Medication Therapy Management in Chronically Ill Populations: Final Report

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EXECUTIVE SUMMARY

Introduction

Medication non-adherence contributes a substantial human and financial toll on the health of Americans. Poor medication adherence has been associated with adverse health outcomes and increased risk of mortality across multiple disease conditions, particularly among patients with chronic conditions.[1-5] Medication non-adherence accounted for 33% - 69% of all medication-related hospital admissions in the U.S. in 2000.[6] The cost of medication non-adherence was estimated to exceed $177 billion, with medication-related hospitalizations accounting for almost 70% ($121.5 billion) of that estimate (2000 U.S. dollars).[7-9]

Medication therapy management (MTM) programs have the potential to positively influence drug adherence and quality of prescribing.[10,11] These programs, provided by both private insurers and Medicare, target high-risk, high-cost patients with chronic medical conditions and aim to optimize their therapeutic outcomes and reduce adverse events through improved medication use. MTM programs have been supported by stakeholders, policymakers, and researchers as compelling efforts to improve the quality of chronic care management and reduce healthcare expenditures.[12,13]

Thus far, most research on MTM programs has been conducted in the private insurance setting and it is unclear whether these research findings apply to older and more complex chronically ill Medicare beneficiaries. Medicare Prescription Drug Benefit Program (Part D) MTM programs generally target chronic conditions that align with the most frequently used medications, focusing on some combination of conditions including heart failure, diabetes, chronic lung disorders, and mental health disorders. Plan sponsors must offer a minimum level of MTM services to each beneficiary enrolled in the program that includes all of the following: (1) interventions for both beneficiaries and prescribers, (2) an annual comprehensive medication review (CMR) with written summaries, and (3) quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary. However, while the general framework of the MTM program – offering CMRs and TMRs to chronically ill beneficiaries – is the same across Part D organizations, their targeted populations and intervention strategies are diverse. The effectiveness of MTM programs on the health of Medicare beneficiaries and the effect of strategies and interventions on outcomes are largely unknown.

To understand the effect of various MTM strategies on outcomes among Medicare beneficiaries, this study investigated how Part D MTM programs in operation in 2010 affected Medicare beneficiaries' adherence, quality of prescribing, resource utilization, and cost of hospital and emergency room (ER) care. Furthermore, this quantitative analysis was coupled with a qualitative investigation aimed at identifying important intervention components for

achieving Part D MTM program success. This study specifically focused on beneficiaries with congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes because these individuals are at high-risk for poor health outcomes and thus could benefit greatly from improved medication management.

Approach

We applied a mixed methods approach, utilizing both quantitative and qualitative methods, 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 adherence, quality of prescribing, resource utilization, and costs for Medicare beneficiaries with CHF, COPD, and diabetes.

The first step was a retrospective cohort analysis evaluating the effects of MTM programs on outcomes for Medicare beneficiaries in 2010 during the first year after enrollment. In addition to analyses on the full cohort of MTM enrollees, we conducted separate analyses for each of eight Part D organizations that used a representative group of MTM service providers with varied approaches to CMR implementation. A subset of these Part D organizations was interviewed as a part of our qualitative analysis. **Table ES 1** provides a summary of key characteristics of the MTM programs used by these eight Part D parent organizations upon which the quantitative analysis was based.

Table ES 1: MTM Program Summary for Selected Part D Parent Organizations in 2010

Part D Parent Organization	*MTM Enrollment*[a]	*CMR Consultation Mode*	*Written Summary of CMR* [b]	*Percent Receiving CMRs*[c]	*Prescriber Outreach Methods*
A[d]	High	Phone	Action plan, recommendations	Low	Phone, fax
B	High	Phone, face-to-face	Action plan, recommendations, personal medication list	Low	Phone, fax, mail
C	Medium	Phone, face–to-face	Action plan, recommendations	Low	Phone, fax, mail
D	Medium	Phone	Personal medication list	High	Fax
E[d]	Low	Phone	Action plan, recommendations, individualized medication list	Low	Phone, fax, mail
F[d]	Low	Phone, face-to-face	Recommendations, reconciled medication list, education materials	High	Phone, EMRs, e-mail and mail
G[d]	Low	Phone	Medication action plan, personal medication list, information on assistance programs	High	Mail, phone
H[d]	Low	Phone, face-to-face	Personal medication list, medication action plan, education materials	Low	Mail, phone

a. For all Part D MTM enrollees annually in 2010: High consists of > 100,000 MTM enrollees; Medium consists of between 40,000 and 100,000 MTM enrollees, and Low consists of < 40,000 MTM enrollees.
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.
c. CMR rates above 25% are denoted as "high." CMR rates below 25% are denoted as "low."
d. Interviewed as part of the qualitative Part D parent organization interviews.
Source: MTM Program data provided by CMS.

