interventions were more successful at improving outcomes related to conditions other than CHF and COPD. In the year preceding the study period, individuals who were included in the study cohorts also had high rates of diabetes, acute myocardial infarction, and stroke, among other conditions. Thus, it may be possible that clinicians providing MTM services to these chronically-ill enrollees focused on improving health outcomes related to those other, potentially more severe conditions, yielding cost-savings in all-cause but not in CHF- or COPD-related adverse events. Future analyses could consider identifying MTM enrollees' most acute or severe conditions in order to determine whether MTM programs specifically improve resource utilization outcomes related to those conditions.

At the overall PDP level and particularly for some parent organizations, the magnitude of inpatient cost savings for individuals with COPD was larger than that for individuals with CHF, though these cost savings were still relatively inconsistent. One potential explanation for this difference is that an average of 90% of individuals with CHF were adherent to their evidence-based CHF medications before they enrolled in MTM, while only 30% of individuals with COPD were adherent to evidence-based COPD medications. Thus, adherence was a relatively "topped-out" measure for the CHF cohort, while a much larger proportion of individuals with COPD had the potential to improve their medication adherence. Because MTM interventions consistently improved adherence for both the CHF and COPD cohorts, one could hypothesize that improved medication adherence was the driving factor behind medical cost savings outside of Part D. Our results may corroborate this hypothesis because they showed more pronounced cost savings for the COPD cohort from MTM program participation, perhaps due to the larger share of individuals with COPD having sub-optimal adherence at baseline; thus, individuals with

COPD had more potential to improve adherence and thereby avoid hospital and ER visits and their associated costs. This finding implies that MTM services might be particularly effective in individuals with chronic conditions such as COPD which have low rates of medication adherence at baseline.

One might have expected that MTM programs offered by MA-PDs might have had more consistent effects on enrollees, as Medicare Advantage plans are financially responsible for beneficiaries' costs outside Part D. Our results, however, showed that MA-PDP MTM programs did not improve enrollees' drug therapy or resource utilization outcomes over PDP MTM programs. This finding could be explained by additional services received by the MA-PDP population not captured with data available. They may have received services similar to MTM through their MA-PDs (e.g., disease management services) before enrolling in the plan's official MTM program, and they therefore would have less room for improvement once the MTM study period began. It may also be the case that beneficiaries in MA-PDPs comparison groups are receiving other disease management services during the study period, so the estimated effects represent the marginal impact of MTM relative to other services.

Finally, the results in this report are limited by several factors. First, the effects of the analyses comparing enrollees in MTM programs who received CMRs versus those who did not may have been confounded by the "healthy user effect," which refers to individuals' health-preserving behavioral tendencies that globally affect health-promoting or risk reducing activities (including CMR participation). Those who opted to receive CMRs as part of their MTM programs, in other words, may have been more likely to engage in other activities to stay healthy as well; our overall PDP and MA-PD analyses may not have been able to separate the effect of CMR from other, unobserved, intrinsic behaviors or positive behavioral health tendencies. These behaviors or characteristics cannot be measured with the data available in Medicare claims. However, our analysis of the determinants of CMR receipt shows enrollment in certain parent organizations is one of the strongest factors determining that an individual will receive a CMR. Moreover, our sub-population analyses provide results that may clarify the behavioral effect, as there was particularly strong bias towards healthy users in parent organizations such as Organization A (with less than 5% of MTM enrollees receiving CMRs) and a weaker bias in parent organizations such as Organization D (with 81%+ enrollees receiving CMRs). Second, our analyses were limited to individuals who were newly enrolled in MTM programs in 2010. While this analytic framework provided a way to cleanly compare individuals who received MTM to those who did not over a six-month study period, we might not be able to assume that the results could be generalized to Medicare beneficiaries who might have received MTM services outside of this period. Third, the analysis is limited in the extent that it focuses on CHF and COPD-specific outcomes on a population that has multiple chronic conditions besides those.

CHF or COPD may not be the most the most acute conditions for some beneficiaries in our cohorts, or these may not be the conditions specifically targeted by MTM programs. Finally, limitations in our data bias our estimates downward. For example, this analysis does not account for Medicare beneficiaries who were offered MTM by their health plan despite the fact that they did not meet CMS requirements for participating in MTM. Plans which offer MTM to an expanded population do not currently report these additional enrollees to CMS. As a result, some members of the comparison group may have received MTM services despite that they did not meet CMS eligibility requirements. However, any MTM services offered to the comparison are not expected to have included CMR.[a] Additionally, some of the parent organization sub-population analyses had small sample sizes that led to results which should probably be interpreted cautiously, and 2009 RxHCCs (used for risk-adjustment) might not have provided a complete representation of a beneficiary's health status. Furthermore, we plan to risk-adjust the outcomes for the PDP population using claims diagnosis data; however, these data were not available at the time of our initial analysis.

Next Steps

This study will be followed by qualitative analysis that includes expert interviews, case studies of specific parent organizations, and a Technical Expert Panel, to understand how MTM programs are implemented. In particular, the qualitative analysis will investigate what policies and procedures are in place in programs that are successful in delivering CMRs. The qualitative analysis will also investigate how MTM programs are implemented, and how MTM programs tailor their interventions to beneficiaries who are most vulnerable. The qualitative findings will provide CMS with the in-depth knowledge it needs to assess the scalability of various MTM practices and to evaluate the effectiveness of MTM programs in the Medicare context.

We will expand the quantitative analysis in several dimensions. First, we will evaluate the effect of MTM program participation on individuals with diabetes. Second, we will conduct outlier analyses to pinpoint beneficiaries within each disease cohort who had especially high costs or high prevalence of medication issues at baseline, to determine whether MTM programs particularly affected those beneficiaries' outcomes. Third, we will supplement one or two case studies from the qualitative study to evaluate the impact of narrowly defined drug therapy interventions

[a] We learned through phone conversations with the health plans that they did not offer CMR to the MTM enrollees who did not meet the CMS requirements for MTM.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

1 INTRODUCTION

Acumen, LLC and its partner, Westat, Inc., have been contracted by the Centers for Medicare & Medicaid Services (CMS) to conduct a quantitative and qualitative study on the impact of medication therapy management (MTM) programs in the Medicare Part D population, focusing on specific chronically ill populations with strong clinical incentive to maintain drug therapy. In particular, this study focuses on high-risk, high-cost beneficiary populations who may benefit significantly from MTM services.

This Interim Report summarizes the results of the quantitative analyses conducted by Acumen thus far. It provides information on the impact of MTM on Medicare beneficiaries diagnosed with congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). We investigated the impact of MTM programs for these beneficiaries along the following metrics:

1. The extent to which MTM programs targeted populations with medication therapy issues;
2. The impact of MTM programs on key drug therapy outcomes, including medication adherence, drug interactions, use of contraindicated drugs, use of medications considered high risk for the elderly, and take-up of evidence-based medications; and
3. The impact of MTM programs on resource utilization in the emergency room (ER) and hospital settings, and within Medicare Part D.

The remainder of this report is organized into six sections. These sections are as follows:

- Chapter 2: Background information on MTM programs in the United States.
- Chapter 3: Methodology for evaluating the impact of MTM programs on beneficiaries diagnosed with: a) CHF, and b) COPD.
- Chapter 4: Results of our analysis for the cohort of beneficiaries diagnosed with CHF.
- Chapter 5: Results of our analysis for the cohort of beneficiaries diagnosed with COPD.
- Chapter 6: Conclusions and next steps.

2 BACKGROUND

Medication therapy management programs (MTM programs) have been a part of the Medicare Part D program since its inception in 2006, though they existed outside of the Medicare context well before then.[1] These programs, targeted at high-risk, high-cost individuals with chronic conditions, represent an effort to optimize therapeutic outcomes through improved medication use and reduce the risk of adverse events. They have been supported by stakeholders, policymakers, and researchers as compelling efforts to improve the quality of chronic care and to reduce healthcare expenditures.[2,3] MTM Providers administer patient-centered care by providing annual one-on-one comprehensive medication reviews (CMRs) and quarterly targeted medication reviews (TMRs), developing personal medication lists and medication-related action plans, and communicating with physicians and other healthcare professionals on behalf of patients to resolve medication-related problems.[2] In this way, they work with patients individually and over time to help them manage their health conditions and avoid adverse health outcomes. Pharmacists working within Part D MTM programs can play a unique role in helping patients manage their drug therapies because they are generally considered accessible and trustworthy,[2] they have the ability to consolidate their patients' drug claims to offer the most informed recommendations, and they can provide care in a cost-effective way.

Part D MTM programs hold promise to make an impact on Medicare beneficiaries' health outcomes and expenditures by alleviating the burden of inadequate drug treatments that lead to costly health events. Medication non-adherence, for example, contributes a substantial human and financial toll in the U.S., with 33 to 69% of all medication-related hospital admissions due to non-adherence.[4] The cost of medication non-adherence is staggering, estimated to exceed $177 billion in 2000 in the U.S., with hospital admissions accounting for almost 70% ($121.5 billion) of that amount.[5-7] Mechanisms or interventions that focus on improving medication adherence and other outcomes related to prescription drug use (e.g., drug interactions or use of contraindicated medications for particular health conditions), such as MTM programs,[8,9] have been postulated to lower overall healthcare costs by preventing adverse outcomes such as medication-related hospital admissions. In particular, MTM programs may be impactful for individuals who have chronic diseases, whose health outcomes depend more on long-term use of prescription medications.

The following sections provide information on the existing evidence of the impact of MTM programs on clinical (i.e., drug therapy-related) outcomes, as well as background information on the evolution of MTM programs in the Medicare Part D context. This chapter concludes with the rationale for CMS, Acumen, and Westat's goal to investigate the drug therapy and resource utilization outcomes in a population of chronically ill Medicare beneficiaries.

2.1 Evidence of MTM Effectiveness outside the Medicare Context

Thus far, research on MTM programs has focused on analyzing programs targeting non-Medicare beneficiaries in specific regions of the country. This research has generally concentrated on specific chronic diseases, and some studies have used claims from the private sector to quantify outcomes and costs.

The Asheville Project is a North Carolina-based MTM program providing education to individuals with chronic diseases such as diabetes, asthma, hypertension, and high cholesterol. One longitudinal study on this MTM program used health claims to demonstrate that patients receiving education and long-term MTM services experienced significant reductions in blood pressure and HDL cholesterol levels, and their risk of having a cardiovascular event decreased by 53%. Further, patients' use of the emergency department and need for hospitalization, in response to an acute cardiovascular event, decreased by 54%, reducing average costs to health plans by 46.5%.[8] Another study on the same MTM program found that among asthmatic patients, those receiving education and MTM services experienced sustained improvement in asthma control and were six times less likely to experience an emergency department visit or hospitalization. This resulted in direct cost savings of approximately $725 per patient, per year.[11] While these studies used health insurance claims to determine emergency department and hospitalization utilization and costs, they focused only on one MTM program. Thus, because they did not have comparison groups using other types of MTM program services, they were unable to draw conclusions about specific MTM program processes that promote health and reduce costs.

Other studies on MTM programs outside of Asheville have also found improvements in health outcomes. A randomized controlled trial in Tulsa, Oklahoma found that patients receiving comprehensive medication assessments and education on diet, lifestyle modification, and the role of medication in health were able to reduce blood pressure at a statistically higher rate than those who did not receive such services.[9] Another prospective study conducted on a Minnesota-based MTM program utilized health insurance claims to calculate outcomes as well as cost savings for patients with hypertension and hypercholesterolemia. This intervention yielded a significantly higher proportion of patients meeting Healthcare Effectiveness Data and Information Set (HEDIS) outcomes criteria for controlling blood pressure and cholesterol, compared to a non-intervention group. Claims data showed that patients receiving these MTM services had much lower health expenditures, leading to cost savings of $12.15 for every $1.00 spent on the MTM program.[12] A few other studies conducted outside of the Medicare context reported similar findings, as described in the 2008 Abt Associates report to CMS.[13]

2.2 Evolution of Medicare Part D Requirements for MTM programs

Research reports similar to those described in Section 2.1 above do not exist in the Part D MTM program context yet, partly because these programs have evolved considerably since they were introduced in January 2006. When the Medicare Modernization Act of 2003 established the Part D prescription drug program, it mandated that all stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) implement MTM programs targeting beneficiaries with multiple chronic conditions and complex drug regimens. Medicare requires that MTM programs automatically enroll those who qualify, but participation is voluntary, and members are given the opportunity to opt out at any time.

However, the Medication Modernization Act did not specify a set of standardized MTM program requirements for each Part D sponsor. This lack of standardization allowed Part D sponsors flexibility in designing and implementing their own programs, and some sponsors merely modified the MTM-like programs that had already been in place in their network pharmacies to align with CMS requirements. The lack of standardization also created marked differences in the types of services provided across contracts. For example, through the first year after Part D's enactment, there was little consistency across plans regarding the health conditions required for beneficiaries to quality for the MTM programs.[14] Additionally, MTM programs were providing a wide range of services involving education, compliance, monitoring, and medication review, with varying methods of content delivery and interventions frequency.[14] Some MTM programs, for example, provided significant, personalized information for their eligible beneficiaries by offering yearly, face-to-face comprehensive medical reviews. Other, less involved MTM programs offered general patient education materials transmitted by mail or phone.

In 2010, there were 678 active Part D contracts with an approved MTM program (585 Medicare Advantage prescription drug plans [MA-PDs] and 93 fee-for-service plans [PDPs]). The majority of their MTM programs targeted conditions that align with the most commonly used medications utilized by Medicare Part D beneficiaries, including cardiovascular and metabolic syndrome agents. In 2010, all MTM programs reported that they offered annual CMRs and quarterly TMRs to their enrollees. However, these programs differed in the ways in which they offered these interventions: for example, 81.1% of these programs presented enrollees with a list of medication therapy recommendations, while 29.4% provided enrollees with a reconciled medication list.

To promote MTM program consistency starting in program year 2010, CMS outlined stricter guidelines for three requirement categories. They are as follows:[10]

- CMS more specifically defined targeted beneficiaries for MTM programs as those with at least two or three chronic diseases. CMS required sponsors to target or accept at least four out of seven chronic diseases outlined by CMS.[a] Additionally, beneficiaries were required to be taking a minimum of two to eight covered Part D drugs.[b] They must also have had expected costs likely to exceed $3,000 for all covered drugs.[c]
- CMS standardized program enrollment options. In previous years, plans either used an opt-out method (in which MTM program-eligible beneficiaries were automatically enrolled in the program), an opt-in method of enrollment (in which MTM program-eligible beneficiaries had to choose to enroll in the MTM program), or a combination of the two. In 2010, all plans were required to enroll targeted beneficiaries using exclusively the opt-out method.
- CMS specified beneficiary-level and prescriber-level interventions for MTM programs to administer. On a beneficiary level, CMS requires MTM programs to offer a CMR for all of its beneficiaries annually, with additional quarterly targeted medical reviews (TMRs). On a prescriber level, sponsors are required to offer interventions to beneficiaries' prescribers (e.g., physicians or nurse practitioners) to resolve medication-related problems.

In 2010, CMS also expanded reporting requirements for MTM services. Before 2010, sponsors of MTM programs were required to report the number of beneficiaries eligible for MTM services, the reasons that eligible beneficiaries opted out of the program, and the costs and total numbers of 30-day prescription equivalents for each participating beneficiary. Starting in 2008 sponsors were also required to submit more specific information about services rendered at the beneficiary level, and reporting of CMRs began in 2010. Thus, 2010 MTM data includes whether a CMR was provided for each participating beneficiary, the date of the CMR, the number of targeted medication reviews (TMRs), the number of prescriber interventions, and the number of change(s) in therapy directly resulting from MTM interventions.[10] MTM program sponsors were required to provide 2010 information to CMS by February 2011.

Even with the increasingly standardized program and reporting requirements, plans have a degree of flexibility in many of the implementation criteria, and thus differences in MTM programs still exist. For example, in 2010, 72% of Part D plans required beneficiaries to have a minimum of three chronic diseases to be eligible for the MTM program, while 28% required a minimum of two chronic diseases. With respect to the number of covered drugs, a third of plans targeted beneficiaries who have filled a minimum of 2-7 Part D drugs, while two-thirds of plans

[a] These include the following diseases: Bone Disease-Arthritis, Diabetes, Dyslipidemia, Heart Failure, Hypertension, Mental Health Diseases, and Respiratory Disease.

[b] Eight Part D drugs is the maximum number of drugs a Part D sponsor may require for targeted enrollment.

[c] The annual cost threshold regulation will be revised for 2012 and subsequent years for the costs of covered Part D drugs, in an amount great than or equal to $3000.

required at least 8 Part D drugs for beneficiary inclusion in an MTM program. While the expected costs eligibility threshold has been standardized at $3,000, Part D sponsors have a great deal of flexibility on ways to forecast expenditures. Additionally, while CMS requires all plans to offer CMRs, the content of these reviews varies greatly. CMRs range from providing beneficiaries with basic educational materials to providing concrete, personalized action plans.[10]

2.3 Limitations of Current Research and Opportunities to Address Gaps

The North Carolina, Oklahoma, and Minnesota studies, along with others described in the 2008 Abt Associates report, provide valuable evidence for the health and financial benefits of MTM programs for those with specific diseases. However, they have several limitations. The study conducted in Minnesota did not use claims data, and it was therefore unable to provide analyses of cost savings as a result of the intervention.[9] The other studies that did tie their analyses to health insurance claims were able to connect health outcomes to expenditures, but they only focused on the aggregate effect of one MTM program at a time. Thus, their results cannot be used to draw conclusions about specific MTM program practices that yield beneficial results. In addition to their inability to pinpoint the types of MTM services that are most effective, all of these studies focused on a highly selected group of patients. Thus, they are not generalizable to the entire population of individuals in the United States that receive MTM services, or even the subset of that population that can access MTM services through Medicare Part D.

The universe of MTM programs operating under Medicare Part D provides a rich source of data that avoids such limitations. In 2008, Abt Associates conducted a qualitative study on Medicare Part D and other private sector MTM programs. Although the Abt report identified program definitions and intervention types, it was a purely qualitative study and it acknowledged that further research was needed to identify populations of Medicare beneficiaries most likely to benefit from MTM programs and the most effective intervention methods.[13]

To address this gap in the body of knowledge on MTM programs, CMS contracted Acumen, partnered with Westat, to build on Abt's research. We aimed to identify the impact of Part D MTM programs on Medicare beneficiaries' drug therapy and resource utilization outcomes, including hospital and ER visits which may be associated with adverse events. We particularly focused on high-cost, high-risk beneficiaries with congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), because those individuals may stand to benefit significantly from MTM interventions and their health impacts are relatively easy to identify over a six-month outcome period.

3 OVERVIEW OF THE EMPIRICAL APPROACH

We used a retrospective cohort study design to investigate how enrollment in a PDP or MA-PD MTM program[a], with or without receipt of a CMR, influenced drug therapy and resource utilization outcomes among beneficiaries with CHF or COPD. In particular, we compared outcomes experienced during a 180-day study period for beneficiaries with CHF and/or COPD who were newly enrolled in MTM in 2010 against outcomes experienced by a comparison group. Both all-cause and disease-specific outcomes were included because MTM programs, which provide general medication use recommendations for beneficiaries with multiple chronic conditions, may impact CHF- and COPD-specific outcomes as well as outcomes related to management of other conditions.

We used a two-step approach to adjust for differences between MTM enrollees and non-MTM enrollees. First, we narrowed the set of non-MTM enrollees in the comparison group to include only beneficiaries who were never enrolled in an MTM program in 2010 but who were potential candidates for MTM enrollment based on 2010 eligibility rules. To this end, we exploited variations in the MTM eligibility rules and implementation policies set by Part D sponsors to identify beneficiaries who were not eligible for MTM in their plan, but who would have been eligible if they had enrolled in another plan within the Medicare system. This first step guaranteed that beneficiaries in the comparison group had chronic conditions and drug utilization levels similar to the MTM enrollees included in our intervention groups. Second, to adjust for remaining differences in demographic and health characteristics between MTM enrollees and the comparison group, we used a regression framework that included health and demographic risk factors observed before enrollment in a MTM program.