We evaluated two types of outcomes: drug therapy and resource utilization. Drug therapy outcomes were divided into: (i) adherence, (ii) quality of prescribing (the use of evidence-based medications), and (iii) drug safety (the presence of drug-drug interactions, high-risk medication use in the elderly, and disease-contraindicated medications). Resource utilization outcomes were divided into: (i) hospitalization rates and ER visits, and (ii) drug, hospitalization and ER costs.

The quantitative method used a two-step approach to estimate the effects of MTM based on a comparison of outcomes between MTM enrollees and non-MTM enrollees. First, we narrowed the set of non-MTM enrollees (comparison group) to include only beneficiaries who were potential candidates for MTM. We did this by identifying patients who satisfied eligibility criteria for MTM enrollment of the four largest Part D parent organizations (i.e., combinations of 2-3 chronic diseases, at least $3,000 in preceding annual drug costs, and a minimum threshold of 2-8 prescriptions) but who did not meet the MTM eligibility criteria of the Part D plan in which they were enrolled. We thus took advantage of variations in the MTM eligibility criteria set by

Part D sponsors to identify patients with equivalent MTM eligibility characteristics but who happened to be in plans with different rules that made them ineligible for MTM. As a result, our comparison group consisted of Medicare beneficiaries not enrolled in MTM who were matched on important characteristics to MTM enrollees. Next, we used ordinary least squares (OLS) regression models to adjust for remaining differences in demographics, medical conditions and health service utilization between MTM enrollees and the comparison cohort. This part of the model adjusted for patient-level demographics including age, gender, race/ethnicity, socioeconomic status; medical comorbidities and condition severity using Medicare RxHCC flags; the number of maintenance drugs prescribed; and the numbers of providers visited in the year prior to MTM enrollment. The regression approach also accounted for drug benefit plan enrollment (i.e., cost saving incentives) by using indicators for gap coverage. Finally, for the analysis of each outcome, the model adjusted for the incidence or level of that specific outcome in the year preceding MTM enrollment.

We further tested the sensitivity of our main findings from the OLS analysis by using a second approach – a difference-in-differences (DiD) estimator method - to analyze the same set of outcomes. This method matched MTM enrollees with beneficiaries in the general Medicare Part D population on a similar set of demographic and health characteristics as in the main analysis. However, unlike the main approach, MTM enrollees were individually matched with controls on each of the selected matching variables using a fully interacted model. The DiD estimator then calculated the difference in outcome changes between MTM enrollees and their matched controls from the 12 months preceding MTM enrollment to the 12 months following enrollment. Since the DiD estimator captures changes in an outcome and not the level of the outcome, it has the potential to reduce the bias introduced by time-invariant factors differing in the two groups. The DiD method was also better suited to calculate MTM program effects at the level of the Part D parent organizations when sample sizes were inherently smaller, and also to conduct a supplementary analysis for identifying sub-populations of MTM enrollees who were the most responsive (as compared to their matched controls) to MTM interventions.

Next, we engaged in 9 MTM stakeholder (i.e., individuals with past experience and interest in MTM program success) interviews to better understand the best practices of Part D MTM program design and implementation, and to help interpret the drivers of outcomes observed in the quantitative analysis. We chose a group of stakeholder organizations with a history of MTM involvement including pharmacists, physicians, and representatives of pharmacy and beneficiary organizations who have studied, designed, or delivered MTM interventions. These interviews served as an important hypothesis-generating activity to determine the range of operations employed by MTM programs and to gauge the relative importance of various MTM interventions or components considered influential by knowledgeable MTM stakeholders.

Finally, we invited MTM representatives from 13 Part D parent organizations for interviews and completed five interviews by the date of this report. We selected this set of organizations based on differences across key variables including rates of CMR delivery, adherence effects, MTM program eligibility, regional location, representation of both MA-PDs and PDPs, and variation in MTM vendors. We investigated the performance of these organizations across measures of drug adherence and quality, resource utilization and cost as reported in our methods. We used this information to develop an interview protocol to explore the range of MTM operations, processes and strategies including those most likely accounting for positive outcomes. A final synthesis and assessment step generated the set of potential strategies, practices and operations used by Part D parent organization's MTM programs to achieve success across key MTM outcome measures.