The following sections describe the construction of intervention and comparison groups, outcomes of interest, and statistical analyses we conducted to estimate the association of participation in an MTM program and drug therapy and resource utilization outcomes. The final two sections describe the additional subpopulation and sensitivity analyses we conducted. A description of the data files we used is available in Appendix A.

[a] While we focused on measuring the outcomes of CHF and COPD patients in this report, the Part D MTM programs in question may serve enrollees with a variety of chronic conditions, and they do not necessarily limit their enrollment to patients with CHF or COPD or their treatment to CHF or COPD conditions. Of the 471 Medicare Part D MTM programs that passed data validation and enrollment criteria for our study, 96.0% of the programs specified that they targeted CHF patients, and 49.0% specified that they targeted COPD patients.

3.1 MTM Intervention Groups

Our initial MTM population included Medicare Part D beneficiaries who were newly enrolled in a Part D MTM program in 2010[a] and who had a CHF or COPD diagnosis in 2009 according to the Part D Hierarchical Condition Category (RxHCC).[b] Beneficiaries were considered to be newly enrolled in a Part D MTM program in 2010 if they were not enrolled in any Part D MTM program in any plan in 2009. Several additional exclusions were made to restrict the cohort of MTM enrollees included in the final study populations. First, beneficiaries were excluded if they had an end-stage renal disease (ESRD) diagnosis in 2009.[c15] Beneficiaries were also excluded if they resided in a long term institution for over 90 days in 2010, as MTM programs are not required to offer CMR to these beneficiaries. MTM enrollees who were enrolled in standalone Prescription Drug Plans (PDPs) or Medicare Advantage plans (MA-PDs) who submitted MTM eligibility and participation data that did not pass data validation[d] were also excluded. Finally, to be assigned to an intervention group, beneficiaries were required to be continuously enrolled in the same Part D contract during the 180-day study period. Beneficiaries who met these criteria were included in one of two intervention groups: 1) those who did not receive a CMR in the 180-day study period, and 2) those who did receive a CMR during that period. Please see **Table 3-1** for an illustration of the stepwise implementation of the exclusion criteria to build the final CHF and COPD intervention groups, and see **Table 3-2** for a description of the final intervention groups. These groups were further stratified into beneficiaries enrolled in PDPs or MA-PDs or specific parent organizations for the subpopulation analyses described in Section 3.5.

[a] We used an Intention to Treat (ITT) model, so MTM enrollees were included in our intervention group even if they later opted out of the MTM program. About 6.7% of beneficiaries in PDPs and 8.5% of enrollees in MA-PDs opted out of MTM during the study period.
[b] The Part D Hierarchical Condition Categories (RxHCC) were obtained from the 2010 Risk Adjustment System (RAS) file. CHF was defined as RxHCC 91, and COPD was defined as RxHCCs 109 and 110.
[c] Beneficiaries with ESRD were excluded from this analysis due to the systematic differences in Medicare eligibility and resource utilization between ESRD patients and other MTM-eligible patients.
[d] In 2010, 133 out of 604 contracts submitted MTM files that did not pass data validation.

Table 3-1: Stepwise Implementation of Cohort Selection for Final CHF and COPD Intervention Groups

Inclusion Criteria	*CHF Intervention Group Selection*			*COPD Intervention Group Selection*		
	N	***Remaining from total (%)***	***Remaining from previous step (%)***	***N***	***Remaining from total (%)***	***Remaining from previous step (%)***
Part D beneficiaries with 2009 risk data	2,734,601			2,734,601		
Have CHF or COPD (respectively)[a]	777,839	28.4%	28.4%	772,905	28.3%	28.3%
Not new in risk file	774,065	28.3%	99.5%	768,486	28.1%	99.4%
Have at least one PDE claim in 2010	771,846	28.2%	99.7%	766,761	28.0%	99.8%
Did not have ESRD in 2009[b]	739,431	27.0%	95.8%	751,607	27.5%	98.0%
Non-LTI in 2010	646,214	23.6%	87.4%	679,502	24.8%	90.4%
Enrolled in contract that passed data validation for MTM section	552,891	20.2%	85.6%	573,056	21.0%	84.3%
Enrolled in one MTM program in 2010	535,286	19.6%	96.8%	553,938	20.3%	96.7%
Enrolled in a MTM program at least one day in 2010	531,164	19.4%	99.2%	549,911	20.1%	99.3%
New to MTM in 2010	288,600	10.6%	54.3%	299,410	10.9%	54.4%
Same contract reported in MTM Beneficiary-Level file and Part D enrollment file	287,456	10.5%	99.6%	298,210	10.9%	99.6%
Continuously enrolled in Part D during study period	261,443	9.6%	91.0%	274,198	10.0%	91.9%
Enrolled in the same contract during outcome period	242,865	8.9%	92.9%	253,288	9.3%	92.4%

[a] Some beneficiaries are included in both the CHF and COPD cohorts because they met criteria for both chronic conditions.
[b] Patients with a diagnosis of ESRD were excluded from the analysis due to their systematically different Medicare eligibility criteria and resource utilization profile.

Table 3-2: Composition of Intervention Groups

Intervention Group	*Included in the MTM Intervention Groups*	*MTM with CMR*		*MTM without CMR*	
	N	*N*	*% of Total*	*N*	*% of Total*
CHF	242,865	25,207	10.4%	217,658	89.6%
COPD	253,288	29,011	11.5%	224,277	88.5%

3.2 MTM Comparison Groups

Comparison groups for each MTM disease cohort were constructed from the pool of beneficiaries in the same disease cohort who were not enrolled in MTM at any point in 2010 based on the plan-reported data to CMS. Because beneficiaries in the disease cohort who were not enrolled in MTM were, on average, healthier and using fewer prescription drugs (see **Table 3-3**); additional steps were required to identify beneficiaries suitable for inclusion in the comparison group.

Table 3-3: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with CHF and COPD, by MTM Eligibility

Demographic Characteristics and Drug Use Patterns	*Individuals with CHF*		*Individuals with COPD*	
	MTM Eligible	*MTM Ineligible*	*MTM Eligible*	*MTM Ineligible*
N	531,164	1,828,055	549,911	2,311,866
Average Age (years)	75.3	77.4	72.4	73.5
Male (%)	40.9%	43.3%	39.4%	43.8%
Female (%)	59.1%	56.7%	60.6%	56.2%
Average Risk Score	1.7	1.4	1.7	1.4
Average Number of RxHCCs	9.8	8.1	9.5	7.5
Average Number of Any Part D Drugs	18.0	11.3	18.4	11.0
Average Number of Maintenance Drugs	12.3	7.5	12.0	6.7
Average Part D Cost	$ 6,472.37	$ 2,945.75	$7,016.14	$3,266.74

To narrow the set of beneficiaries in the comparison group to include only beneficiaries with chronic conditions and drug utilization levels similar to those experienced by MTM enrollees, we exploited variations in MTM eligibility rules and implementation methods set by Part D sponsors. While CMS dictates thresholds for each eligibility criterion (i.e., on metrics

such as numbers of drugs, numbers of chronic diseases, and Part D cost), Part D sponsors have flexibility in determining the specific eligibility criteria for their MTM programs. In 2010, Part D sponsors had the ability to:

- Select the minimum number of chronic diseases and choose which chronic diseases to target from a list of chronic condition options;
- Set the minimum number of covered Part D drugs a beneficiary must have filled to be eligible for MTM;
- Restrict the list of drugs that count towards MTM eligibility to include either only drugs to treat certain conditions, drugs in certain classes or chronic/maintenance drugs; and
- Rely on different statistical methods and data to forecast beneficiary Part D costs.

When constructing our comparison groups, we used the flexible criteria above to create an algorithm to identify Part D beneficiaries who were not eligible for their contract's MTM program (i.e., they failed to meet specific eligibility parameters established by their chosen contract), but who would have been eligible for MTM had they been enrolled in a different contract. Since assessing eligibility for every single MTM program required an enormous amount of effort, we opted to apply MTM eligibility parameters used by the largest MTM programs in 2010. To illustrate this approach, assume Contracts A and B both required that a beneficiary fill a minimum number of eight covered Part D drugs, but Contract A restricted the list of eligible drugs to include only chronic/maintenance drugs. A beneficiary who was enrolled in Contract A and filled eight covered Part D drugs, only six of which were chronic/maintenance, would not have been eligible for MTM. However, this beneficiary would have been eligible for enrollment in an MTM program had he been enrolled in Contract B. This beneficiary would be identified as a control by our algorithm.

To implement the comparison group selection algorithm, we linked CHF and COPD non-enrollees to their Medicare Risk- Adjustment System (RAS) files as well as Part D PDE claims to identify health conditions, drug utilization and Part D costs for each beneficiary. We then applied the criteria listed in **Table 3-4** to identify those eligible for MTM.

Table 3-4: MTM Eligibility Criteria Used to Select Comparison Group

Eligibility Criteria	***Parameters for Comparison Group Selection***
Part D Drugs	At least 8 of any covered Part D drugs
Targeted Chronic Conditions	At least 2 of the following chronic diseases: CHF, Diabetes Mellitus, Hypertension, Dyslipidemia; OR At least 3 of the following chronic diseases: CHF, Diabetes mellitus, Hypertension, Dyslipidemia, COPD, Rheumatoid Arthritis, Osteoarthritis, Osteoporosis, Asthma

Eligibility Criteria	*Parameters for Comparison Group Selection*
Part D Drugs	At least 8 of any covered Part D drugs
Part D Total Drug Costs	Observed cost of $750 in first quarter, $1,500 in second quarter, $2,250 in third quarter and $3,000 in fourth quarter; OR Expected annual cost of $3,000 after applying the following formula: YTD Rx$ + Estimated Daily Rx$ *Days Left in Yr.

Beneficiaries who met the eligibility criteria above were assigned a random index date in 2010 at which point their 180-day study periods started. They were then assigned to the final comparison group if they were continuously enrolled in Part D during the 180-day study period, and if they were enrolled in the same Part D contract during that study period.

Table 3-5 and **Table 3-6** below demonstrate the results of narrowing the set of beneficiaries to be included in the CHF and COPD comparison groups: individuals assigned to the comparison group, on average, used about the same number of prescription medications and had similar severity of health conditions (identified using risk scores) in 2010.

Table 3-5: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with CHF, by MTM Eligibility and Comparison Group Assignment

Demographic Characteristics and Drug Use Patterns	*MTM Eligible*	*Not MTM Eligible*	
		Assigned to Comparison Group	*Not Assigned to Comparison Group*
N	531,164	350,415	1,477,640
Average Age (years)	75.3	75.7	77.8
Male (%)	40.9%	37.7%	44.6%
Female (%)	59.1%	62.3%	55.4%
Average Risk Score	1.7	1.7	1.4
Average Number of RxHCCs	9.8	9.7	7.7
Average Number of Any Part D Drugs	18.0	17.1	9.9
Average Number of Maintenance Drugs	12.3	11.1	6.6
Average Part D Cost	$6,472.37	$6,986.56	$1,987.49

Table 3-6: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with COPD, by MTM Eligibility and Comparison Group Assignment

Demographic Characteristics and Drug Use Patterns	**MTM Eligible**	***Not MTM Eligible***	
		Assigned to Comparison Group	*Not Assigned to Comparison Group*
N	549,911	440,920	1,870,946
Average Age (years)	72.4	72.3	73.7
Male (%)	39.4%	36.3%	45.6%
Female (%)	60.6%	63.7%	54.4%
Average Risk Score	1.7	1.7	1.3
Average Number of RxHCCs	9.5	9.3	7.1
Average Number of Any Part D Drugs	18.4	17.4	9.5
Average Number of Maintenance Drugs	12.0	10.7	5.7
Average Part D Cost	$7,016.14	$7,364.76	$2,300.97

Finally, we investigated whether individuals in our intervention and comparison groups were drawn mostly from plans that had implemented relatively restrictive MTM eligibility criteria. **Table 3-7**, **Table 3-8**, and **Table 3-9** show the distribution of health plans in our study population stratified by the selectivity of their MTM eligibility criteria. To assign levels of selectivity, we first identified the total number of individuals from each plan who were assigned either to our CHF or COPD intervention groups or the corresponding comparison groups. Next, we calculated the proportion of individuals who were included in our intervention groups (i.e., who were identified by the plan as eligible for MTM) or our comparison groups (i.e., who were not identified by the plan as eligible for MTM). If the vast majority of these individuals (>80%) were deemed eligible for MTM by their plan, we inferred that the plan's eligibility criteria were relatively lenient; therefore, we assigned that plan to the "low selectivity" group. Contrastingly, if only a minority of these individuals (<20%) were deemed eligible for MTM by that plan, we inferred that the plan's eligibility criteria were relatively stringent; we assigned that plan to the "high selectivity" group. The remaining plans, which enrolled between 20% and 80% of these individuals in their MTM program, were assigned to the "medium selectivity" group. As shown in **Table 3-7**, the distribution of health plans by their level of selectivity was approximately uniform across these different levels of restrictiveness. In other words, our eligibility algorithm, which assigned individuals with CHF and/or COPD to our comparison groups, drew individuals at roughly equivalent proportions from plans across the range of low to high selectivity in eligibility criteria. Further, we found that at least one individual from each 2010 MTM program

that passed data validation was included in each of our CHF and COPD intervention and comparison groups.

Table 3-7: Distribution of Drug Plans by Selectivity of Their MTM Eligibility Criteria

Drug Plans	*Selectivity of MTM Eligibility Criteria*	*Number of Drug Plans*	*% of Drug Plans*
PDP	*Low**	94	11%
	*Medium***	560	68%
	*High****	169	21%
	Total	823	100%
MA-PD	*Low*	229	26%
	Medium	568	64%
	High	90	10%
	Total	887	100%
Overall	*Low*	323	19%
	Medium	1128	66%
	High	259	15%
	Total	1710	100%

*We defined the selectivity of a health plan's MTM eligibility criteria as low when <20% of members who met these criteria had not been enrolled in the MTM intervention and were thus included in our comparison group.

** We defined the selectivity of a health plan's MTM eligibility criteria as medium when 20-80% of members who met these criteria had not been enrolled in the MTM intervention and were thus included in our comparison group.

*** We defined the selectivity of a health plan's MTM eligibility criteria as high when >80% of members who met these criteria had not been enrolled in the MTM intervention and were thus included in our comparison group.

3.3 Outcomes

The outcome period was 180 days after date of MTM enrollment (for beneficiaries in the intervention groups) or a randomly-assigned date in 2010 (for those in the comparison group). We assessed the drug therapy and resource utilization outcomes described in **Table 3-8** and **Table 3-9** below for individuals in the intervention and comparison groups.

Table 3-8: Outcome Measures During 180-Day Study Period for Individuals with Congestive Heart Failure

OUTCOMES	*DEFINITION*
Drug Therapy Outcomes[a]	
Use of Evidence-Based Medication for CHF	At least one fill of a Tier 1 medication in the study period.
PDC with Evidence-Based Medication for CHF	Proportion of days covered (PDC) across all Tier 1 (evidence-based) medications. PDC was calculated as the proportion of days during the 180-day study period when an individual possessed any of the Tier 1 medications. Patients who had overlapping supply of medications within the same drug class were considered to possess those medications for the total days of supply for all prescription fills for that drug class. See **Table B-1** for a list of all CHF-specific medications included in this analysis.
Adherent to any Evidence-Based Medication for CHF	Individuals are defined as adherent to any evidence-based medication for CHF when their PDC for that regimen is $\geq$ 80%. PDC with Evidence-Based Medication for CHF is defined above.
At Least One Drug-Drug Interaction	At least one fill of a target medication and one fill of a contraindicated medication during the 180-day study period. The list of drug-drug interactions is maintained by the Pharmacy Quality Alliance (PQA) for their measure concept and provided in **Table B-3**.[b]
Drug Contraindicated for CHF	At least one fill of a Non-Steroidal Anti-Inflammatory Drug (NSAID), contraindicated for individuals with CHF.
Use of At Least One High Risk Medication	At least one fill of a drug indicated as a high-risk medication for the elderly, out of the population of individuals $\geq$ 65 years of age. See the list of high-risk medications maintained by the PQA in **Table B-4**.
Resource Utilization Outcomes	
All-Cause Hospitalization	Occurrence of at least one hospitalization identified using IP claims data.

[a] Drug therapy outcomes were based on the patient safety measures used by CMS in 2010 for calculating the use of high risk medications (HRM), occurrence of drug-drug interactions (DDI), and adherence to medications (ADH). Patient Safety measures are based on measures created by the Pharmacy Quality Alliance (PQA) and are used by CMS to calculate and assign Star Ratings to Part D plans each year.

[b] To measure drug-drug interactions, Acumen used the PQA HRM measure specifications in place during the 2010 study period. The PQA updated its technical specifications for the HRM measure in early-2012 based on new clinical recommendations from the American Geriatrics Society (AGS). At this time PQA adjusted the HRM measure so that patients would only be included if they received at least two prescription fills of the same high-risk medication. (**16.** Pharmacy Quality Alliance (PQA). PQA Approved Measures. 2012; http://pqaalliance.org/measures/default.asp. Accessed October 1, 2012.)

OUTCOMES	*DEFINITION*
CHF-Related Hospitalization	Occurrence of at least one hospitalization with CHF listed as a primary or other diagnosis on the IP claim.
All-Cause ER Visit	Occurrence of at least one emergency room visit identified using OP claims data.*
CHF-Related ER Visit	Occurrence of at least one ER visit, with CHF listed as a primary or other diagnosis on the OP claim.*
Resource Utilization Outcomes: Medications and Costs	
Number of Medications	Number of unique medication fills. Medications are defined at the therapeutic-class level.**
Generic Substitution Ratio	Ratio of prescription fills for generic medications to prescription fills for all medications that have existing generic options.
Part D Costs	Total payments recorded on Part D claims for all prescription medications not used for treatment of CHF. See the list of all CHF-related medications in **Table B-1**.
All-Cause Inpatient Costs	Medicare payments recorded on IP claims.*
CHF-Related Inpatient Costs	Medicare payments recorded on IP claims with CHF listed as a primary or other diagnosis.*
All-Cause ER Costs	Medicare payments recorded on out-patient emergency room (OP ER) claims.*
CHF-Related ER Costs	Medicare payments recorded on OP ER claims with CHF listed as a primary or other diagnosis.*

* This outcome was only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
** Therapeutic class is defined at the Medi-Span Generic Product Identifier 10-digit level.

Table 3-9: Outcome Measures During 180-Day Study Period for Individuals with Chronic Obstructive Pulmonary Disease[a]

OUTCOMES	*DEFINITION*
Drug Therapy Outcomes	
PDC to LABA-Only Regimen[b] [17]	Proportion of days covered with long-acting beta-agonists (LABAs). PDC was calculated as the proportion of days during the 180-day study period when an individual possessed any of the LABAs medications. See **Table B-2** for a list of all COPD-specific medications included in this analysis.
PDC to LAAC-Only Regimen	PDC with long-acting anticholinergic (LAACs).
PDC to LABA + LAAC Combination Regimen	PDC with LABAs and LAACs. Individuals must have had supply of both a LABA and a LAAC to be counted as having full possession of their COPD regimen on each day.
Adherent to PDC to LABA-Only Regimen	Individuals are defined as adherent to a medication regimen when their PDC for that regimen is $\geq$ 80%. PDC to LABA-Only Regimen is defined above.
Adherent to LAAC-Only Regimen	Individuals are defined as adherent to any evidence-based medication for CHF when their PDC for that regimen is $\geq$ 80%. PDC to LAAC-Only Regimen is defined above.
Adherent to Combination Regimen	Individuals are defined as adherent to any evidence-based medication for CHF when their PDC for that regimen is $\geq$ 80%. PDC to PDC to LABA + LAAC Combination Regimen is defined above.
At Least One Drug-Drug Interaction (DDI)[c]	At least one fill of a target medication and one fill of a contraindicated medication during the 180-day study period. The list of drug-drug interactions was created by the Pharmacy Quality Alliance and provided in **Table B-3**.
High Risk Medication (HRM)[d]	At least one fill of a drug indicated as a high-risk medication for the elderly, out of the population of individuals $\geq$ 65 years of age. See the list of high-risk medications in **Table B-4.**

[a] We did not measure optimal uptake of evidence-based medications for COPD. This is because, for COPD, the optimal uptake of evidence-based medications is dependent on disease severity. The claims-based information on disease severity was not adequate to determine whether a beneficiary should be taking a specific evidence-based medication for COPD.

[b] The PDC adherence measure is used by the Pharmacy Quality Alliance (PQA) and considered to provide a more conservative estimate of adherence rates compared to the alternative MPR measure.

[c] We measured Drug-Drug Interaction (DDI) using the 2010 version of the DDI measure, which is maintained by the Pharmacy Quality Alliance (PQA)

[d] We used the Pharmacy Quality Alliance (PQA) High-Risk Medication (HRM) measure specifications in place during the 2010 study period. PQA updated its technical specifications for the HRM measure in early-2012 based upon new clinical recommendations from the American Geriatrics Society (AGS). At this time PQA adjusted the HRM measure so that patients would only be included if they received at least two prescription fills of the same high-risk medication. (**16.** Pharmacy Quality Alliance (PQA). PQA Approved Measures. 2012; http://pqaalliance.org/measures/default.asp. Accessed October 1, 2012.)

OUTCOMES	*DEFINITION*
Resource Utilization Outcomes: Hospital and ER Visits	
All-Cause Hospitalization	Occurrence of at least one hospitalization identified using IP claims data.
COPD-Related Hospitalization	Occurrence of at least one hospitalization with COPD listed as a primary or other diagnosis on the IP claim.
All-Cause ER Visit	Occurrence of at least one emergency room (ER) visit identified using OP claims data.*
COPD-Related ER Visit	Occurrence of at least one emergency room (ER) visit, with COPD listed as a primary or other diagnosis on the OP claim.
Resource Utilization Outcomes: Medications and Costs	
Number of Medications	Number of unique medications an individual fills. Medications are defined at the therapeutic-class level.**
Generic Substitution Ratio	Ratio of prescription fills for generic medications to prescription fills for all medications that have existing generic options.
Part D Costs	Total payments recorded on Part D claims for all prescription medications not used for treatment of COPD. Medications used for treatment of COPD include those listed in **Table B-2** as well as theophylline and inhaled corticosteroids.
All-Cause Inpatient Costs	Medicare payments recorded on IP claims.
COPD-Related Inpatient Costs	Medicare payments recorded on IP claims with COPD listed as a primary or other diagnosis.
All-Cause ER Costs	Medicare payments recorded on OP ER claims.*
COPD-Related ER Costs	Medicare payments recorded on OP ER claims with COPD listed as a primary or other diagnosis.*

* This outcome was only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
** Therapeutic class is defined at the Medi-Span Generic Product Identifier 10-digit level.

3.4 Empirical Specifications

Applying the MTM eligibility algorithm described in Section 3.2 restricted the final comparison groups to individuals who had relatively similar chronic condition profiles and drug utilization patterns compared to those who received MTM interventions. We accounted for remaining differences between the MTM intervention and comparison groups by applying several statistical specifications to estimate the empirical association between participating in an MTM program (with or without receipt of a CMR) and each outcome listed in **Table 3-8** and **Table 3-9** above. For each disease cohort, we used multivariate logistic regression models to estimate how participating in an MTM program impacted each of the drug therapy outcomes as well as the number of hospital and emergency department visits, after adjusting for sociodemographic and health characteristics before the enrollment date. For several outcome metrics, we restricted the population included in each drug therapy outcome model to beneficiaries who experienced the outcome during the 180-days preceding the start of the study period. Then, we used multivariate logistic regressions to estimate the impact of MTM participation on the probability that an individual would experience a different outcome by the end of the study period. For example, the High Risk Medication (HRM) model specifications estimated the probability of discontinuing the use of HRMs during the last 90 days of the study period among individuals who filled at least one high risk medication during the 180-days preceding the index date. Due to small sample sizes in the sub-population analyses, the model specifications for the drug therapy analysis at the parent organization level estimated the probability of experiencing a given outcome during the study period across all beneficiaries in the study.[a]

We also used ordinary least squares (OLS) regression to estimate the association of participating in an MTM program, with or without receipt of a CMR, and cost outcomes. When calculating cost outcomes for the hospital (IP) and emergency room (ER) settings, we estimated a two-part model to account for the large proportion of individuals with zero costs and the positively skewed distribution of costs among individuals with nonzero costs in each setting. In the first part of the model, we used logistic regression to estimate the statistical relationship between MTM participation and the event of incurring positive costs. In the second part of the model, we used OLS regression with heteroskedastic robust standard errors to estimate the

[a] An alternative specification commonly used to reduce the bias due to differences in health-seeking behavior is the difference in difference estimator (DiD). The DiD compares changes in outcomes for MTM enrollees to the change in outcomes for beneficiaries in the control group. This estimation strategy controls for time-invariant differences between the intervention and control group, but requires complete data for the observation and outcome period. Because data on risk factors for the outcome period were not available at the time of this study, this analysis did not rely on this specification.

empirical associations between MTM participation and the costs restricted to individuals who had at least one claim.

All models incorporated a wide variety of covariates to adjust for differences in the makeup of MTM enrollee and comparison populations. First, we adjusted for demographic characteristics using an interaction of age and gender; self-reported race/ethnicity; socioeconomic status, using indicator variables for low-income status (LIS) and Medicaid eligibility; and regional variations, using indicator variables representing Hospital Referral Regions (HRR) stratified into octiles by mean prescription drug and acute care costs.[18] We further adjusted for health status, using Medicare RxHCC flags for 84 combinations of health conditions, the numbers of chronic condition maintenance drugs and therapeutic categories of drugs an individual filled in the six months preceding the study period, the numbers of prescribers from whom an individual received a prescription in the outcome period, and the number of providers an individual visited in the outcome period. To control for differences in drug benefit plans that may be associated with better health outcomes, we adjusted for individual drug benefit plan enrollment (i.e., cost-saving incentives) using a dummy variable for enhanced drug plans with gap coverage, enhanced drug plans with no gap coverage, and plans that were not enhanced. Finally, for each outcome, we also adjusted for incidence or level of that outcome in the six months preceding each individual's 180-day study period: for example, when estimating the association of MTM program participation with medication adherence, we adjusted for each individual's level of adherence in the six months prior to the study period. This final adjustment served as a proxy for beneficiary behavior in terms of health-seeking characteristics or high levels of utilization. For all analyses, significance was assessed at the $p<0.05$ level.

3.5 Subpopulation Analyses

We also conducted sub-population analyses exploring the outcomes listed above among beneficiaries enrolled in MTM programs offered by PDPs or MA-PDs associated with specific parent organizations. For these analyses, intervention and comparison groups were constructed from those described in Sections 3.1 and 3.2 above, restricted to individuals enrolled in MTM programs associated with the specific parent organization in question.

Information about the parent organizations' MTM programs is available in **Table 3-10**. It summarizes MTM programs in terms of the format of the CMRs and the method by which MTM programs reached out to the prescribers of enrollees' medication, based on the information they provided in the MTM Submission Files. One important metric on which parent organizations showed significant variation, was on the administration of CMRs. Organizations A, C, and E's MA-PDs provided CMRs to less than 5% of individuals enrolled in their MTM

programs, while Organizations B, D, and F provided CMRs to 21-40%, 81%+, and 41-60% of COPD or CHF beneficiaries in their MTM programs, respectively. While Organization D provided CMRs to most of their MTM enrollees, its intervention was the least intensive of the group. Organization D's CMR is conducted by phone only and it does not include an action plan, recommendations, or education materials like other organizations. Organization D reached out to prescribers of beneficiary medication by fax only, while other organizations use additional methods such as phone, mail, e-mail, and even electronic medical records (EMRs). Among all organizations in this study, Organization F had the most intensive program and at the same time conducted CMR for a substantial share of their MTM enrollees.

Table 3-10: MTM Programs Summary for Selected Parent Organizations

Parent Organization	*MTM Enrollment* [a]	*CMR Consultation Mode*	*Written Summary of CMR* [b]	*Percent Receiving CMRs*	*Prescriber Outreach Methods*
Organization A	High*	Phone	Action plan, recommendations	Under 5%	Phone, fax
Organization B	High*	Phone, face to face	Action plan, recommendations, personal medication list	21-40%	Phone, fax, mail
Organization C	Medium**	Phone, face to face	Action plan, recommendations	Under 5%	Phone, fax, mail
Organization D	Medium**	Phone	Personal medication list	81%+	Fax
Organization E	Low***	Phone	Action plan, recommendations, personal medication list	Under 5%	Phone, fax, mail
Organization F	Low***	Phone, face to face	Recommendations, reconciled medication list, education materials	41-60%	Phone, EMRs, e-mail and mail

*High enrollment plans consist of over 100,000 MTM enrollees.
** Medium enrollment plans consist of over 40,000 MTM enrollees and less than 100,000 MTM enrollees.
***Low enrollment plans consist of less than 40,000 MTM enrollees.

[a] This number includes all MTM enrollees, not just enrollees with CHF and COPD.
b This analysis occurred before there was a required standardized format for the CMR action plan and summary. Section 10328 of the Affordable Care Act requires standardized format requirements effective 1/1/2013.

4 RESULTS: IMPACT OF MTM ON BENEFICIARIES WITH CHF

Beneficiaries with CHF who enrolled in MTM programs consistently experienced higher quality prescription drug therapies and lower total prescription drug costs relative to a comparison group, but these outcomes did not necessarily correspond to improvements beyond Part D. This section provides the results of the retrospective cohort study comparing risk adjusted outcomes among beneficiaries with CHF who were newly enrolled in MTM programs in 2010 against risk adjusted outcomes experienced by a comparison group. It presents results stratified by beneficiaries enrolled in PDPs or MA-PDs and by specific parent organizations. Sections 4.1 and 4.2 offer descriptions of the general demographic and health characteristics of the intervention and comparison groups, as well as their baseline drug therapy and resource utilization patterns before the study period. Sections 4.3, 4.4, and 4.5 then summarize the risk-adjusted results of our overall PDP, overall MA-PD, and parent organization-specific analyses of the association between MTM participation and each outcome of interest.

4.1 Characteristics of the Study Population

An initial group of 29,751,040 individuals were enrolled in Part D in 2010 and had prior RxHCC risk data that could be used to identify disease diagnoses. Of those, 3,506,350 (11.8%) were identified as having CHF. Out of those individuals with CHF who were enrolled in PDPs, 208,850 were assigned to the comparison group, 136,305[a] to the intervention group for individuals in MTM programs who did not receive a CMR ("MTM without CMR"), and 14,858[b] to the intervention group for individuals in MTM programs who did receive a CMR ("MTM with CMR"). For those enrolled in MA-PDs, 62,119 were assigned to the comparison group, 81,353[c] to the MTM without CMR intervention group, and 10,349[d] to the MTM with CMR intervention group. In other words, for beneficiaries with CHF who met our inclusion criteria for any of the intervention groups (i.e., those who were enrolled in an MTM program in 2010 but not in a prior year), 9.8% of those in PDPs, and 11.3% of those in MA-PDs received a CMR.

As shown in **Table 4-1**, the intervention and comparison groups for beneficiaries enrolled in PDPs varied in terms of distributions of gender, age, and race. All three groups tended to have relatively similar rates of most health conditions, excluding diabetes and dyslipidemia. Because all beneficiaries in the comparison group were eligible for MTM based on their RxHCC indicators, this finding suggests that MTM programs were more successful at identifying and targeting beneficiaries with diabetes and dyslipidemia relative to other conditions. Also, the

[a] Of these, 9,263 opted out during the measurement period.
[b] Of these, 35 opted out during the measurement period.
[c] Of these, 6,898 opted out during the measurement period.
[d] Of these, 66 opted out during the measurement period.

difference in the proportion of individuals in the MTM intervention groups that were taking a high number of maintenance drugs relative to the comparison group suggest MTM programs were more likely to target this type of beneficiaries. MTM beneficiaries who received a CMR were more likely to be LIS eligible and disable, relative to the other groups. Intervention and comparison groups for beneficiaries enrolled in MA-PDs also demonstrated some similar trends, but they differed in terms of their proportions of disabled and LIS eligible beneficiaries across the three groups. In comparison to all PDP groups, those in the MA-PD groups tended to have comparable rates of specific health conditions but took fewer maintenance drugs at baseline. The intervention and comparison groups for each of these parent organizations generally had demographic and health characteristics similar to those shown for overall PDP and MA-PD comparison and intervention groups.

Table 4-1: Demographic and Health Characteristics of Individuals with CHF Assigned to PDP and MA-PD Intervention and Comparison Groups

	Beneficiaries Enrolled in PDPs			*Beneficiaries Enrolled in MA-PDs*		
Demographic and Health Characteristics	*Comparison*	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	208,850	136,305	14,858	62,119	81,353	10,349
% in MTM Receiving CMR			9.8%			11.3%
Gender						
Male	36.5%	39.9%	32.9%	41.4%	46.1%	47.7%
Female	63.5%	60.1%	67.1%	58.6%	53.9%	52.3%
Age						
≤65	16.8%	14.4%	24.9%	12.5%	12.1%	8.5%
66-75	28.3%	31.6%	33.6%	32.4%	35.3%	35.2%
76-85	34.3%	36.1%	30.6%	37.6%	37.7%	41.9%
>85	20.6%	18.0%	10.9%	17.6%	14.9%	14.5%
Race						
White	81.0%	81.2%	75.8%	79.4%	79.2%	80.7%
Black	12.6%	11.9%	18.4%	13.9%	13.4%	11.6%
Hispanic	2.8%	2.9%	3.3%	3.4%	3.8%	3.0%
Other or Unknown	3.6%	4.0%	2.6%	3.3%	3.6%	4.7%
SES						
LIS Eligible	54.5%	47.7%	69.4%	36.9%	35.8%	22.6%
General Health Status in Observation Period						
≤8 Maintenance Drugs	38.0%	26.7%	14.1%	46.1%	33.3%	29.0%
9-10 Maintenance Drugs	29.3%	27.6%	25.9%	29.0%	28.8%	28.8%
11-12 Maintenance Drugs	17.8%	21.6%	24.9%	15.2%	20.4%	22.3%
>12 Maintenance Drugs	14.8%	24.1%	35.2%	9.8%	17.6%	20.0%
Disabled	18.5%	16.2%	27.5%	14.6%	14.2%	10.2%
Specific Health Conditions						
Diabetes	46.2%	65.7%	70.7%	44.8%	66.3%	65.0%
Dyslipidemia	72.1%	78.7%	77.2%	73.7%	82.5%	84.0%
Rheumatoid Arthritis	6.0%	4.4%	6.4%	6.0%	4.0%	4.0%
AMI & Unstable Angina	67.1%	71.1%	68.0%	65.2%	71.4%	68.2%
Stroke & Cerebral Hemorrhage	26.3%	25.9%	23.5%	24.7%	24.4%	21.4%
Vascular Disease	34.3%	33.4%	32.9%	35.9%	36.0%	36.4%
Asthma & COPD	52.9%	47.0%	59.7%	55.5%	45.4%	46.4%

4.2 MTM Effectiveness at Targeting Individuals with CHF and Medication Issues

Table 4-2 below provides baseline rates or averages of drug therapy patterns, use of the hospital and ER, and factors contributing to health system efficiency (e.g., use of generic medications, costs) among the PDP and MA-PD intervention and comparison groups in the six months preceding their study periods. It displays the unadjusted magnitude of each outcome of interest in the observation period, and it shows how individuals in the intervention groups differed from the comparison groups before any MTM services were rendered.

Differences in baseline characteristics between the comparison and the MTM without CMR groups provide insights on MTM programs' ability to identify beneficiaries with poor outcomes. Because MTM programs rely heavily on drug use to identify their eligible population, beneficiaries who were already in evidence-based treatment were more likely to be identified eligible by MTM programs. Moreover, relative to the comparison groups, beneficiaries targeted by MTM programs were more likely to use evidence-based medications and be adherent to those medications. These measures were relatively "topped-up," with 90.1% and 91.1% of individuals who received MTM (in PDPs and MA-PDs, respectively) already adherent to evidence-based medications in the six months preceding MTM enrollment.

At the same time, beneficiaries targeted by MTM programs experienced higher rates of adverse outcomes. They were more likely to have drug-drug interactions, use high-risk medications, and include medications contraindicated for CHF in their medication regimens in the observation period. They also were more likely to experience all-cause and CHF-related hospitalizations in that period. The proportion of individuals experiencing a hospitalization due to any cause in the six months preceding the outcome period ranged from 31.0% (comparison group) to 34.7% (MTM without CMR) for those in PDPs, and slightly lower at 24.1% (comparison group) to 30.3% (MTM without CMR) for those in MA-PDs. Individuals in the MTM without CMR groups also had higher absolute all-cause and CHF-related costs relative to the comparison group. For example, those who enrolled in PDP MTM programs who did not receive CMRs incurred about $1,034 more in inpatient costs than those in the comparison group, in the six-month period before they received any MTM services.

Among those who were enrolled in MTM programs, individuals who opted to receive a CMR had slightly better drug treatment outcomes at baseline: they were more likely to use evidence-based medications and more likely to be adherent compared to other MTM enrollees. Such differences illustrate the "healthy user effect," showing that individuals who were already inclined to be adherent to their medications – or behave in other ways to promote their own

health – were also slightly more likely to choose to receive a CMR once they enrolled in an MTM program. Relative to MTM enrollees who chose not to receive a CMR, they were also slightly less likely to experience a hospitalization in the observation period and incurred lower hospitalization costs. In particular, individuals enrolled in PDPs who received a CMR incurred approximately $601 less in all-cause hospitalizations and $320 in CHF-related hospitalizations during the six months preceding MTM enrollment compared to other MTM enrollees who opted out of having a CMR. These baseline trends, as well as others presented in **Table 4-2**, illustrate the differences in our study cohorts before individuals received any MTM services and how these individuals may have been more or less likely to experience adverse outcomes and incur resulting costs based on their health characteristics as well as their intrinsic behavioral characteristics.

Table 4-2: Baseline Drug Therapy and Resource Utilization Patterns among PDP and MA-PD Intervention and Comparison Groups [a]

Drug Therapy and Resource Utilization Measures	***Beneficiaries Enrolled in PDPs***			***Beneficiaries Enrolled in MA-PDs***		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	208,850	136,305	14,858	62,119	81,353	10,349
Drug Therapy						
Use of Evidence-Based Medication for CHF	81.6%	90.1%	91.0%	81.3%	91.1%	92.5%
Adherent to Any Evidence-Based Medications for CHF	86.9%	88.7%	90.4%	87.4%	88.0%	92.2%
At Least One Drug-Drug Interaction	11.5%	13.4%	15.5%	9.4%	11.2%	9.8%
Use of at Least One High Risk Medication	39.8%	42.5%	45.9%	33.2%	37.1%	31.8%
Use of at Least One Medication Contraindicated for CHF	16.8%	18.8%	29.3%	16.0%	13.8%	11.7%
Resource Utilization: Hospital and ER Visits						
Any (All-Cause) Hospitalization	31.0%	34.7%	33.5%	24.1%	30.3%	27.5%
Any CHF-Related Hospitalization	16.5%	21.5%	20.1%	12.3%	18.9%	18.8%
Any (All-Cause) ER Visit	28.7%	27.6%	32.3%	---	---	---
Any CHF-Related ER Visit	7.2%	7.9%	9.5%	---	---	---
Resource Utilization: Medications and Costs (Average)						
Number of Medications	13.6	14.3	16.3	12.4	13.1	13.4
Generic Substitution Ratio	87.8%	88.5%	91.1%	89.2%	89.1%	88.4%
Part D Costs for Non-CHF Drugs	$2,730.97	$2,310.97	$3,129.64	$2,344.07	$1,768.89	$1,763.89
All-Cause Hospitalization Costs	$4,634.73	$5,668.27	$5,067.24	---	---	---
CHF-Related Hospitalization Costs	$2,214.19	$3,206.69	$2,886.66	---	---	---
All-Cause ER Costs	$229.18	$221.03	$265.85	---	---	---
CHF-Related ER Costs	$54.44	$63.12	$72.82	---	---	---

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

4.3 Impact of MTM on Drug Therapy Outcomes for Individuals with CHF

The impact of MTM on drug therapy outcomes was generally positive for the PDP and MA-PD cohorts; further, the magnitude of that impact was generally greater for individuals receiving MTM with CMR compared to those who did not receive CMRs. In other words, results consistently suggested that individuals who received a CMR were more likely to experience positive impacts in their drug therapy outcomes, while those results were less consistent for individuals in MTM programs who did not receive a CMR. The following two sections provide the risk-adjusted results for overall PDP and MA-PD groups and stratified by parent organization.