Summary of Findings

The major findings of this research are summarized as follows:

1. ***MTM programs enrolled Medicare patients with complex medical conditions and high preceding drug and health resource utilization. CMRs were completed for 11-14% of MTM enrollees in the study population and these beneficiaries had more chronic conditions and higher preceding hospital and drug costs than other MTM enrollees when in the PDP, but not MA-PD, setting.***

MTM programs enrolled Part D beneficiaries with more chronic conditions and preceding medication use than the general Medicare population, which is in large part attributable to the MTM eligibility requirements, and CMRs were completed on the most complex MTM enrollees in the PDP setting. The MTM-enrolled population encompassed 13.4% of the overall Part D population with a claims-based diagnosis of CHF, COPD or diabetes, for both PDP and MA-PD plans. PDP and MA-PD plans successfully delivered CMRs to 11% and 14% (respectively) of MTM enrollees.

MTM programs effectively enrolled individuals who had high-risk medication use prior to enrollment.[6] For PDP plans, patients receiving CMRs showed the highest prior use of high-risk medications in the elderly, with 51.5% having one or more high-risk medication prescriptions in the year preceding MTM enrollment (as compared to 34.4% of the chronic condition Part D cohort). MA-PD plans also enrolled more patients in MTM with prior high-risk medication use (40.4%) compared with 28.7% in the chronic condition Part D cohort but patients receiving CMR in MA-PD plans had lower prior high-risk medication use (36.0%) than overall MTM enrollees.

PDP and MA-PD plans enrolled beneficiaries with high rates of preceding hospitalizations. PDP plans delivered CMRs to beneficiaries with slightly higher rates of

preceding hospitalization (38.0%) as compared with all MTM enrollees (36.6%), which was higher than the general Part D cohort with these chronic conditions (27.0%). Patients in MA-PD plans receiving CMR did not have higher rates of preceding hospitalization than MTM enrollees (30.8% and 30.4%), but the rates were higher than in the MA-PD Part D population with these chronic conditions (19.2%).

Part D drug spending in the year prior to enrollment was higher for patients in PDP plans receiving CMR ($7,477) as compared to all PDP MTM enrollees ($5,939). MA-PD plans, however, did not deliver CMRs to enrollees with higher Part D costs in the preceding year; MA-PD MTM enrollees receiving CMR had $4,452 in Part D costs in the year prior compared with $4,595 for all MTM enrollees. These results suggest that PDP plans are recruiting higher-risk MTM enrollees for the CMR intervention while the beneficiaries recruited by MA-PD plans for CMRs are similar to other MA-PD MTM enrollees in terms of risk characteristics. These findings are reported in **Table ES 2** below.

Table ES 2: MTM Effectiveness at Targeting Individuals with Preceding Medication Issues, Hospital and ER Visits, and High Costs

Baseline Period High-risk Characteristics	***Medicare Beneficiaries with CHF, COPD or Diabetes***					
	Enrolled in PDPs			***Enrolled in MA-PDs***		
	All Part D	***MTM Enrollees***	***MTM with CMR***	***All Part D***	***MTM Enrollees***	***MTM with CMR***
N	2,276,205	304,602	32,492	1,455,474	194,488	26,470
Drug Therapy						
Use of at Least One High Risk Medication	34.4%	46.4%	51.5%	28.7%	40.4%	36.0%
Resource Utilization: Hospital and ER visits						
All-cause Hospitalization	27.0%	36.6%	38.0%	19.2%	30.8%	30.4%
All-cause ER visits	29.5%	35.9%	41.8%	---	---	---
Resource Utilization: Medication and costs						
Number of Medications	11.32	16.20	18.51	10.02	14.67	15.26
Part D costs for All Part D Drugs	$3,426.57	$5,939.17	$7,477.25	$2,429.70	$4,595.84	$4,542.43
All-Cause Hospitalization Costs	$4,265.81	$6,428.99	$6,243.12	---	---	---
All-Cause ER Costs	$238.14	$320.73	$395.53	---	---	---

2. ***MTM programs improved medication adherence and quality of prescribing for CHF, COPD and diabetes patients, particularly when CMRs were provided.***