4.3.1 Risk-Adjusted Drug Therapy Outcomes for PDP and MA-PD Cohorts

While MTM programs provided by PDPs and MA-PDs showed similar impacts on enrollees for uptake and adherence to evidence-based medications, their impacts were not as consistent for several other metrics. These metrics are as follows:

- **Discontinue use of High-Risk Medications (HRM):** Among all treatment groups, who filled at least one HRM during the 180-days period prior to the index date, only Beneficiaries in MA-PDs had lower odds (OR =0.954) of discontinuing the use of high risk medications if they received a CMR, compared to the MA-PD comparison group; those in the corresponding PDP group showed no significant difference compared to the comparison group.
- **Contraindicated Medications:** Individuals in PDPs who received MTM services were less likely to discontinue use of contraindicated medications relative to the comparison group (MTM with CMR OR=0.643, MTM without CMR: OR=0.879). However, individuals in MA-PDPs who were enrolled in MTM programs, without receiving CMRs, had higher odds (MTM without CMR: OR=1.105) of discontinuing contraindicated medications by the end of the study period, compared to the PDP comparison group. The difference in odds for individuals in MA-PDs who received CMRs was not statistically significant.

As shown in **Table 4-3**, individuals in MTM programs were more likely to start and increase their adherence to evidence-based medications for CHF compared to those who did not receive MTM services. Relative to the comparison groups, beneficiaries who were not taking evidence-medications before enrolling into an MTM program had higher odds of uptake of evidence-based medications for CHF during the outcome period (PDP: OR=1.198; MA-PD: OR=1.377). However, those receiving CMRs as part of their MTM programs were not consistently more likely to experience these two drug therapy outcomes.

Table 4-3: Risk-Adjusted Drug Therapy Outcomes for Individuals with CHF (OR with 95% CI)

	Comparison or Intervention Group Assignment	*N*	*Take Up of Evidence-Based Medication for CHF*	*Adherent to Any Evidence-Based Medications for CHF*	*Remove Drug-Drug Interaction*	*Discontinue Use of High Risk Medications*	*Discontinue use of Medication Contraindicated for CHF*
Beneficiaries Only Enrolled in PDPs	Comparison	208,850	---	---	---	---	---
	MTM without CMR	136,305	1.198* (1.123, 1.277)	1.036* (1.009, 1.064)	1.050 (.988, 1.117)	1.041* (1.014, 1.069)	.879* (.847, .912)
	With CMR	14,858	1.100 (.928, 1.303)	1.141* (1.065, 1.222)	0.952 (.819, 1.106)	1.039 (.970, 1.113)	0.643* (.596, .693)
Beneficiaries Only Enrolled in MA-PDs	Comparison	62,119	---	---	---	---	---
	MTM without CMR	81,353	1.377* (1.253, 1.513)	1.032 (.990, 1.075)	1.137* (1.022, 1.265)	0.954* (.914, .995)	1.105* (1.038, 1.178)
	With CMR	10,349	1.302* (1.057, 1.604)	1.239* (1.135, 1.352)	1.117 (.917, 1.360)	1.177* (1.077, 1.287)	1.140 (.997, 1.304)

* Indicates significance at the $p<0.05$ level.

4.3.2 Risk-Adjusted Drug Therapy Outcomes for PDP and MA-PD Cohorts, by Parent Organization

After stratifying the analyses by parent organization and adjusting for all covariates, the estimated impacts of MTM on drug therapy outcomes were consistent across parent organizations for some metrics while differing substantially across others. These results are shown in **Table 4-4** and **Table 4-5**.

The drug therapy outcomes analysis on parent organizations for PDPs yielded several noteworthy results. These results are as follows:

- **Use of and Adherence to Evidence-Based Medications for CHF:**
  - **Organizations A, C and E's** MTM enrollees who did not receive a CMR had higher odds of filling an evidence-based medication regimen for CHF during the outcome period (OR=1.468, 1.515, and 1.822, respectively). For their corresponding MTM with CMR groups, only **Organization C** showed significant differences from the comparison group (OR=1.846), but the lack of significant differences for other parent organizations could be due to imprecise estimates resulting from the relatively small number of individuals in their MTM programs who received CMRs.
  - Individuals enrolled in **Organizations A, D and E** had higher odds of being adherent to any evidence-based medication for CHF if they were enrolled in an MTM program and did not receive a CMR, as compared to each parent organization's comparison group (OR=1.150, 1.900 and 1.986, respectively). Of these three organizations, only **Organization D**'s enrollees showed higher odds (OR=1.267) on this metric if they were enrolled in an MTM program and did receive a CMR, though the insignificant results for Plan A and Plan E' s MTM enrollees with CMR could be explained by small sample size and imprecise estimates.
- **Use of High-Risk and Contraindicated Medications:**
  - Individuals enrolled in **Organization A's** MTM program had lower odds of using high risk medications relative to the comparison group, with those receiving CMRs showing a larger magnitude of impact (MTM without CMR: OR=0.941; MTM with CMR: OR=0.475).
  - Those enrolled in **Organization A's** MTM program also had lower odds of using medications contraindicated for CHF (MTM without CMR: OR=0.817; MTM with CMR: OR=0.495). **Organization C's** MTM enrollees who did not receive a CMR also had lower odds (OR=0.746). Contrastingly, **Organization B, D, and E's** MTM enrollees experienced opposite results, with participation in MTM (with and/or without CMR) associated with higher odds of using contraindicated medications. However, the results for **Organization B** should be interpreted with caution, since the sample size of their CMR recipients included less than 200 beneficiaries.

Drug therapy outcomes analysis on parent organizations for MA-PDs also yielded several noteworthy results. They are as follows:

- **Use of and Adherence to Evidence-Based Medications for CHF:**
  - Individuals enrolled in **Organization A, E, and F's** MTM programs had higher odds of filling an evidence-based medication during the outcome period. **Organization F**'s MTM enrollees, for example, had 1.419 times the odds of starting such a regimen if they did not receive a CMR, relative to the comparison group, and 1.597 times those odds if they received a CMR.
  - **Organization B's** MTM enrollees who did not receive a CMR, on the other hand, had lower odds of filling an evidence-based medication in the outcome period, relative to the comparison group (OR = 0.561).
  - Individuals enrolled in **Organizations A, D, and F** also had higher odds of being adherent to any evidence-based medication for CHF if they were enrolled in an MTM program and received a CMR, relative to their corresponding comparison groups (OR=2.022, 1.507, and 1.286, respectively). Individuals in these parent organizations' MTM programs who did not receive a CMR were not significantly different from the comparison group in terms of adherence.
  - **Organization E's** MTM enrollees who did not receive a CMR also had higher odds (OR=2.393) of being adherent to any evidence-based medication for CHF, while its enrollees who did receive a CMR did not show a significant difference from the comparison group. However, the number of individuals eligible for inclusion in **Organization E's** MTM with CMR group was only 27 and our estimate may therefore be imprecise.
- **Use of High-Risk and Contraindicated Medications:**
  - Individuals in **Organization B's** MTM programs had lower odds of using high-risk medications. Those who did not receive a CMR had 0.671 times the odds of using a high-risk medication, and those who received a CMR had 0.520 times those odds, relative to the comparison group. However, the results for **Organization B** should be interpreted with caution, since their sample size of CMR recipients included less than 200 beneficiaries.
  - Individuals in **Organization A's** MTM programs who did not receive a CMR had lower odds of using a medication contraindicated for individuals with CHF (OR=0.709). On the other hand, **Organization B's** MTM enrollees had higher odds (MTM without CMR: OR=1.721; MTM with CMR: OR=2.452). However, please note the small sample size of CMR recipients for **Organization B**.

Table 4-4: Risk-Adjusted Drug Therapy Outcomes for Individuals with CHF, by PDP Parent Organization (OR with 95% CI)

Parent Organization	*Intervention Type*	*Use of Evidence-Based Medication for CHF*	*Adherent to Any Evidence-Based Medications for CHF*	*At Least One Drug-Drug Interaction*	*Use of at Least One High Risk Medication*	*Use of at Least One Medication Contraindicated for CHF*
Organization A	MTM without CMR	1.468* (1.398, 1.542)	1.150* (1.088, 1.216)	1.073 (.971, 1.185)	.941* (.897, .986)	.817* (.772, .865)
	With CMR	1.429 (.924, 2.210)	1.077 (.684, 1.696)	1.206 (.590, 2.467)	.475* (.304, .742)	.495* (.271, .904)
Organization B	MTM without CMR	.932.* (.872, .996)	0.959 (.899, 1.024)	1.057 (.942, 1.186)	0.970 (.917, 1.026)	1.928* (1.815, 2.048)
	With CMR	1.023 (.909, 1.151)	1.123* (1.001, 1.259)	1.307* (1.088, 1.571)	1.104* (1.005, 1.213)	2.195* (2.010, 2.397)
Organization C	MTM without CMR	1.515* (1.343, 1.711)	0.900 (.761, 1.064)	.690* (.482, .990)	0.949 (.837, 1.077)	.746* (.635, .876)
	With CMR	1.846* (1.212, 2.812)	0.889 (.553, 1.431)	0.818 (.285, 2.348)	0.940 (.611, 1.443)	0.734 (.415, 1.298)
Organization D	MTM without CMR	1.306 (.903, 1.887)	1.900* (1.278, 2.826)	0.755 (.426, 1.337)	1.163 (.872, 1.552)	0.731 (.503, 1.602)
	With CMR	1.151* (1.024, 1.293)	1.267* (1.118, 1.435)	0.818 (.641, 1.045)	1.073 (.952, 1.210)	1.137* (1.010, 1.280)
Organization E	MTM without CMR	1.822* (1.604, 2.069)	1.986* (1.740, 2.266)	1.264 (.991, 1.611)	0.980 (.873, 1.100)	1.135 (.999, 1.290)
	With CMR	1.612 (.762, 3.410)	2.031 (.963, 4.282)	2.305 (.831, 6.391)	0.573 (.311, 1.057)	1.876* (1.001, 3.517)

* Indicates significance at the 5% level.

Table 4-5: Risk-Adjusted Drug Therapy Outcomes for Individuals in with CHF, by MA-PD Parent Organization (OR with 95% CI)

Parent Organization	***Intervention Type***	*Use of Evidence-Based Medication for CHF*	*Adherent to Any Evidence-Based Medications for CHF*	*At Least One Drug-Drug Interaction*	*Use of at Least One High Risk Medication*	*Use of at Least One Medication Contraindicated for CHF*
Organization A	MTM without CMR	1.383* (1,273, 1.501)	1.083 (.985, 1.191)	0.86 (.712, 1.039)	1.043 (.958, 1.136)	.709* (.642, .782)
	With CMR	1.561 (.952, 2.560)	2.022* (1.140, 3.585)	0.779 (.319, 1.900)	.606* (.387, .949)	1.318 (.813, 2.136)
Organization B	MTM without CMR	.561* (.381, .825)	.675* (.460, .990)	1.156 (.445, 2.999)	.671* (.477, .943)	1.721* (1.165, 2.542)
	With CMR	0.829 (.466, 1.474)	0.979 (.544, 1.760)	0.804 (.250, 2.589)	.520* (.309, .876)	2.452* (1.503, 4.001)
Organization C	MTM without CMR	1.252* (1.100, 1.425)	0.934 (.791, 1.104)	0.876 (.601, 1.276)	1.151* (1.006, 1.317)	0.931 (.799, 1.085)
	With CMR	1.420* (1.029, 1.960)	0.872 (.615, 1.236)	1.116 (.526, 2.367)	1.001 (.720, 1.391)	0.656 (.429, 1.005)
Organization D	MTM without CMR	1.007 (.417, 2.431)	1.203 (.428, 3.380)	0.937 (.121, 7.212)	0.834 (.339, 2.054)	2.078 (.688, 6.277)
	With CMR	1.272 (.958, 1.690)	1.507* (1.076, 2.111)	0.797 (.399, 1.595)	0.978 (.720, 1.329)	1.172 (.809, 1.696)
Organization E	MTM without CMR	2.083* (1.376, 3.153)	2.393* (1.607, 3.564)	3.144 (.815, 12.116)	1.562* (1.056, 2.309)	1.401 (.943, 2.083)
	With CMR	17.547* (1.280, 240.554)	1.823 (.369, 9.002)	27.083* (1.127, 650.702)	2.664 (.725, 9.780)	1.607 (..436, 5.919)
Organization F	MTM without CMR	1.419* (1.258, 1.600)	1.102 (.925, 1.313)	1.076 (.752, 1.541)	1.064 (.884, 1.281)	0.826 (.676, 1.009)
	With CMR	1.597* (1.405, 1.814)	1.286* (1.068, 1.548)	0.907 (.629, 1.309)	0.861 (.710, 1.043)	0.703* (.567, .870)

* Indicates significance at the p<0.05 level.

4.4 Impact of MTM on Resource Utilization Outcomes for Individuals with CHF: Hospital and ER Visits

Results at the overall PDP and MA-PD levels suggested that individuals who received a CMR were consistently less likely to experience hospitalizations and ER visits during the study period. In contrast, individuals enrolled in MTM programs had higher rates of hospitalization and ER visits during the 180-days preceding the start of the study period (see **Table 4-2**). Those results were less consistent for individuals in MTM programs who did not receive a CMR. Results were also inconsistent at the parent organization level. The following two sections provide the adjusted results for overall PDP and MA-PD groups and stratified by parent organization.

4.4.1 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts: Hospital and ER Visits

Even after adjusting for covariates, individuals in PDP and MA-PD MTM programs who did not receive a CMR tended to have higher or the same odds of hospitalization and ER visits compared to their respective comparison groups (see **Table 4-6**). However, those who did receive a CMR tended to have lower – and in the case of PDPs, significantly lower – odds of these events.

While we observe fewer hospitalizations among beneficiaries enrolled in PDP MTM programs, there is no evidence that these reductions are due to fewer CHF-related hospitalizations, which account for about only half of the hospitalizations for these group. For example, those who did not receive a CMR had slightly higher odds of CHF-related hospitalization (OR=1.037) compared to the comparison group, while those who received CMRs had lower odds of experiencing such a hospitalization (OR=0.926). Individuals enrolled in MA-PDs who did not receive a CMR had higher odds of all-cause and CHF-related hospitalization (OR=1.032 and 1.128, respectively); those who received a CMR had slightly lower odds of these events, although this effect was still significant for CHF-related hospitalization (OR=1.077). However, most intervention groups experienced lower odds of having an ER visit.

Table 4-6: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital and ER Visits (OR with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Any (All-Cause) Hospitalization*	*Any CHF-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any CHF-Related ER Visit*
Beneficiaries Only Enrolled in PDPs	Comparison	208,850	---	---	---	---
	MTM without CMR	136,305	0.987 (.970, 1.005)	1.037* (1.015, 1.060)	.960* (.943, .978)	1.030* (1.000, 1.061)
	With CMR	14,858	.879* (.840, .919)	.926* (.877, .978	.907* (.867, .949)	.930* (.866, .999)
Beneficiaries Only Enrolled in MA-PDs	Comparison	62,119	---	---	---	---
	MTM without CMR	81,353	1.032* (1.002, 1.063)	1.128* (1.087, 1.169)	---	---
	With CMR	10,349	0.993 (.937, 1.052)	1.077* (1.007, 1.153)	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

4.4.2 Risk-Adjusted Resource Utilization Outcomes: Hospital and ER Visits for PDP and MA-PD Cohorts, by Parent Organization

After stratifying the analyses by parent organization and adjusting for all covariates, some patterns in hospital and ER visits arose for specific parent organizations. These results are shown in **Table 4-7** and **Table 4-8.**

The main results of the hospital and ER visit outcomes analysis on parent organizations for PDPs are as follows:

- **Organization B's** MTM program enrollees (regardless of CMR) had lower odds of all-cause and CHF-related hospitalization and ER use compared to the comparison group. Those who did not receive a CMR had lower odds of all-cause and CHF-related ER visits (OR = 0.879 and 0.881, respectively), and those who received a CMR had lower odds of all-cause and CHF-specific hospital and ER visits. However, **Organization B's** CMR results should be interpreted cautiously, due to the small sample size.
- In **Organizations A and C**, which had CMR rates below 5%, MTM enrollees who did not receive CMRs had higher odds of all-cause and CHF-related hospitalization and ER visits. Their enrollees who did receive CMRs had lower odds of these events; however, these odds were only significantly different from those of the comparison group in the case of all-cause hospitalizations.

The hospital and ER visit outcomes analysis on parent organizations for MA-PDs yielded similar patterns. Noteworthy results are as follows:

- **Organization E's** MTM program enrollees had significantly lower odds of all-cause hospitalization (OR =0.275 for those who received a CMR and OR=0.669 for those who did not receive a CMR). The odds of CHF-related hospitalization were also lower than the comparison group (OR=0.360 and OR=0.704, respectively), though these odds ratios were not significant at the 5% level.
- **Organizations A and Organization C's** MA-PD enrollees who received MTM with no CMR had higher odds of all-cause and CHF-related hospitalization compared to their respective comparison groups. Those in **Organization A** who received a CMR, however, had lower odds of all-cause hospitalization (OR=0.534).
- **Organization F's** MTM program enrollees who did not receive CMRs had lower odds of CHF-related hospitalization (OR = 0.880) relative to Plan F's comparison group; however, those who received a CMR were not significantly different from the comparison group.

Table 4-7: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital and ER Visits, by PDP Parent Organization (OR with 95% CI)

Parent Organization	*Intervention Type*	*Any (All-Cause) Hospitalization*	*Any CHF-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any CHF-Related ER Visit*
Organization A	MTM without CMR	1.041* (1.008, 1.076)	1.230* (1.183, 1.279)	0.975 (.942, 1.008)	1.165 * (1.103 , 1.232)
	With CMR	.717* (.520, .989)	1.095 (.763, 1.572)	1.015 (.747, 1.379)	0.791 (.446 , 1.403)
Organization B	MTM without CMR	0.969 (.930, 1.010)	.951* (.905, .999)	.879 * (.843 , .916)	.881 * (.825 , .941)
	With CMR[a]	0.858* (.798, .922)	.846* (.776, .922)	.890 * (.829 , .956)	.839 * (.750 , .939)
Organization C	MTM without CMR	1.094 (.989, 1.209)	1.542* (1.342, 1.771)	1.127* (1.019, 1.245)	1.700 * (1.385 , 2.087)
	With CMR	0.752 (.537, 1.055)	1.177 (.778, 1.780)	. 0.872 (.623 , 1.222)	0.808 (.383 , 1.701)
Organization D	MTM without CMR	1.204 (.967, 1.500)	1.327* (1.034, 1.703)	0.984 (.785 , 1.234)	0.878 (.616 , 1.252)
	With CMR	0.979 (.906, 1.059)	1.103* (1.004, 1.211)	.819 * (.756 , .886)	0.939 (.832 , 1.061)
Organization E	MTM without CMR	.846* (.775, .924)	0.966 (.869, 1.073)	.869 * (.796 , .948)	0.959 (.833 , 1.103)
	With CMR	0.68 (.419, 1.105)	0.935 (.538, 1.622)	0.736 (.456 , 1.189)	1.438 (.773 , 2.675)

* Indicates significance at the 5% level.

[a] CMR sample size under 200.

Table 4-8: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital Visits, by MA-PD Parent Organization (OR with 95% CI) [a]

Parent Organization	***Intervention Type***	*Any (All-Cause) Hospitalization*	*Any CHF-Related Hospitalization*
Organization A	MTM without CMR	1.082 * (1.016 , 1.153)	1.371 * (1.266 , 1.485)
	With CMR	.534 * (.359 , .795)	0.882 (.562 , 1.386)
Organization B	MTM without CMR	1.171 (.873 , 1.569)	0.945 (.654 , 1.365)
	With CMR	0.961 (.624 , 1.482)	0.776 (.444 , 1.356)
Organization C	MTM without CMR	1.351 * (1.200 , 1.521)	2.038 * (1.690 , 2.458)
	With CMR	1.093 (.834 , 1.432)	1.598 * (1.112 , 2.295)
Organization D	MTM without CMR	1.007 (.502 , 2.020)	0.717 (.266 , 1.932)
	With CMR	1.017 (.820 , 1.261)	1.229 (.945 , 1.598)
Organization E	MTM without CMR	.669 * (.503 , .889)	0.704 (.483 , 1.024)
	With CMR	.275 * (.078 , .969)	0.36 (.077 , 1.681)
Organization F	MTM without CMR	0.917 (.826 , 1.018)	.880 * (.786 , .986)
	With CMR	1.056 (.952 , 1.172)	1.11 (.993 , 1.240)

* Indicates significance at the 5% level.

[a] Emergency room outcomes were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

4.5 Impact of MTM on Resource Utilization Outcomes for Individuals with CHF

Across overall and parent organization-specific PDP and MA-PD cohorts, individuals enrolled in MTM programs generally filled fewer medications and more generic equivalents, but not to the extent to suggest important cost savings. Further, they did not generally have lower costs in the Part D, hospital, or ER settings. The following two sections provide the adjusted results for overall PDP and MA-PD groups and stratified by parent organization.

4.5.1 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts

After adjusting for covariates, individuals in PDP MTM programs – regardless of receipt of CMRs – tended to show slight differences in their resource utilization outcomes compared to the PDP comparison group. Their results are shown in **Table 4-9** and can be summarized as follows:

- **Number of Medications:** After adjusting for individuals' drug utilization during the six months preceding the index date, as well as other risk factors, individuals enrolled in MTM filled fewer medications relative to the comparison group.
- **Non-CHF Part D Costs:** Individuals enrolled in MTM programs who did not receive a CMR also had $21.15 lower overall Part D costs in the observation period, an average of $3.53 per month less for non-CHF Part D prescription drugs than the comparison group over the six-month outcome period. Individuals who received CMRs did not have different Part D costs relative to those of the comparison group.
- **Hospital and ER Costs:**
    - Those enrolled in MTM programs who received a CMR had lower average inpatient costs ($490.15 lower than the comparison group, or approximately $81.69 per enrollee per month in savings relative to their predicted costs without a MTM intervention).
    - Individuals with CMRs had all-cause ER costs of $15.60 less than the comparison group over the observation period, translating to ER-related cost savings of $2.60 per member per month.

Individuals in MA-PD MTM programs demonstrated similar trends to the PDP MTM programs. Their results, also shown in **Table 4-9**, can be summarized as follows:

- **Number of Medications:** Individuals in both intervention groups filled fewer medications relative to the comparison group (MTM without CMR: -.285, or .285 fewer medications over the six-month outcome period, on average; MTM with CMR: -.274, or .274 fewer medications). However, these slight decreases may not be associated with important savings in costs.
- **Generic Substitution Ratio:** Neither of the MA-PD intervention groups had different generic substitution ratios relative to the comparison group. Note, however, that most individuals in the comparison and intervention groups were using generic medications

at baseline, particularly because there are generic equivalents for most evidence-based CHF medications (see

- **Non-CHF Part D Costs:** Those in MTM programs who did not receive a CMR had lower Part D costs of an average of $30.75 less on non-CHF Part D prescription drugs than the comparison group over the six-month outcome period. This translates to non-CHF Part D cost savings of $5.13 per individual, per month. Again, this difference was not significant for the group of individuals in MTM programs who received a CMR.

Table 4-9: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Medications and Costs (OLS Estimate with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-CHF Drugs*	*All-Cause Hospitalization Costs*	*CHF-Related Hospitalization Costs*	*All-Cause ER Costs*	*CHF-Related ER Costs*
Beneficiaries Only Enrolled in PDPs	Comparison	208,850	---	---	---	---	---	---	---
	MTM without CMR	136,305	-.138 * (-.154 , -.122)	0 (-.001 , .000)	-$21.15 * (-35.945 , -6.362)	$11.99 (-105.36 , 129.33)	$94.02 (-2.37 , 190.41)	-$5.06 (-10.56 , .45)	$0.45 (-3.22 , 4.12)
	With CMR	14,858	-.049 * (-.091 , -.007)	0 (-.002 , .002)	-$30.217 (-67.889 , 7.455)	-$490.15* (-764.66 , -215.64)	-$211.87 (-429.23 , 5.5)	-$15.60* (-28.6 , -2.6)	-$6.47 (-13.66 , .72)
Beneficiaries Only Enrolled in MA-PDs	Comparison	62,119	---	---	---	---	---	---	---
	MTM without CMR	81,353	-.285 * (-.308 , -.262)	-.002 * (-.003 , -.000)	-$30.75 * (-52.553 , -8.951)	---	---	---	---
	With CMR	10,349	-.274 * (-.319 , -.229)	-.006 * (-.009 , -.004)	-$31.33 (-74.072 , 11.420)	---	---	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

4.5.2 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts, by Parent Organization

Risk-adjusted results for parent organizations for PDPs and MA-PDs are provided in **Table 4-10** and **Table 4-11**. Noteworthy results for PDP parent organizations can be summarized as follows:

- **Number of Medications:**
  - Individuals enrolled in **Organization A's** MTM programs filled fewer medications in the outcome period. Individuals in **Organization E's** MTM programs who did not receive CMRs also filled fewer medications in the outcome period.
- **Generic Substitution Ratio:**
  - **Organization B** and **Organization C's** intervention groups who received CMRs showed higher generic substitution ratios compared to their respective comparison groups. **Organization B's** intervention group who did not receive a CMR also showed a slightly higher generic substation ratio.
- **Non-CHF Part D Costs:**
  - **Organization A's** MTM enrollees who did not receive a CMR had lower non-CHF Part D costs relative to the comparison group ($77.55 less in the six-month outcome period). This translates to non-CHF Part D savings of $12.93 per MTM enrollee per month.
  - No other parent organization-specific intervention groups were significantly different from their corresponding comparison groups in terms of non-CHF Part D cost savings.
- **Hospital and ER Costs:**
  - **Organization A's** MTM enrollees who received CMRs had lower overall inpatient costs of $1,888.90 less than the comparison group which translates to savings on overall inpatient costs of approximately $314.82 per individual per month.). Note however, that this result was found in a small group of beneficiaries and may not be representative of the potential effect of the CMR when applied to a larger group.
  - **Organization A's** MTM enrollees who did not receive CMRs had higher CHF-specific hospital costs of $318.63 over six months. **Organization C's** MTM enrollees had higher all-cause hospitalization costs of $818.84 over six months).

Noteworthy results for MA-PD parent organizations can be summarized as follows:

- **Number of Medications:**
  - Individuals enrolled in **Plan A, Plan C, and Plan F's** MTM programs filled fewer medications in the outcome period.
- **Non-CHF Part D Costs:**
  - **Organization A's** and **Organization E's** MTM enrollees who did not receive a CMR had lower non-CHF Part D costs relative to the comparison group.

Organization A enrollees cost $104.94 less in the outcome period, which translates to non-CHF Part D savings of $17.49 per member per month. **Organization E's** MTM enrollees who did not receive a CMR cost $213.80 less in non-CHF Part D costs relative to the comparison group. This translates to $35.63 less in non-CHF Part D costs per member per month. No other parent organization-specific intervention groups were significantly different from their corresponding comparison groups.

Table 4-10: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Medications and Costs, by PDP Parent Organization (OLS Estimate with 95% CI)

Parent Organization	*Intervention Type*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-CHF Drugs*	*All-Cause Hospitalization Costs*	*CHF-Related Hospitalization Costs*	*All-Cause ER Costs*	*CHF-Related ER Costs*
Organization A	MTM without CMR	-.437 * (-.469 , -.405)	-.007 * (-.009 , -.005)	-$77.554 * (-106.677 , -48.432)	$161.26 (-87.01 , 409.52)	$318.63* (106.01 , 531.24)	-$4.39 (-15.1 , 6.31)	$4.80 (-2.24 , 11.84)
	With CMR	-.898 * (-1.182 , -.614)	-0.009 (-.027 , .008)	-$227.93 (-490.278 , 34.409)	-$1888.90* (-3150.38 , -627.42)	-$725.27 (-1696.03 , 245.49)	-$10.02 (-89.79 , 69.75)	-$16.27 (-51.55 , 19.02)
Organization B	MTM without CMR	.364 * (.322 , .406)	.005 * (.003 , .007)	$10.57 (-21.654 , 42.797)	$198.45 (-89.27 , 486.18)	$210.84 (-34.18 , 455.86)	-$9.63 (-24.46 , 5.2)	-$2.87 (-13.53 , 7.78)
	With CMR	.261 * (.190 , .332)	.009 * (.005 , .012)	-$12.09 (-67.305 , 43.127)	-$358.75 (-814.70 , 97.2)	-$190.85 (-577.25 , 195.54)	-$12.02 (-34.75 , 10.71)	-$15.46* (-29.71 , -1.22)
Organization C	MTM without CMR	-1.091 * (-1.167 , -1.015)	0.003 (-.002 , .009)	-$1.75 (-81.943 , 78.434)	$818.84* (245.43 , $1392.25)	$563.72 (-36.36 , 1163.8)	$27.61* (1.83 , 53.38)	$19.72 (-5.4 , 44.85)
	With CMR	-1.040 * (-1.284 , -.796)	.019 * (.001 , .037)	-$52.06 (-308.351 , 204.237)	-$253.54 (-1587.95 , 1080.88)	$199.56 (-1048.73 , 1447.85)	-$41.57 (-101 , 17.85)	-$0.41 (-42.51 , 41.7)
Organization D	MTM without CMR	0.219 (-.013 , .451)	-.011 * (-.021 , -.001)	$57.00 (-165.582 , 279.580)	$89.34 (-1171.19 , 1349.87)	$320.58 (-659.6 , 1300.76)	-$8.84 (-75.73 , 58.04)	-$24.12 (-67.61 , 19.37)
	With CMR	0.017 (-.062 , .097)	-.007 * (-.011 , -.004)	-$56.58 (-133.365 , 20.208)	$74.31 (-553.89 , 702.5)	$123.08 (-331.81 , 577.97)	-$29.15 (-60.37 , 2.07)	-$4.96 (-22.56 , 12.65)
Organization E	MTM without CMR	-.158 * (-.239 , -.077)	-0.001 (-.004 , .002)	$53.59 (-24.733 , 131.912)	-$773.45* (-1525.71 , -21.18)	-$452.87 (-989.76 , 84.02)	$1.00 (-29.66 , 31.66)	-$2.90 (-22.63 , 16.83)
	With CMR	0.013 (-.415 , .443)	-0.013 (-.033 , .005)	$148.23 (-274.946 , 571.403)	-$2947.93* (-5054.65 , -841.20)	-$1,055.50 (-2744.74 , 633.74)	-$44.85 (-163.12 , 73.42)	$2.45 (-64.96 , 69.85)

* Indicates significance at the 5% level.

Table 4-11: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Medications and Costs, by MA-PD Parent Organization (OLS Estimate with 95% CI) [a]

Parent Organization	*Intervention Type*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-CHF Drugs*
Organization A	MTM without CMR	-.472 * (-.524 , -.420)	-.006 * (-.009 , -.003)	-$104.945 * (-150.512 , -59.378)
	With CMR	-.725 * (-1.011 , -.439)	-.020 * (-.038 , -.003)	-$245.44 (-496.819 , 5.937)
Organization B	MTM without CMR	0.178 (-.057 , .414)	0.01 (-.001 , .022)	-$209.99 (-449.241 , 29.264)
	With CMR	0.204 (-.130 , .540)	0.002 (-.014 , .019)	-$54.25 (-397.203 , 288.708)
Organization C	MTM without CMR	-.911 * (-.993 , -.828)	-0.002 (-.008 , .003)	-$11.58 (-77.861 , 54.711)
	With CMR	-.953 * (-1.150 , -.756)	0.004 (-.008 , .016)	-$75.30 (-233.236 , 82.638)
Organization D	MTM without CMR	0.425 (-.148 , .999)	-0.011 (-.045 , .023)	$67.72 (-530.464 , 665.913)
	With CMR	0.008 (-.167 , .185)	-0.006 (-.017 , .004)	-$138.88 (-322.547 , 44.784)
Organization E	MTM without CMR	-0.145 (-.371 , .080)	0 (-.012 , .012)	-$213.799 * (-418.981 , -8.617)
	With CMR	-0.229 (-1.014 , .555)	0.017 (-.025 , .060)	-$21.27 (-747.282 , 704.747)
Organization F	MTM without CMR	-.367 * (-.449 , -.286)	-.021 * (-.026 , -.015)	-$47.08 (-124.227 , 30.076)
	With CMR	-.505 * (-.590 , -.420)	-.022 * (-.027 , -.016)	-$38.82 (-118.739 , 41.092)

* Indicates significance at the p<0.05 level.

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

5 RESULTS: IMPACT OF MTM ON BENEFICIARIES WITH COPD

Beneficiaries with COPD who enrolled in MTM programs consistently experienced higher quality prescription drug therapies and lower total prescription drug costs relative to a comparison group, but these outcomes did not necessarily correspond to improvements beyond Part D. This section provides the results of the retrospective cohort study comparing risk adjusted outcomes among beneficiaries with COPD who were newly enrolled in MTM programs in 2010 against outcomes experienced by a comparison group. It presents results stratified by beneficiaries enrolled in PDPs or MA-PDs and specific parent organizations. Sections 5.1 and 5.2 offer descriptions of the general demographic and health characteristics of the intervention and comparison groups, as well as their baseline drug therapy and resource utilization patterns before the measurement period. Sections 5.3, 5.4, and 5.5 then summarize the risk-adjusted results of our overall PDP, overall MA-PD, and parent organization-specific analyses of the association between MTM participation and each outcome of interest.

5.1 Characteristics of the Study Population

An initial group of 29,751,040 individuals were enrolled in Part D in 2010 and had prior risk data that could be used to identify disease diagnoses. Of those, 3,973,578 (13.4%) had COPD. Out of those individuals with COPD who were enrolled in PDPs, 250,593 were assigned to the comparison group, 141,324[a] to the MTM without CMR intervention group, and 19,149[b] to the MTM with CMR intervention group. For those enrolled in MA-PDs, 86,725 were assigned to the comparison group, 82,953[c] to the MTM without CMR intervention group, and 9,862[d] to the MTM with CMR intervention group. In other words, for beneficiaries with COPD who met our inclusion criteria for any of the intervention groups (i.e., those who were enrolled in an MTM program in 2010 but not in a prior year), 11.9% of those in PDPs and 10.6% of those in MA-PDs received a CMR.

As shown in **Table 5-1**, the intervention and comparison groups for beneficiaries enrolled in PDPs varied in terms of distributions of gender, age, and race. A higher proportion of individuals in the MTM with CMR group were disabled and taking 12 or more maintenance drugs compared to the other two groups. However, all three groups tended to have relatively similar rates of most health conditions, excluding diabetes and dyslipidemia. Intervention and comparison groups for beneficiaries enrolled in MA-PDs also demonstrated some similar trends, but they differed in terms of their proportions of disabled and LIS eligible beneficiaries across

[a] Of these, 9,146 opted out during the measurement period.
[b] Of these, 49 opted out during the measurement period.
[c] Of these, 7,033 opted out during the measurement period.
[d] Of these, 78 opted out during the measurement period.

the three groups. In comparison to all PDP groups, those in the MA-PD groups tended to have comparable rates of specific health conditions but took fewer maintenance drugs at baseline. The intervention and comparison groups for each of these parent organizations generally had demographic and health characteristics similar to those shown for overall PDP and MA-PD comparison and intervention groups.

Table 5-1: Demographic and Health Characteristics of Individuals with COPD Assigned to PDP and MA-PD Intervention and Comparison Groups [a]

	Beneficiaries Enrolled in PDPs			*Beneficiaries Enrolled in MA-PDs*		
Demographic and Health Characteristics	*Comparison*	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	250,593	141,324	19,149	86,725	82,953	9,862
% in MTM Receiving CMR			11.9%			10.6%
Gender						
Male	35.4%	38.3%	31.8%	38.0%	44.1%	45.2%
Female	64.6%	61.7%	68.2%	62.0%	55.9%	54.8%
Age						
≤65	25.3%	23.1%	33.9%	18.1%	15.8%	10.6%
66-75	32.5%	35.6%	34.8%	37.2%	40.9%	38.4%
76-85	29.7%	30.5%	24.8%	33.7%	33.8%	39.8%
>85	12.6%	10.8%	6.6%	11.0%	9.5%	11.2%
Race						
White	84.8%	84.7%	82.0%	83.9%	84.5%	85.1%
Black	9.3%	9.4%	13.4%	10.1%	9.8%	9.1%
Hispanic	2.5%	2.4%	2.4%	2.9%	2.9%	2.5%
Other or Unknown	3.4%	3.5%	2.1%	3.1%	2.8%	3.4%
SES						
LIS Eligible	59.3%	56.3%	75.5%	41.7%	38.3%	25.0%
General Health Status in Observation Period						
≤8 Maintenance Drugs	46.3%	33.4%	19.2%	55.0%	43.5%	37.0%
9-10 Maintenance Drugs	26.0%	25.0%	25.8%	25.1%	25.0%	26.9%
11-12 Maintenance Drugs	14.9%	19.0%	23.1%	12.3%	16.5%	18.9%
>12 Maintenance Drugs	12.8%	22.6%	31.9%	7.6%	15.0%	17.2%
Disabled	27.4%	25.3%	36.7%	20.4%	18.1%	12.6%
Specific Health Conditions						
Diabetes	41.4%	55.9%	57.3%	38.8%	56.6%	54.6%
Dyslipidemia	69.2%	74.1%	72.1%	69.7%	78.6%	78.9%
Rheumatoid Arthritis	6.8%	4.7%	6.7%	6.7%	4.3%	4.3%
AMI & Unstable Angina	50.1%	53.2%	51.0%	45.3%	52.5%	50.2%
Stroke & Cerebral Hemorrhage	21.8%	21.1%	19.2%	19.6%	20.6%	18.0%
Hypertension & Heart Failure	91.8%	92.3%	93.4%	90.3%	92.8%	93.4%
Vascular Disease	29.6%	29.3%	27.5%	30.3%	32.5%	32.8%

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

5.2 MTM Effectiveness at Targeting Individuals with Medication Issues

Table 5-2 below provides baseline rates or averages of drug therapy patterns, use of the hospital and ER, and factors contributing to health system efficiency (e.g., use of generic medications, costs) among the PDP and MA-PD intervention and comparison groups in the six months preceding their study periods. It displays the unadjusted magnitude of each outcome of interest in the observation period, and it shows how individuals in the intervention groups differed from the comparison groups before any MTM services were rendered.

Individuals in the PDP and MA-PD intervention groups were more likely to be adherent to evidence-based COPD medication regimens before they received MTM services, relative to the comparison groups who did not receive MTM services. Because MTM programs rely heavily on drug use to identify their eligible population, beneficiaries who were already in evidence-based treatment were more likely to be identified eligible by MTM programs. Individuals who eventually enrolled in MTM programs and chose to receive a CMR were also more likely to be adherent to their evidence-based COPD medications compared to those who did not receive a CMR. This comparison suggests there is a "healthy user effect," showing that individuals who were already inclined to be adherent to their medications – or behave in other ways to promote their own health – were also more likely to choose to receive a CMR once they enrolled in an MTM program. Across all comparison and intervention groups, a much smaller proportion (approximately 15-30%) of individuals with COPD were adherent to their medications, however, relative to individuals with COPD taking evidence-based COPD medications (81-93%, see **Table 5-2**).