Improvements in drug therapy outcomes from MTM enrollment were robust and persistent for adherence and use of evidence-based medications. Further, these adherence effects were generally larger for beneficiaries receiving CMRs. **Table ES 3**, **Table ES 4**, and **Table ES 5** show that MTM enrollees who received CMRs were more likely to experience increases in medication adherence and improvements in quality of prescribing, suggesting that the annual CMR may be one of the more important components of the MTM program. For example, MTM enrollees with CHF had a higher odds of being adherent to their evidence-based medications than the comparison group and the magnitude of this effect was greater for those who received a CMR compared to those who did not (PDP: OR[a] = 1.28 with CMR and 1.12 without CMR; MA-PD: OR = 1.40 with CMR and 1.11 without CMR). Similarly, CHF beneficiaries had higher rates of initiation on evidence-based medications after MTM, relative to the comparison group (PDP: OR 1.18 without CMR and 1.01 with CMR; MA-PD: OR 1.29 without CMR and 1.28 with CMR). The effects for MTM in beneficiaries with COPD and diabetes were consistent with those described above for enrollees with CHF. These patterns were consistent in both PDPs and MA-PDs.

[a] 'OR' stands for odds ratio, or the ratio of odds of a given outcome occurring in the intervention group to the odds of the same outcome occurring in the comparison group.

Table ES 3: Risk-Adjusted Drug Therapy Outcomes for Individuals with CHF (Odds Ratio with 95% Confidence Interval)

Part D Contract Type	*Cohort*	*N*	*Take-Up of Evidence-Based Medication, OR[a]*	*Adherent to Evidence-Based Medications, OR[a]*
PDPs	Comparison	156,441	N/A	N/A
	MTM without CMR	103,080	1.18* (CI[b]:1.10 to 1.26)	1.12* (CI: 1.08 to 1.15)
	With CMR	12,658	1.01 (CI: 0.88 to 1.26)	1.28* (CI: 1.19 to 1.37)
MA-PDs	Comparison	51,938	N/A	N/A
	MTM without CMR	62,983	1.29* (1.16, 1.44)	1.11* (1.06, 1.16)
	With CMR	11,260	1.36* (CI: 1.09 to 1.71)	1.40* (CI: 1.29 to 1.52)

* Indicates significance at the 5% level.
a. OR = odds ratio
b. CI = confidence interval

Table ES 4: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD (Odds Ratio with 95% Confidence Interval)

Part D Contract Type	*Cohort*	*N*	*Adherent to LABA-Only Regimen, OR[a]*	*Adherent to LAAC-Only Regimen, OR[a]*	*Adherent to LABA and LAACs, OR[a]*
PDP	Comparison	184,350	N/A	N/A	N/A
	MTM without CMR	110,042	1.22* (CI[b]: 1.16, 1.29)	1.14* (CI[b]: 1.05, 1.24)	1.26* (CI[b]: 1.18, 1.35)
	With CMR	16,372	1.26* (1.14, 1.40)	1.36* (CI[b]: 1.12, 1.65)	1.43* (CI[b]: 1.26, 1.62)
MA-PD	Comparison	73,623	N/A	N/A	N/A
	MTM without CMR	64,637	1.06 (CI[b]: 0.98, 1.15)	1.06 (CI[b]: 0.95, 1.18)	1.11* (CI[b]: 1.01, 1.23)
	With CMR	10,575	1.11 (CI[b]: 0.95, 1.29)	1.01 (CI[b]: 0.83, 1.24)	1.20 (CI[b]: 1.00, 1.44)

* Indicates significance at the 5% level.
a. OR = odds ratio
b. CI = confidence interval

Table ES 5: Risk-Adjusted Drug Therapy Outcomes for Individuals with Diabetes (Odds Ratio with 95% CI)

Part D Contract Type	*Comparison or Intervention Group*	*N*	*Adherent to Any Diabetes Drugs, OR[a]*	*Adherent to Biguanides, OR[a]*	*Adherent to DPP-IV Inhibitors OR[a]*	*Adherent to Sulfonylureas, OR[a]*	*Adherent to Thiazolidinediones OR[a]*	*Use of ACE Inhibitors or ARBs OR[a]*	*Use of Statins, OR[a]*
PDP	Comparison	133,925	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	149,803	1.15* (CI[b]: 1.12 to 1.18)	1.12* (CI: 1.09 to 1.15)	1.14* (CI: 1.06 to 1.21)	1.09* (CI: 1.06 to 1.12)	1.12* (CI: 1.07 to 1.16)	1.03 (CI: 0.99 to 1.07)	1.10* (1.05 to 1.16)
	MTM with CMR	16,545	1.33* (CI: 1.25 to 1.41)	1.27* (CI: 1.19 to 1.36)	1.32* (CI: 1.12 to 1.55)	1.22* (CI: 1.13 to 1.31)	1.31* (CI: 1.19 to 1.45)	0.99 (CI: 0.90 to 1.08)	1.01 (CI: 0.91 to 1.13)
MA-PD	Comparison	53,912	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	95,299	1.17* (CI: 1.13 to 1.21)	1.11* (CI: 1.07 to 1.15)	1.19* (CI: 1.07 to 1.31)	1.08* (CI: 1.04 to 1.13)	1.09* (CI: 1.03 to 1.15)	1.07* (CI: 1.01 to 1.12)	1.12* (CI: 1.05 to 1.20)
	MTM with CMR	13,527	1.35* (CI: 1.27 to 1.45)	1.20* (CI: 1.12 to 1.29)	1.19 (CI: 0.96 to 1.48)	1.28* (CI: 1.19 to 1.38)	1.16* (CI: 1.04 to 1.29)	1.24* (CI: 1.12 to 1.38)	1.33* (CI: 1.16 to 1.52)