While individuals in the intervention groups were more likely to be adherent to their medications, they were also more likely to have drug-drug interactions and use high-risk medications in the observation period. Further, they were more likely to experience all-cause and COPD-related hospitalizations in that period, with individuals in PDPs and MA-PDs who opted not to receive CMRs having a higher rate of all-cause hospitalization in the observation period relative to the comparison groups as well as the MTM with CMR groups. The proportion of individuals experiencing a hospitalization due to any cause in the six months preceding the outcome period ranged from 28.8% (comparison group) to 32.2% (MTM without CMR) for those in PDPs, and slightly lower at 21.3% (comparison group) to 27.1% (MTM without CMR) for those in MA-PDs. Of the individuals who did experience a hospitalization, those in the MTM without CMR groups also had higher absolute all-cause and COPD-related costs relative to both other groups. For example, those who enrolled in PDP MTM programs who did not receive CMRs incurred about $603 more in inpatient costs than those who received CMRs and about $827 more than those in the comparison group, in the six-month period before they

received any MTM services. These differences imply that MTM programs were generally effective in targeting individuals who had issues with their complex medication regimens.

Table 5-2: Baseline Drug Therapy and Resource Utilization Patterns among PDP and MA-PD Intervention and Comparison Groups [a]

Drug Therapy and Resource Utilization Measures	*Beneficiaries Enrolled in PDPs*			*Beneficiaries Enrolled in MA-PDs*		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	250,593	141,324	19,149	86,725	82,953	9,862
Drug Therapy						
Adherent to LABAs	18.9%	19.9%	25.6%	20.6%	15.8%	20.5%
Adherent to LAACs	26.0%	24.4%	28.8%	27.9%	21.6%	26.4%
Adherent to LABA + LAAC Combination Regimen	12.9%	12.5%	16.4%	13.5%	9.1%	10.4%
At Least One Drug-Drug Interaction	9.4%	11.3%	13.1%	7.4%	9.1%	8.5%
Use of at Least One High Risk Medication	38.0%	39.6%	44.6%	31.1%	33.0%	28.8%
Resource Utilization: Hospital and ER Visits						
Any (All-Cause) Hospitalization	28.8%	32.2%	31.4%	21.3%	27.1%	23.5%
Any COPD-Related Hospitalization	18.1%	21.4%	22.3%	13.4%	17.0%	15.6%
Any (All-Cause) ER Visit	29.6%	28.9%	32.3%	---	---	---
Any COPD-Related ER Visit	11.1%	11.7%	14.7%	---	---	---
Resource Utilization: Medications and Costs (Average)						
Number of Medications	12.3	13.7	15.5	11.6	12.2	12.4
Generic Substitution Ratio	83.9%	70.0%	70.8%	71.0%	72.9%	75.0%
Part D Costs for Non-COPD Drugs	$3,775.64	$3,518.85	$4,395.26	$3,139.53	$2,627.03	$2,611.56
All-Cause Hospitalization Costs	$4,022.06	$4,848.47	$4,245.60	---	---	---
COPD-Related Hospitalization Costs	$2,060.12	$2,601.29	$2,583.31	---	---	---
All-Cause ER Costs	$234.37	$230.71	$262.90	---	---	---
COPD-Related ER Costs	$80.79	$89.02	$110.72	---	---	---

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

5.3 Impact of MTM on Drug Therapy Outcomes for Individuals with COPD

The empirical association between MTM and drug therapy outcomes was generally positive for the PDP and MA-PD cohorts; further, the magnitude of that impact was generally greater for individuals receiving MTM with CMR compared to those who did not receive CMRs. In other words, results consistently suggested that individuals who received a CMR were more likely to experience positive impacts in their drug therapy outcomes, while those results were less consistent for individuals in MTM programs who did not receive a CMR. The following two sections provide the risk-adjusted results for overall PDP and MA-PD groups and stratified by parent organization.

5.3.1 Risk-Adjusted Drug Therapy Outcomes for PDP and MA-PD Cohorts

As shown in **Table 5-3**, beneficiaries in PDPs were more likely to experience statistically significant increases in adherence to LABA-only and LABA + LAAC combination regimens for COPD if they were in an MTM program, relative to individuals in the comparison group. The impact of MTM on adherence to a combination regimen increased with the added effect of CMRs. However, beneficiaries in MA-PDs did not experience statistically significant increases in adherence to these regimens during the study period if they were in an MTM program, relative to individuals in the comparison group. Among individuals with CMRs who were taking a HRM during the six month preceding the start of the study period, MTM enrollees in both PDPs and MA-PDPs were more likely to discontinue filling HRMs relative to the comparison group. Individuals in MA-PDs without CMRs were slightly less likely to discontinue filling HRMs. Individuals in the all intervention groups were not different from the comparison group in terms of discontinue drug-drug interactions by the end of the study period.

Table 5-3: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD (OR with 95% CI)

	Comparison or Intervention Group Assignment	*N*	*Adherent to LABA-Only Regimen*	*Adherent to LAAC-Only Regimen*	*Adherent to Combination Regimen*	*Remove Drug-Drug Interaction*	*Discontinue Use of High Risk Medications*
Beneficiaries Only Enrolled in PDPs	Comparison	250,593	---	---	---	---	---
	MTM without CMR	141,324	1.080 * (1.030 , 1.133)	1.019 (.949 , 1.095)	1.119 * (1.059 , 1.183)	1.055 (.981 , 1.134)	1.049 * (1.021 , 1.078)
	With CMR	19,149	1.166 * (1.059 , 1.284)	1.19 (.989 , 1.432)	1.296 * (1.160 , 1.449)	0.97 (.821 , 1.146)	1.049 (.982 , 1.121)
Beneficiaries Only Enrolled in MA-PDs	Comparison	86,725	---	---	---	---	---
	MTM without CMR	82,953	1.029 (.960 , 1.103)	1.021 (.922 , 1.130)	1.05 (.965 , 1.144)	1.023 (.904 , 1.157)	.954 * (.914 , .995)
	With CMR	9,862	1.095 (.948 , 1.264)	1.062 (.869 , 1.298)	0.965 (.809 , 1.152)	1.043 (.823 , 1.323)	1.122 * (1.023 , 1.232)

* Indicates significance at the 5% level.

5.3.2 Risk-Adjusted Drug Therapy Outcomes for PDP and MA-PD Cohorts, by Parent Organization

After stratifying the analyses by parent organization and adjusting for all covariates, the estimated impacts of MTM on drug therapy outcomes were consistent across parent organizations for some metrics while differing substantially across others. These results are shown in **Table 5-4** and **Table 5-5.**

The drug therapy outcomes analysis on parent organizations for PDPs yielded several noteworthy results. These results are as follows:

- **Adherence to Evidence-Based Medications for COPD:**
  - **Organization B**, **Organization D**, and **Organization E** MTM enrollees improved their LABA-only, LAAC-only, and combination therapy regimens for COPD during the outcome period, relative to their comparison groups. Their corresponding MTM with CMR groups increased their adherence even more. While these results may be inflated due selection of health seeking beneficiaries in the CMR groups, these findings are not less strong in Organization D, who applied CMR for almost every one of its MTM enrollees. However, for **Organization A** enrollees without CMRs, all adherence measures decreased significantly over the outcomes period.
- **Drug-Drug Interaction:**
  - Only individuals enrolled in **Organization A** demonstrated statistically lower odds of having a drug-drug interaction in their drug therapy regimens during the outcome period.
- **Use of High-Risk Medications:**
  - Individuals enrolled in **Organization A, B and C's** MTM programs had higher odds (OR=1.081; OR=1.288, respectively). Individuals enrolled in **Organization D's** MTM programs who did not receive CMRs had lower odds of using high risk medications relative to the comparison group (OR=0.517).

Drug therapy outcomes analysis on parent organizations for MA-PDs did not yield consistent statistically significant changes ($p<.05$) regarding the measures in question.

Table 5-4: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD, by PDP Parent Organization (OR with 95% CI)

Parent Organization	*Intervention Type*	*Adherent to LABA-Only Regimen*	*Adherent to LAAC-Only Regimen*	*Adherent to Combination Regimen*	*At Least One Drug-Drug Interaction*	*Use of at Least One High Risk Medication*
Organization A	MTM without CMR	.786 * (.696 , .888)	.751 * (.629 , .896)	.836 * (.718 , .974)	.854 * (.731 , .997)	1.06 (.998 , 1.125)
	With CMR	0.311 (.060 , 1.608)	1.109 (.329 , 3.734)	1.672 (.491 , 5.686)	0.349 (.090 , 1.351)	2.788 * (1.560 , 4.982)
Organization B	MTM without CMR	1.504 * (1.338 , 1.690)	1.09 (.908 , 1.309)	1.387 * (1.214 , 1.585)	1.14 (.974 , 1.334)	1.081 * (1.016 , 1.150)
	With CMR	1.406 * (1.210 , 1.635)	1.002 (.704 , 1.426)	1.576 * (1.326 , 1.873)	1.011 (.794 , 1.287)	0.993 (.903 , 1.093)
Organization C	MTM without CMR	.726 * (.570 , .924)	1.007 (.737 , 1.377)	0.801 (.570 , 1.127)	0.936 (.547 , 1.602)	1.288 * (1.131 , 1.468)
	With CMR	0.772 (.291 , 2.051)	0.965 (.208 , 4.479)	1.351 (.285 , 6.385)	2.185 (.344 , 13.886)	1.668 (.973 , 2.859)
Organization D	MTM without CMR	1.063 (.641 , 1.761)	3.101 * (1.369 , 7.023)	1.34 (.755 , 2.381)	0.993 (.469 , 2.105)	.517 * (.368 , .726)
	With CMR	1.234 * (1.005 , 1.515)	1.889 * (1.321 , 2.702)	1.293 * (1.018 , 1.642)	0.848 (.590 , 1.218)	0.95 (.833 , 1.084)
Organization E	MTM without CMR	1.976 * (1.567 , 2.492)	2.199 * (1.437 , 3.365)	2.741 * (2.078 , 3.616)	0.702 (.464 , 1.060)	0.928 (.810 , 1.062)
	With CMR	6.026 * (1.766 , 20.551)	2.36 (.200 , 27.784)	6.197 * (2.145 , 17.899)	0.213 (.020 , 2.172)	0.916 (.453 , 1.851)

* Indicates significance at the 5% level.

Table 5-5: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD, by MA-PD Parent Organization (OR with 95% CI)

Parent Organization	*Intervention Type*	*Adherent to LABA-Only Regimen*	*Adherent to LAAC-Only Regimen*	*Adherent to Combination Regimen*	*At Least One Drug-Drug Interaction*	*Use of at Least One High Risk Medication*
Organization A	MTM without CMR	.750 * (.617 , .912)	0.95 (.724 , 1.247)	.787 * (.622 , .995)	0.982 (.736 , 1.311)	0.961 (.869 , 1.062)
	With CMR	0.377 (.073 , 1.940)	1.58 (.434 , 5.746)	1.591 (.471 , 5.367)	1.149 (.277 , 4.749)	1.355 (.747 , 2.457)
Organization B	MTM without CMR	1.239 (.472 , 3.250)	1 (1 , 1)	0.831 (.174 , 3.961)	0.208 (.004 , 10.754)	1.166 (.816 , 1.664)
	With CMR	1.897 (.669 , 5.379)	8.080 (8.080 , 8.080)	1.009 (.180 , 5.629)	0.069 (.000 , 5.106)	1.03 (.647 , 1.638)
Organization C	MTM without CMR	1.031 (.834 , 1.275)	1.164 (.819 , 1.656)	1.147 (.849 , 1.549)	1.445 (.871 , 2.399)	0.997 (.877 , 1.132)
	With CMR	1.253 (.675 , 2.325)	0.827 (.250 , 2.735)	1.854 (.714 , 4.813)	1.707 (.520 , 5.602)	1.042 (.721 , 1.505)
Organization D	MTM without CMR	2.075 (.149 , 28.776)	0.299 (.009 , 9.730)	0.596 (.083 , 4.261)	1 (1 , 1)	.264 * (.072 , .962)
	With CMR	1.214 (.590 , 2.499)	0.554 (.166 , 1.844)	1.131 (.558 , 2.292)	0 (0 , 0)	0.957 (.665 , 1.377)
Organization E	MTM without CMR	1.357 (.676 , 2.724)	1.830 (1.830 , 1.830)	2.575 (.316 , 20.931)	4.29 (4.29 , 4.29)	0.968 (.618 , 1.514)
	With CMR	2.637 (.267 , 25.961)	1 (1 , 1)	1 (1 , 1)	1 (1 , 1)	1.617 (.359 , 7.283)
Organization F	MTM without CMR	0.929 (.721 , 1.196)	0.872 (.624 , 1.218)	0.819 (.602 , 1.115)	0.687 (.369 , 1.278)	0.814 (.655 , 1.012)
	With CMR	0.955 (.732 , 1.246)	0.979 (.708 , 1.355)	0.808 (.591 , 1.104)	0.998 (.536 , 1.856)	0.985 (.781 , 1.241)

* Indicates significance at the 5% level.

5.4 Impact of MTM on Resource Utilization Outcomes for Individuals with COPD: Hospital and ER Visits

Across all PDP and MA-PD cohorts, individuals enrolled in MTM programs had higher rates of hospitalization and ER use during the six months preceding the outcome period (see **Table 5-2**). However, after controlling for previous hospitalizations and other health characteristics, results at the overall PDP and MA-PD levels did not consistently suggest that individuals who received MTM interventions – regardless of receipt of CMR – had different odds of experiencing hospitalizations and ER visits. Results were also varied at the parent organization level. The following two sections provide the risk adjusted results for overall PDP and MA-PD groups and stratified by parent organization.

5.4.1 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts: Hospital and ER Visits

During the outcome period, individuals in PDP and MA-PD MTM programs who did not receive a CMR continued to have higher or the same odds of hospitalization and ER visits compared to their respective comparison groups (see **Table 5-6**). However, those who did receive a CMR tended to have lower odds of these events.

For example, beneficiaries enrolled in PDP MTM programs who did not receive a CMR had higher odds of all cause hospitalization relative to the comparison group (OR=1.053), while those who received CMRs were not different from the comparison group. Those who received CMRs also had lower odds of COPD-related hospitalization relative to the comparison group (OR=.904). Among individuals enrolled in MA-PDs, those who received CMRs had lower odds of all-cause hospitalization and ER visits (OR=0.856 and 0.882, respectively). Those who were enrolled in MTM but did not receive a CMR also had lower odds of all-cause ER visits (OR=0.965).

Table 5-6: Risk-Adjusted Resource Utilization for Individuals with COPD: Hospital and ER Visits (OR with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Any (All-Cause) Hospitalization*	*Any COPD-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any COPD-Related ER Visit*
Beneficiaries Only Enrolled in PDPs	Comparison	250,593	---	---	---	---
	MTM without CMR	141,324	.976 * (.959 , .994)	1.006 (.986 , 1.026)	.965 * (.948 , .982)	1.016 (.992 , 1.041)
	With CMR	19,149	.856 * (.822 , .892)	0.963 (.919 , 1.008)	.882 * (.847 , .918)	1.034 (.980 , 1.091)
Beneficiaries Only Enrolled in MA-PDs	Comparison	86,725	---	---	---	---
	MTM without CMR	82,953	1.053 * (1.023 , 1.083)	1.031 (.998 , 1.066)	---	---
	With CMR	9,862	0.964 (.908 , 1.023)	.904 * (.843 , .969)	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

5.4.2 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts: Hospital and ER Visits, by Parent Organization

After stratifying the analyses by parent organization and adjusting for all covariates, some patterns in hospital and ER visit outcomes arose for specific parent organizations. These results are shown in **Table 5-7** and **Table 5-8**.

The main results of the hospital and ER visit outcomes analysis on parent organizations for PDPs are as follows:

- Individuals enrolled in **Organization E's** MTM programs had lower rates of hospital and ER visits relative to the comparison group. Those receiving the added effect of CMRs had lower odds of visiting the hospital and ER than those who received MTM with no CMR. For example, individuals in MTM who did not receive CMRs had .808 times the odds of experiencing a hospitalization due to any cause, while those who received a CMR had 0.445 times those odds.
- Individuals enrolled in MTM programs provided by parent organizations **A, B, C, and D** who received CMRs also had lower odds of experiencing all-cause and/or COPD -specific hospitalizations relative to their comparison groups.
- Individuals enrolled in **Organization B**, and **Organization C** who did not receive CMRs had higher odds of experiencing all-cause or COPD-specific hospitalizations and/or ER visits relative to their comparison groups.

The hospital and ER visit outcomes analysis on parent organizations for **MA-PDs** yielded similar patterns. Noteworthy results are as follows:

- Those enrolled in **Organization F's** MTM programs had lower odds of COPD-specific hospitalizations relative to the comparison group. Individuals who received MTM services with no CMR had OR=0.765, and those who received CMRs had OR=0.841.
- Individuals in some MTM programs who did not receive a CMR had higher odds of hospitalization, while their counterparts who did receive a CMR were not different from the comparison group.

Table 5-7: Risk-Adjusted Resource Utilization for Individuals with COPD: Hospital and ER Visits, by PDP Parent Organization (OR with 95% CI)

Parent Organization	*Intervention Type*	*Any (All-Cause) Hospitalization*	*Any COPD-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any COPD-Related ER Visit*
Organization A	MTM without CMR	1.034 (.996 , 1.072)	.875 * (.838 , .913)	1.024 (.986 , 1.063)	.841 * (.797 , .888)
	With CMR	.566 * (.378 , .847)	.443 * (.260 , .756)	0.989 (.684 , 1.430)	0.716 (.398 , 1.290)
Organization B	MTM without CMR	.921 * (.887 , .957)	1.129 * (1.082 , 1.178)	.869 * (.838 , .902)	1.158 * (1.102 , 1.216)
	With CMR	.802 * (.754 , .853)	1.041 (.972 , 1.114)	.805 * (.758 , .855)	1.102 * (1.019 , 1.192)
Organization C	MTM without CMR	1.123 * (1.035 , 1.220)	0.997 (.906 , 1.096)	1.109 * (1.023 , 1.203)	1.023 (.910 , 1.149)
	With CMR	.633 * (.435 , .921)	0.735 (.479 , 1.128)	0.755 (.524 , 1.086)	0.591 (.323 , 1.084)
Organization D	MTM without CMR	0.995 (.814 , 1.217)	1.127 (.899 , 1.412)	0.894 (.730 , 1.096)	1.036 (.796 , 1.349)
	With CMR	.896 * (.832 , .965)	1.028 (.944 , 1.118)	.820 * (.762 , .882)	1.011 (.917 , 1.114)
Organization E	MTM without CMR	.808 * (.740 , .882)	.812 * (.735 , .898)	.866 * (.795 , .944)	.850 * (.756 , .955)
	With CMR	.445 * (.260 , .759)	.399 * (.208 , .766)	0.877 (.554 , 1.388)	1.251 (.712 , 2.198)

* Indicates significance at the 5% level.

Table 5-8: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Hospital Visits, by MA-PD Parent Organization (OR with 95% CI) [a]

Parent Organization	***Intervention Type***	*Any (All-Cause) Hospitalization*	*Any COPD-Related Hospitalization*
Organization A	MTM without CMR	1.142 * (1.074 , 1.214)	0.988 (.919 , 1.061)
	With CMR	0.845 (.558 , 1.279)	.576 * (.332 , .997)
Organization B	MTM without CMR	1.104 (.845 , 1.442)	1.543 * (1.138 , 2.091)
	With CMR	1.174 (.824 , 1.672)	1.288 (.853 , 1.945)
Organization C	MTM without CMR	1.247 * (1.139 , 1.366)	1.141 * (1.022 , 1.273)
	With CMR	1.074 (.834 , 1.383)	1.053 (.777 , 1.426)
Organization D	MTM without CMR	1.453 (.715 , 2.954)	2.568 * (1.218 , 5.410)
	With CMR	1.027 (.823 , 1.281)	1.191 (.919 , 1.543)
Organization E	MTM without CMR	0.775 (.588 , 1.021)	0.908 (.650 , 1.267)
	With CMR	0.57 (.180 , 1.805)	0.679 (.148 , 3.118)
Organization F	MTM without CMR	0.937 (.845 , 1.039)	.765 * (.681 , .858)
	With CMR	1.008 (.908 , 1.118)	.841 * (.750 , .944)

* Indicates significance at the 5% level.

[a] Emergency room outcomes were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

5.5 Impact of MTM on Resource Utilization for Individuals with COPD

Across overall and parent organization-specific PDP and MA-PD cohorts, individuals enrolled in MTM programs did not generally fill fewer medications or more generic equivalents to a large enough extent to suggest cost savings. Further, they did not generally have lower costs in the Part D, hospital, or ER settings. The following two sections provide the adjusted results for overall PDP and MA-PD groups, stratified by parent organization.

5.5.1 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts

After adjusting for covariates, individuals in PDP MTM programs – regardless of receipt of CMRs – tended to show slight differences in their cost outcomes compared to the PDP comparison group. Their results are shown in **Table 5-9** and can be summarized as follows:

- **Number of Medications:** Individuals enrolled in PDPs took fewer medications if they were enrolled in an MTM program, regardless of receipt of a CMR. However, these slight decreases may not be associated with significant savings in costs.
- **Generic Substitution Ratio:** Those enrolled in MTM programs had higher average generic substitution ratios (0.2-0.4% more fills of generic drugs over the six-month outcome period) relative to the comparison group. Please note that individuals in the comparison and intervention groups were using mostly generic medications at baseline (see **Table 5-2**).
- **Non-COPD Part D Costs:** Individuals enrolled in MTM programs also had lower overall Part D costs, costing an average of $42.18 (MTM without CMR) and $34.62 (MTM with CMR) less on non-COPD Part D prescription drugs than the comparison group over the six-month outcome period. This translates to monthly non-COPD Part D cost savings of $7.03 and $5.77 per MTM enrollee, respectively.
- **Hospital and ER Costs:** Individuals who were enrolled in MTM programs only had lower costs in the all-cause hospitalization category, with individuals who received a CMR saving an average of $369.55 in the outcomes period, which translates to all-cause hospitalization cost savings of $61.59 per enrollee, per month.

Individuals in MA-PD MTM programs demonstrated similar trends to the PDP MTM programs. Their results, also shown in **Table 5-9**, can be summarized as follows:

- **Number of Medications:** Individuals enrolled in MA-PDs took fewer medications if they were enrolled in an MTM program, regardless of receipt of a CMR.
- **Generic Substitution Ratio:** Those enrolled in MTM programs had higher average generic substitution ratios (0.6% more fills of generic drugs over the six-month outcome period regardless of receipt of CMR) relative to the comparison group; however, this slight increase in use of generic drugs may not be associated with significant savings in costs. Again, individuals in the comparison and intervention groups were using mostly generic medications at baseline (see **Table 5-2**).

- **Non-COPD Part D Costs:** Those in MTM programs did not have different non-COPD Part D total prescription drug costs relative to the comparison group.

Table 5-9: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Medications and Costs (OLS Estimate with 95% CI) [a]

	Comparison or Intervention Group Assignment	*N*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-COPD Drugs*	*All-Cause Hospitalization Costs*	*COPD-Related Hospitalization Costs*	*All-Cause ER Costs*	*COPD-Related ER Costs*
Beneficiaries Only Enrolled in PDPs	Comparison	250,593	---	---	---	---	---	---	---
	MTM without CMR	141,324	-.126 * (-.142 , -.110)	.002 * (.001 , .004)	-42.176 * (-56.191 , -28.161)	$61.9 (-45.17 , 168.97)	$35.15 (-38.09 , 108.4)	-$5.60* (-10.89 , -.3)	-$1.23 (-4.96 , 2.49)
	With CMR	19,149	-.079 * (-.117 , -.042)	.004 * (.001 , .006)	-34.616 * (-67.498 , -1.734)	-$369.55* (-592.31 , -146.78)	-$50.55 (-218.72 , 117.62)	-$20.3* (-31.8 , -8.80)	$2.13 (-5.9 , 10.17)
Beneficiaries Only Enrolled in MA-PDs	Comparison	86,725	---	---	---	---	---	---	---
	MTM without CMR	82,953	-.143 * (-.164 , -.122)	.006 * (.004 , .007)	-$17.394 (-36.517 , 1.728)	---	---	---	---
	With CMR	9,862	-.050 * (-.095 , -.006)	.006 * (.002 , .009)	-$10.621 (-50.290 , 29.047)	---	---	---	---

* Indicates significance at the 5% level.

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

5.5.2 Risk-Adjusted Resource Utilization Outcomes for PDP and MA-PD Cohorts, by Parent Organization

Risk-adjusted results for parent organizations for PDPs and MA-PDs are provided in **Table 5-10** and **Table 5-11**. Results for PDP parent organizations can be summarized as follows:

- **Number of Medications:**
  - Individuals enrolled in **Organization B's** MTM programs filled fewer medications in the outcome period relative to the comparison group.
  - Individuals enrolled in **Organization C's** MTM program who did not receive CMR also filled fewer medications, while those in the corresponding group for **Organization E** filled significantly more medications.
  - However, these slight increases and decreases may not be associated with any impact on costs.
- **Generic Substitution Ratio:**
  - Individuals enrolled in **Organization A** and **Organization C's** MTM programs had higher generic substitution ratios than their comparison groups, of 0.3 and 1.9 % more fills of generic medications over the six-month outcome period, respectively.
- **Non-COPD Part D Costs:**
  - Those enrolled in **Organization A** and **Organization C's** MTM programs who did not receive CMRs had lower Part D costs for non-COPD medications. Enrollees in Organization A cost $83.87 less in the six-month outcome period, translating to Part D cost savings of $13.97per member per month. Organization C's MTM programs cost $71.24 less in the six-month outcome period, translating to Part D cost savings of $11.87 per enrollee per month.
  - Individuals enrolled in **Organization E** who received MTM services with no CMR had higher Part D costs ($96.47) relative to the comparison group.
- **Hospital and ER Costs:** Hospital and ER cost calculations were restricted to individuals who had at least one such event, for both the intervention and comparison groups.
  - Individuals enrolled in **Organization A's** MTM program enrollees who received CMRs cost $2,133.20 less than the comparison group on all-cause hospitalizations, translating to all-cause hospitalization savings of $355.53 per enrollee per month. **Organization A's** MTM program enrollees who received CMRs also cost $1,444.05 less for COPD-related hospitalizations over the outcomes period, translating to monthly cost savings of $240.68 per enrollee. Individuals enrolled in **Organization B** and **C** who received MTM services with CMR also had lower all-cause hospital costs relative to the comparison groups.
  - Individuals enrolled in **Organization B** and **C's** MTM programs who did not receive CMRs cost more than their comparison groups on COPD-related hospitalizations and all-cause hospitalizations, respectively.

Noteworthy results for MA-PD parent organizations can be summarized as follows:

- **Number of Medications:**
  - Individuals enrolled in **Organization C's** MTM programs filled fewer medications in the outcome period relative to the comparison group (MTM without CMR: 0.210 fewer medications in the six-month outcome period).
  - Individuals enrolled in **Organization E** and **Organization F's** MTM program who did not receive CMR also filled more medications (0.497 and 0.329 more medications, respectively). **Organization F** enrollees who received CMR also filled 0.323 more medications in the six-month outcome period.
  - However, these slight increases and decreases may not be associated with any impact on costs.
- **Generic Substitution Ratio:**
  - Individuals enrolled in **Organization A**, **C**, and **E's** MTM programs had higher generic substitution ratios than their comparison groups. However, this slight increase in use of generic drugs may not be associated with any savings in costs.
- **Non-COPD Part D Costs:**
  - Those enrolled in **Organization A** and **B's** MTM programs who did not receive CMRs had lower Part D costs for non-COPD medications $87.78 and $202.27 less in the six-month outcome period, respectively). This translates to non-COPD Part D medication cost savings of $14.63 per month for enrollees in **Organization A**, and $33.71 per month for enrollees in **Organization B**.

Table 5-10: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Medications and Costs, by PDP Parent Organization (OLS Estimate with 95% CI)

Parent Organization	***Intervention Type***	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-COPD Drugs*	*All-Cause Hospitalization Costs*	*COPD-Related Hospitalization Costs*	*All-Cause ER Costs*	*COPD-Related ER Costs*
Organization A	MTM without CMR	.119 * (.085 , .154)	.003 * (.000 , .006)	-$83.869 * (-114.493 , -53.244)	$309.12* (76.40 , 541.85)	-$288.59* (-436.97 , -140.21)	-$1.45 (-11.99 , 9.1)	-$13.55* (-20.74 , -6.37)
	With CMR	-0.114 (-.449 , .220)	-0.013 (-.042 , .015)	-$143.81 (-440.417 , 152.796)	-$2133.2* (-3359.24 , -907.16)	-$1444.05* (-2263.61 , -624.49)	-$57.91 (-132.04 , 16.22)	-$26.01 (-89.711 , 37.69)
Organization B	MTM without CMR	-.128 * (-.166 , -.091)	-0.001 (-.004 , .000)	$2.14 (-27.044 , 31.326)	-$1.05 (-240.41 , 238.31)	$403.34* (235.61 , 571.07)	-$15.78* (-28.71 , -2.85)	$11.5* (1.95 , 21.05)
	With CMR	-.191 * (-.251 , -.131)	0.001 (-.000 , .004)	-$39.34 (-86.156 , 7.477)	-591.07* (-941.01 , -241.13)	$123.64 (-154.1 , 401.38)	-$34.91* (-53.52 , -16.31)	$6.16 (-7.71 , 20.04)
Organization C	MTM without CMR	-.278 * (-.338 , -.218)	.019 * (.013 , .026)	-$71.244 * (-126.933 , -15.555)	$636.28* (192.56 , 1079.99)	-$9.65 (-343.29 , 323.99)	$15.41 (-3.96 , 34.78)	$0.72 (-12.59 , 14.03)
	With CMR	-0.145 (-.395 , .105)	0.014 (-.014 , .042)	-$124.04 (-353.122 , 105.035)	-$1,093.79 (-2420.24 , 232.67)	-$452.02 (-1605.45 , 701.4)	-$45.01 (-121.43 , 31.4)	-$24.85 (-65.11 , 15.41)
Organization D	MTM without CMR	0.179 (-.028 , .387)	0.007 (-.003 , .018)	-$77.22 (-272.779 , 118.333)	$298.09 (-809.1 , 1405.28)	$222.49 (-485.65 , 930.62)	-$17.81 (-80.90, 45.27)	$3.16 (-39.47 , 45.78)
	With CMR	.129 * (.055 , .204)	0 (-.003 , .005)	-$44.77 (-114.591 , 25.053)	$179.36 (-280.49 , 639.22)	$248.77 (-66.59 , 564.13)	-$32.97* (-59.9 , -6.05)	$2.77 (-12.96 , 18.5)
Organization E	MTM without CMR	.245 * (.168 , .322)	0.003 (-.000 , .008)	$96.471 * (26.976 , 165.967)	-$732.47* (-1355.41 , -109.53)	-573.19* (-1021.59 , -124.8)	-$7.40 (-35.2 , 20.4)	-$3.84 (-24.25 , 16.56)
	With CMR	0.284 (-.132 , .702)	-0.009 (-.036 , .017)	$116.75 (-263.088 , 496.581)	-2774.12* (-4647.24 , -901)	-$1,388.23 (-3090.56 , 314.11)	-$61.30 (-179.94 , 57.34)	-$2.00 (-83.99 , 79.98)

* Indicates significance at the p<0.05 level.

Table 5-11: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Medications and Costs, by MA-PD Parent Organization (OLS Estimate with 95% CI) [a]

Parent Organization	*Intervention Type*	*N*	*Number of Medications*	*Generic Substitution Ratio*	*Part D Total Drug Costs for Non-COPD Drugs*
Organization A	MTM without CMR	12,866	.123 * (.074 , .172)	0.001 (-.002 , .006)	-$87.775 * (-134.423 , -41.127)
	With CMR	155	0.23 (-.094 , .555)	0 (-.028 , .028)	$25.17 (-284.084 , 334.424)
Organization B	MTM without CMR	624	-.216 * (-.414 , -.019)	0 (-.015 , .015)	-$202.27 * (-351.78 , -52.755)
	With CMR	274	-0.182 (-.449 , .085)	0.004 (-.014 , .023)	-$144.35 (-346.711 , 58.002)
Organization C	MTM without CMR	21,502	-.210 * (-.272 , -.149)	.018 * (.012 , .024)	$32.449 (-15.450 , 80.349)
	With CMR	528	-0.054 (-.232 , .123)	0.013 (-.005 , .031)	$1.13 (-136.583 , 138.837)
Organization D	MTM without CMR	43	0.439 (-.164 , 1.044)	0.042 (-.009 , .093)	-$157.23 (-750.613 , 436.159)
	With CMR	890	0.04 (-.130 , .212)	0.005 (-.010 , .021)	$1.44 (-166.553 , 169.424)
Organization E	MTM without CMR	594	.497 * (.281 , .713)	0.007 (-.009 , .023)	$53.42 (-157.178 , 264.025)
	With CMR	26	0.239 (-.575 , 1.053)	-0.002 (-.059 , .054)	$157.99 (-635.915 , 951.898)
Organization F	MTM without CMR	4,550	.329 * (.257 , .401)	-0.002 (-.008 , .002)	-$15.60 (-77.287 , 46.088)
	With CMR	4,040	.323 * (.248 , .398)	0.001 (-.004 , .007)	-$29.60 (-93.832 , 34.639)

* Indicates significance at the p<0.05 level.

[a] Emergency room outcomes and all costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.

6 CONCLUSIONS

In comparison to Medicare beneficiaries with CHF or COPD who did not receive any MTM services in 2010, those who were enrolled in MTM programs experienced significant improvements in the quality of their drug therapies. Often, these improvements included increased use of and adherence to evidence-based medications for individuals' chronic conditions and reduced use of high risk medications. Those who received CMRs as part of their MTM program were more likely to experience such positive effects, suggesting that the annual comprehensive medication review may be one of the more crucial components of MTM. Research in non-Medicare settings[8] has postulated that by improving drug therapies, MTM programs may also decrease the risk of adverse events and their associated costs in the inpatient and ER settings; however, our results showed that the relationship between higher-quality drug therapy and such downstream outcomes was more tenuous and varied among the Medicare beneficiaries included in our study groups. Results from our sub-population analyses further indicated that some parent organizations' MTM programs may have offered services that reduced the risk of hospitalizations and ER visits and attenuate inpatient and ER costs. However, those parent organizations conducted CMR for a small share of their MTM enrollees (less than 5%), and therefore those results may not be representative of the potential impact of those programs if they were to be applied to a larger group. Those parent organizations' MTM programs may be of particular interest for further qualitative investigation.

The following two sections provide a more detailed summary of the results and limitations of our analyses. The final section presents final commentary and our planned next steps.

6.1 Summary of Results

In 2010, 3,506,350 individuals enrolled in Part D were identified within the risk adjustment data as having CHF; 3,973,578 were identified with COPD (11.8% and 13.4%, respectively). From these patients, 8.3% with CHF and 8.7% with COPD participated in an MTM program.

In the CHF and COPD cohorts, individuals who had problems in their drug therapy regimens in the six months preceding MTM enrollment were more likely to be targeted for inclusion in MTM programs. For example, 18-30% of individuals in PDPs who had CHF and enrolled in a MTM program used a contraindicated medication in the six months prior to MTM enrollment, while only 16.8% of individuals in the comparison group used a contraindicated medication during that time period. This difference at baseline shows that out of individuals with CHF, those who had an issue in their drug therapy regimen were more likely to be targeted for enrollment in a MTM program in 2010. MTM programs also targeted individuals with CHF

and COPD who used high-risk medications and/or had drug-drug interactions in their treatment regimens.

MTM programs were also effective in targeting individuals who had experienced a recent hospitalization or ER visit. In the CHF cohort, for example, the proportion of individuals experiencing a hospitalization due to any cause in the six months preceding the outcome period ranged from 31.0% (comparison group) to 34.7% (MTM without CMR) for those in PDPs, and 24.1% (comparison group) to 30.3% (MTM without CMR) for those in MA-PDs. Individuals in the MTM without CMR groups also had higher absolute all-cause and CHF-related costs relative to the comparison group. For example, those who enrolled in PDP MTM programs who did not receive CMRs incurred about $1,034 more in inpatient costs than those in the comparison group, in the six-month period before they received any MTM services. These findings were similar across the COPD cohort as well. To investigate this further, the qualitative study will assess whether some parent organizations consider beneficiaries' prior hospitalizations as another factor in determining MTM eligibility.

In comparison to Medicare beneficiaries with CHF or COPD who did not receive any MTM services in 2010, those who were enrolled in MTM programs experienced significant improvements in the quality of their drug regimens. Improvements included increased use of and adherence to evidence-based medications for individuals' chronic conditions, and interruption of high-risk medications. Of the MTM enrollees, 10.4-11.5% received an annual CMR. Those who received CMRs as part of their MTM program were more likely to experience such positive effects, suggesting that the annual CMR may be one of the more crucial components of MTM program. For example, relative to the comparison groups, beneficiaries with CHF who were not taking evidence-medications before enrolling into an MTM program had higher odds of filling at least one evidence-based medication for CHF during the six-month outcome period; further, the magnitude of this impact was greater for those who received a CMR compared to those who did not (PDP: OR = 1.1 without CMR and 1.198 with CMR; MA-PD: OR = 1.377 without CMR and 1.302 with CMR). This finding was constant across most parent organization-specific PDPs and MA-PDs as well (parent organization results not shown in the Executive Summary). Results diverged, however, in terms of impacts on other indicators for quality of drug therapy, including use of high-risk and contraindicated medications. Such findings were similar for individuals included in the COPD cohort.

Research in non-Medicare settings[8] has postulated that by improving drug therapies, MTM programs may decrease the risk of adverse events that led to hospital and ER visits and reduce associated costs; however, our results showed that the relationship between higher-quality drug therapy and such downstream outcomes was weak and not consistent across MTM programs evaluated in this study. While our research on the overall Medicare CHF population

did not find a robust overall cost saving for overall inpatient and ER visits after MTM program enrollment, the results from our sub-population analyses indicated that some parent organizations' MTM programs may have successfully reduced the risk of adverse events associated with hospital and ER visits and led to lower subsequent inpatient and ER costs. These parent organizations' MTM programs will be of particular interest for further qualitative investigation.

Among beneficiaries with CHF in our analyses, those who received MTM interventions were more likely to take up and be adherent to evidence-based medications for CHF during the six-month study period following MTM enrollment. This finding was more pronounced for individuals who received CMRs as part of their MTM program; further, it was constant across the overall PDP and MA-PD groups as well as most parent organization-specific PDPs and MA-PDs. Results diverged, however, in terms of impacts on other indicators for quality of drug therapy, including use of high-risk and contraindicated medications. Among the parent organizations selected for the subpopulation analysis, patients enrolled in MTM programs through Organization A and C did significantly improve these outcomes. MTM program enrollees also did not differ in the number of unique medications they filled or their use of generics as compared to non-MTM program comparisons.

While MTM aims to reduce the IP and OP-ER costs associated with poor medication adherence, some Part D cost savings may also be possible. This is because MTM programs promote the use of cost-effective medications, such as generics, and also identify duplication of treatment. The resource utilization analyses estimated that individuals who received MTM services cost approximately $4-$7 less per month in total prescription drug costs (excluding CHF-specific medications, an adjustment made to exclude costs related to beneficiaries' potential improved adherence to CHF medications) relative to those in the comparison group. Note that beneficiaries in the CHF cohort all had one or more additional chronic conditions, including diabetes, hypertension, and dyslipidemia. Further analysis could explore whether there was improved adherence to drugs used to treat these other conditions.

In contrast with findings during the observation period, beneficiaries with CHF had slightly lower risks of hospitalization and ER visits if they were enrolled in an MTM program, particularly among beneficiaries enrolled in PDPs. These results may have been driven, however, by specific MTM programs that were particularly effective at reducing the risk of adverse events associated with hospital and ER use. For example, among individuals enrolled in an MTM program by Organization B, there were no significant cost differences relative to the comparison group. On the other hand, individuals in Organization A's MTM program who received a CMR did experience significant cost savings ($1889 in the outcome period, translating to which translates to overall inpatient savings of approximately $315 per individual

per month). This result, however, was found based on analysis of a small number of beneficiaries and thus is best approached cautiously.

We found similar results from the analysis of COPD patients for the adherence and high-risk medication measures to those found for individuals in the CHF cohort. Enrollees in PDP MTM programs were more likely to take up and improve their adherence to evidence-based medication regimens for COPD and stop using high risk medications, but again did not show any significant improvements in eliminating of drug-drug interactions. However, those in the MA-PD MTM programs experienced moderate improvement relative to the comparison group on most of these drug therapy measures. Individuals with COPD who were enrolled in MTM programs did not experience a change in the number of unique medications filled or the use of generic equivalents. And finally, results from the resource utilization analyses among specific parent organizations suggest cost-savings for MTM program enrollees in the Part D setting: individuals in selected parent organization MTM programs with CMRs cost $12-$14 less per month for their non-COPD drugs relative to the comparison group.

During the outcome period, beneficiaries with COPD generally had slightly lower risks of all-cause and COPD-related hospitalizations and ER visits if they were enrolled in MTM programs, and this effect was again more pronounced if they received CMRs. Enrollees in some parent organizations (e.g., Organization A and E) had particularly low risks of these events relative to the comparison groups. In concordance with findings from the CHF analysis, the analysis of COPD patients found inconsistent relationships between inpatient and ER visits and associated cost savings. At the overall PDP level, individuals who received MTM services with CMRs saved approximately $370 over six months in hospitalizations related to any cause, translating to related cost savings of approximately $62 per enrollee per month. These findings were not replicated for COPD-specific hospitalizations. Individuals associated with particular parent organizations also experienced inconsistent impacts on resource utilization. For example, those enrolled in Organization A's PDPs saved an average of $2,133 and $1444 on all-cause and COPD-related hospital costs. This is equivalent to per enrollee savings of $356 per month, and $241 per month, respectively. Because fewer than 300 beneficiaries enrolled in Organization A MA-PDP had a CMR, this result may need to be approached cautiously. On the other hand, individuals in other parent organizations' MTM programs (e.g., Organization B's MTM enrollees who did not receive CMRs) accrued significantly higher inpatient costs than the comparison group.

6.2 Discussion

MTM programs within the Medicare setting consistently helped enrollees with CHF and COPD improve adherence to their evidence-based regimens and discontinue the use of high-risk

medications while less consistently impacting other drug therapy outcomes hospital and ER visits, and other resource utilization outcomes including costs. CMRs appeared to exert a strong effect on outcomes, as beneficiaries who received CMRs were more likely to benefit from MTM program participation across almost all outcomes relative to those in MTM programs who did not receive CMRs.

MTM programs impacted all-cause and disease-specific (e.g., CHF-specific and COPD-specific) cost savings inconsistently across individuals included in our study cohorts. At the overall PDP and MA-PD levels, for example, there were significant cost savings associated with all-cause hospitalizations but not with disease-specific (e.g., CHF-specific or COPD-specific) hospitalizations. Because MTM programs are general interventions that aim to improve medication therapy across all of an enrollee's chronic conditions, it is possible interventions were more successful at improving outcomes related to conditions other than CHF and COPD. In the year preceding the study period, individuals who were included in the study cohorts also had high rates of diabetes, acute myocardial infarction, and stroke, among other conditions. Thus, it may be possible that clinicians providing MTM services to these chronically-ill enrollees focused on improving health outcomes related to those other, potentially more severe conditions, yielding cost-savings in all-cause but not in CHF- or COPD-related adverse events. Future analyses could consider identifying MTM enrollees' most acute or severe conditions in order to determine whether MTM programs specifically improve resource utilization outcomes related to those conditions.

At the overall PDP level and particularly for some parent organizations, the magnitude of inpatient cost savings for individuals with COPD was larger than that for individuals with CHF, though these cost savings were still relatively inconsistent. One potential explanation for this difference is that an average of 90% of individuals with CHF were adherent to their evidence-based CHF medications before they enrolled in MTM, while only 30% of individuals with COPD were adherent to evidence-based COPD medications. Thus, adherence was a relatively "topped-out" measure for the CHF cohort, while a much larger proportion of individuals with COPD had the potential to improve their medication adherence. Because MTM interventions most consistently improved adherence for both the CHF and COPD cohorts, one could hypothesize that improved medication adherence was the driving factor behind medical cost savings outside of Part D. Our results may corroborate this hypothesis because they showed pronounced cost savings for the COPD cohort from MTM program participation, perhaps due to the larger share of individuals with COPD having sub-optimal adherence at baseline; thus, individuals with COPD had more potential to improve adherence and thereby avoid hospital and ER visits and their associated costs. This finding implies that MTM services might be more

effective in individuals with chronic conditions such as COPD which have low rates of medication adherence at baseline.

One might have expected that MTM programs offered by MA-PDs might have had more consistent effects on enrollees, as Medicare Advantage plans are financially responsible for beneficiaries' costs outside Part D. Our results, however, showed that MA-PD MTM programs did not improve enrollees' drug therapy or resource utilization outcomes over PDP MTM programs. This finding could be explained by the relatively healthy MA-PD population: relative to MTM enrollees from PDPs, individuals in MA-PDs MTM programs took fewer drugs, had lower Part D costs, and had lower rates of hospital and ER visits before they enrolled in the MTM program. They may have received services similar to MTM through their MA-PDs (e.g., disease management services) before enrolling in the plan's official MTM program, and they therefore would have less room for improvement once the MTM study period began. It may also be the case that beneficiaries in MA-PDPs comparison groups are receiving other disease management services during the study period, so the estimated effects represent the marginal impact of MTM relative to other services.

Finally, the results in this report are limited by several factors. First, the effects of the analyses comparing enrollees in MTM programs who received CMRs versus those who did not may have been confounded by the "healthy user effect," which refers to individuals' health-preserving behavioral tendencies that globally affect health-promoting or risk reducing activities (including CMR participation). Those who opted to receive CMRs as part of their MTM programs, in other words, may have been more likely to engage in other activities to stay healthy as well; our overall PDP and MA-PD analyses may not have been able to separate the effect of CMR from other, unobserved, intrinsic behaviors or positive behavioral health tendencies. However, our analysis of the determinants of CMR participation shows enrollment in certain parent organizations has the strongest effect in the likelihood that an individual will receive a CMR. Moreover, our sub-population analyses provide results that may clarify this effect, as there was particularly strong bias towards healthy users in parent organizations such as Organization A (with less than 5% of MTM enrollees receiving CMRs) and a weaker bias in parent organizations such as Organization D (with 81%+ enrollees receiving CMRs). Second, our analyses were limited to individuals who were newly enrolled in MTM programs in 2010. While this analytic framework provided a way to cleanly compare individuals who received MTM to those who did not over a six-month study period, we might not be able to assume that the results could be generalized to Medicare beneficiaries who might have received MTM services outside of this period. Third, the analysis is limited in the extent that it focuses on CHF and COPD-specific outcomes on a population that has multiple chronic conditions besides those. CHF or COPD may not be the most the most acute conditions for some beneficiaries in our

cohorts, or these may not be the conditions specifically targeted by MTM programs. Finally, limitations in our data bias our estimates downward. For example, this analysis does not account for Medicare beneficiaries who were offered MTM by their health plan despite the fact that they did not meet CMS requirements for participating in MTM. Plans which offer MTM to an expanded population do not currently report these additional enrollees to CMS. As a result, some members of the comparison group may have received MTM services despite that they did not meet CMS eligibility requirements. However, any MTM services offered to the comparison are not expected to have included CMR.[a] Additionally, some of the parent organization sub-population analyses had small sample sizes that led to results which should probably be interpreted cautiously, and 2009 RxHCCs (used for risk-adjustment) might not have provided a complete representation of a beneficiary's health status. Furthermore, we plan to risk-adjust the outcomes for the PDP population using claims diagnosis data; however, these data were not available at the time of our initial analysis.

6.3 Next Steps

This study will be followed by qualitative analyses that include expert interviews, case studies on specific parent organizations, and a Technical Expert Panel to understand how MTM programs are implemented. In particular, the study will investigate what policies and procedures are in place in programs that are successful in delivering CMRs, and the study will investigate how MTM programs are implemented, and how MTM programs tailor their interventions to beneficiaries who are most vulnerable. The qualitative findings will provide CMS with the in-depth knowledge it needs to assess the scalability of various MTM practices and to evaluate the effectiveness of MTM programs in the Medicare context.

We will expand the quantitative analysis in several dimensions. First, we will evaluate the effect of MTM program participation on individuals with diabetes. Second, we will conduct outlier analyses to pinpoint beneficiaries within each disease cohort who had especially high costs or high prevalence of medication issues at baseline, to determine whether MTM programs particularly affected those beneficiaries' outcomes. Third, we will supplement one or two case studies from the qualitative study to evaluate the impact of narrowly defined drug therapy interventions.

[a] We learned through phone conversations with the health plans that they did not offer CMR to the MTM enrollees who did not meet the CMS requirements for MTM.

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APPENDIX A: DATA SOURCES

Medicare is a federal entitlement program and the largest health insurance provider in the United States. It provides inpatient (Medicare Part A), outpatient (Part B), and prescription drug (Part D) coverage on a fee-for-service basis to individuals over the age of 65, as well as to individuals under the age of 65 who are disabled or have been diagnosed with end-stage renal disease or amyotrophic lateral sclerosis. Additionally, the Medicare Program collaborates with private health insurance plans to offer beneficiaries the option to enroll in Medicare Advantage plans (Part C), which in turn provide enrolled beneficiaries with benefit packages covering the standard services offered by Parts A, B, and D as well as additional benefits such as reduced cost sharing. In 2010, Medicare covered 49 million Americans, 28 million of whom were enrolled in a Medicare Part D plan (PDP), 11 million of whom were enrolled in a Medicare Advantage Part D plan (MA-PD), and 83% of whom were over the age of 65. Forty-five percent of Medicare beneficiaries in 2010 had three or more chronic conditions.[19]

Because MTM services are offered through Part D, our study sample was restricted to beneficiaries enrolled in either a PDP or an MA-PD in 2010. Claims data for Part D for all of these beneficiaries were available from the start of their enrollment in Part C or D. For beneficiaries enrolled in PDPs, claims data for Parts A and B were also available; for those enrolled in MA-PDs, claims data were only available for inpatient hospital stays (i.e., a subset of Part A claims). We then linked claims for Parts A, B, and D to the Medicare Enrollment Database to create longitudinal patient histories including demographic and enrollment characteristics and information about diagnoses, procedures, prescription drugs, physician visits, home health and skilled nursing facility care, and durable medical equipment use, depending on data availability for beneficiaries enrolled in PDPs versus MA-PDs. Prescription claims included days of supply and quantities dispensed and were mapped against reference databases[20] to identify drug name and strength using the National Drug Code (NDC) number. Next, we used the MTM Reporting Requirement Files to identify whether or not a beneficiary's longitudinal patient history included enrollment in a 2009 and/or 2010 MTM program that passed data validation, and whether and when a beneficiary received a CMR in 2010.

Final longitudinal patient histories provided the information needed to track drug therapy and resource utilization outcomes for all included beneficiaries. The MTM Submission Files, which include contract-specific MTM information, provided complementary data on the general characteristics of the MTM program in which a beneficiary was enrolled.

APPENDIX B: MEDICATIONS INCLUDED IN ANALYSES

Table B-1: CHF-Specific Medications Included in Analysis

Drug Class and/or Regimens[a]	Reason for Inclusion
• Tier 1 Drugs (**Evidence-Based Medications**): ○ ACE inhibitors[21-24] and ARB[25,26] ○ Cardioselective beta-blockers including metoprolol, bisoprolol, carvedilol[27-30] ○ Selective aldosterone receptor antagonists – spironolactone[31] and eplenerone[32,33]	○ Drugs shown to improve survival in randomized controlled trials and recommended in ACC/AHA Guidelines to CHF patients based upon Level 1 evidence.[34]
• Tier 2 Drugs: ○ Loop diuretics (e.g., *furosemide* or *Lasix*), thiazides, and thiazide-like diuretics ○ Diuretic combinations ○ Cardiac glycosides (e.g., *digoxin*) ○ Nitrates ○ Antihypertensives	○ Drugs used to improve CHF symptoms but not associated with mortality benefit.
• Tier 3 Drugs: ○ All other cardiovascular drugs (e.g., antiplatelets)	

[a] Patients were counted as having an "active prescription" of these drugs if they had possession of that drug at the start of the observation period. Medication possession was determined based on days supply of prescriptions filled on or after April 1, 2009. Thus, a patient would be included in the depression cohort if he or she had a 2009 depression diagnosis flag and filled a 30-day antidepressant prescription on June 15, 2009, meaning that he or she had supply of the antidepressant on July 1, 2009.

Table B-2: COPD-Specific Medications Included in Analysis

Drug Class and/or Regimens[a]	Reason for Inclusion
• Long-acting anticholinergics (LAAC) (*e.g., tiotropium*) • Long-acting beta-adrenergics (LABA) (*e.g., salmeterol*) • LAACs + LABAs	○ Drug regimens shown to reduce acute exacerbations and COPD-related hospitalizations in randomized controlled trials for patients with moderate to severe COPD.[35,36]

[a] Patients were counted as having an "active prescription" of these drugs if they had possession of that drug at the start of the observation period. Medication possession was determined based on days supply of prescriptions filled on or after April 1, 2009. Thus, a patient would be included in the depression cohort if he or she had a 2009 depression diagnosis flag and filled a 30-day antidepressant prescription on June 15, 2009, meaning that he or she had supply of the antidepressant on July 1, 2009.

Table B-3: Drug-Drug Interactions – Target and Contraindicated Drugs [a]

Target Drug or Drug Class	Contraindicated Drug or Drug Class
• ***Benzodiazepines:*** alprazolam, midazolam, triazolam	• ***Azole antifungal agents:*** ketoconazole, itraconazole, fluconazole, posaconazole, voriconazole
• carbamazepine • cyclosporine	• propoxyphene • ***Rifamycins:*** rifampin, rifabutin, rifapentine
• digoxin	• clarithromycin, erythromycin, azithromycin, telithromycin
• ***Ergot alkaloids:*** ergotamine, dihydroergotamine	• clarithromycin, erythromycin, telithromycin
• ***Estrogen/progestin oral contraceptives:*** desogestrel-ethinyl estradiol, drospirenonoe-ethinyl estradiol, estradiol valerate-dienogest, ethinyl estradiol-ethynodiol, ethinyl estradiol-levonorgestrel, ethinyl estradiol-norethindrone, ethinyl estradiol-norgestimate, ethinyl estradiol-norgestrel, mestranol-norethindrone	• ***Rifamycins:*** rifampin, rifabutin, rifapentine
• ***MAO Inhibitors:*** isocarboxazid, linezolid, phenelzine, rasagiline, selegiline, tranylcypromine	• ***Sympathomimetics:*** amphetamines, atomoxetine, benzphetamine, dextroamphetamine, diethylpropion, isometheptene, methamphetamine, methylphenidate, phendimetrazine, phentermine, phenylephrine, pseudoephedrine, tapentadol, dexmethylphenidate, lisdexamfetamine • ***Serotonergic Agents:*** buspirone, citalopram, cyclobenzaprine, desvenlafaxine, dextromethorphan, duloxetine, escitalopram, fluoxetine, fluvoxamine, meperidine, milnacipran, mirtazapine, paroxetine, sertraline, sibutramine, tetrabenazine, tramadol, trazodone, venlafaxine

[a] We used the 2010 DDI (drug-drug interaction) list, which is maintained by the Pharmacy Quality Alliance (PQA), for their measure concept.

Target Drug or Drug Class	Contraindicated Drug or Drug Class
• methotrexate • ***Nitrates:*** amyl nitrite, isosorbide dinitrate, isosorbide mononitrate, nitroglycerin	• trimethoprim/sulfamethoxazole • ***Phosphodiesterase inhibitors:*** sildenafil, tadalafil, vardenafil
• simvastatin (40mg & 80mg)	• amiodarone
• tamoxifen	• bupropion, duloxetine, fluoxetine, paroxetine
• theophylline • mercaptopurine • warfarin	• ciprofloxacin, fluvoxamine • allopurinol • cimetidine, trimethoprim/sulfamethoxazole • ***Fibrates***: fenofibrate, fenofibric acid, gemfibrozil • ***NSAIDs***: diclofenac, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, mefenamic acid, meloxicam, nambumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

Table B-4: Drugs Indicated as High-Risk for Individuals over the Age of 65 [a]

Description	Prescription		
Antianxiety (includes combination medications)	• aspirin-meprobamate	• meprobamate	
Antiemetics	• scopolamine	• trimethobenzamide	
Analgesics (includes combination medications)	• ketorolac		
Antihistamines (includes combination medications)	• APAP/dextromethorphan/diphenhydramine • APAP/diphenhydramine/phenylephrine • APAP/diphenhydramine/pseudoephedrine • acetaminophen-diphenhydramine • carbetapentane/diphenhydramine/phenylephrine • codeine/phenylephrine/promethazine • codeine-promethazine • cyproheptadine • dexchlorpheniramine • dexchlorpheniramine/dextromethorphan/PSE • dexchlorpheniramine/guaifenesin/PSE • dexchlorpheniramine/hydrocodone/phenylephrine • dexchlorpheniramine/methscopolamine/PSE	• dexchlorpheniramine-pseudoephedrine • dextromethorphan-promethazine • diphenhydramine • diphenhydramine/hydrocodone/phenylephrine • diphenhydramine-magnesium salicylate • diphenhydramine-phenylephrine • diphenhydramine-pseudoephedrine • hydroxyzine hydrochloride • hydroxyzine pamoate • phenylephrine-promethazine • promethazine	
Antipsychotic, typical	• thioridazine		
Amphetamines	• amphetamine-dextroamphetamine • benzphetamine • dexmethylphenidate • lisdexamfetamine	• dextroamphetamine • diethylpropion • methamphetamine • methylphenidate	• phendimetrazine • phentermine
Barbiturates	• butabarbital • mephobarbital	• pentobarbital • phenobarbital	• secobarbital

[a] Acumen used the Pharmacy Quality Alliance (PQA) High-Risk Medication (HRM) measure specifications in place during the 2010 study period. PQA updated its technical specifications for the HRM measure in early-2012 based upon new clinical recommendations from the American Geriatrics Society (AGS). At this time PQA adjusted the HRM measure so that patients would only be included if they received at least two prescription fills of the same high-risk medication.

Description	Prescription		
Long-acting benzodiazepines (includes combination medications)	• amitriptyline-chlordiazepoxide • chlordiazepoxide	• chlordiazepoxide-clidinium • diazepam	• flurazepam
Calcium channel blockers	• nifedipine—short-acting only		
Gastrointestinal antispasmodics	• dicyclomine	• propantheline	
Belladonna alkaloids (includes combination medications)	• atropine • atropine/hyoscyamine/PB/scopolamine • atropine/CPM/hyoscyamine/PE/scopolamine • atropine-difenoxin • atropine-diphenoxylate • atropine-edrophonium • belladonna	• belladonna/ergotamine/phenobarbital • butabarbital/hyoscyamine/phenazopyridine • hyoscyamine • hyoscyamine/methenam/m-blue/phenyl salicyl	
Skeletal muscle relaxants (includes combination medications)	• ASA/caffeine/orphenadrine • ASA/carisoprodol/codeine • aspirin-carisoprodol	• aspirin-methocarbamol • carisoprodol • chlorzoxazone • cyclobenzaprine	• metaxalone • methocarbamol • orphenadrine
Oral estrogens (includes combination medications)	• conjugated estrogen • conjugated estrogen-medroxyprogesterone	• esterified estrogen • esterified estrogen-methyltestosterone	• estropipate
Oral hypoglycemics	• chlorpropamide		
Narcotics (includes combination medications)	• ASA/caffeine/propoxyphene • acetaminophen-pentazocine • acetaminophen-propoxyphene • belladonna-opium • meperidine	• meperidine-promethazine • naloxone-pentazocine • pentazocine • propoxyphene hydrochloride • propoxyphene napsylate	
Vasodilators	• dipyridamole—short-acting only	• ergot mesyloid • isoxsuprine	
Others (including androgens and anabolic steroids, thyroid medications, urinary anti-infectives)	• methyltestosterone • nitrofurantoin • nitrofurantoin macrocrystals	• nitrofurantoin macrocrystals-monohydrate • thyroid desiccated	