* Indicates significance at the 5% level.
a. OR = odds ratio
b. CI = confidence interval

3. ***MTM programs initially improved the safety of drugs prescribed in new enrollees (first 6 months) but these positive effects had diminished or reversed by 1 year after enrollment.***

Patients newly enrolled in MTM programs showed improvements in the safety of their prescribed medications at 6 months that had dissipated by 12 months after enrollment. These results were found for MTM enrollees in both PDP and MA-PD plans and are detailed in **Table ES 6** for patients with CHF. This finding was consistent for all disease cohorts evaluated (CHF and COPD). At 6 months, MTM enrollees in PDP plans were more likely to have had their high-risk medications discontinued compared with the comparison group; however, these effects had disappeared at the 12-month follow-up. There were also trends towards significant improvements at 6 months for the removal of drug-drug interactions that were not apparent at 12 months in MTM enrollees in PDP plans. Similarly, MTM enrollees in MA-PD plans were more likely to have drug-drug interactions resolved, high-risk medications discontinued (at least for those receiving CMRs), and contraindicated medications discontinued than the comparison group at 6 months after enrollment. From these outcomes, the only one still showing improvement at 12 months was discontinuation of contraindicated medications for CHF. The drug safety outcomes comparison at 6 and 12 months for beneficiaries with COPD were similar to those described above for CHF patients.

The Part D parent organization interviews elucidated specific practices potentially associated with drug safety outcomes lasting beyond 6 months. Organization F, whose MTM program enrollees showed positive effects for drug safety outcomes at 12 months, indicated that it evaluated patient medication lists and documented recommendations to remove drug-drug interactions and high-risk medications. Organization F also indicated that they tracked and documented prescriber compliance with these recommendations.

In general, the initial improvements in the safety of drug regimens may have been diminished over time due, for example, to the extended opportunity at 12 months for prescribers to add back previously discontinued medications. However, this study did not assess whether patients were re-prescribed previously discontinued medication or if the individual's use of medications was appropriate. Despite the diminished effects for these outcomes at 12 months, it appears that MTM programs had positive effects at 6 months on the safety of prescribed regimens for new enrollees, and some organizations' programs had positive effects at 12 months. Future analyses could address whether multiple CMRs (CMS requires at least one annually) or other reinforcing interventions, such as the TMR, are more effective in improving outcomes over time or if a longer observation period than one year is necessary to observe sustained outcomes.

Table ES 6: Drug Safety Outcomes at 6 and 12 Months after MTM Enrollment in Individuals with CHF

Part D Contract Type	*Comparison or Intervention Group*	*6 Months*			*12 Months*		
		Remove Drug-Drug Interactions	*Discontinue High-Risk Medication Use*	*Discontinue Contraindicated Medications*	*Remove Drug-Drug Interactions*	*Discontinue High-Risk Medication Use*	*Discontinue Contraindicated Medications*
PDP	Comparison	N/A	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	1.05 (CI[a]: 0.99 to 1.12)	1.04* (CI: 1.01 to 1.07)	0.88* (CI: .85, .91)	0.96 (CI: 0.90 to 1.02)	0.98 (CI: 0.95 to 1.00)	0.81* (CI: 0.78 to 0.84)
	With CMR	0.95 (CI: 0.82 to 1.11)	1.04 (CI: 0.97 to 1.11)	0.64* (CI: 0.60, .69)	0.87 (CI: 0.76 to 1.00)	1.04 (CI: 0.97 to 1.11)	0.63* (CI: 0.58 to 0.67)
MA-PD	Comparison	N/A	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	1.14* (CI: 1.02 to 1.27)	0.95* (CI: 0.91 to 1.0)	1.11* (CI: 1.04, 1.18)	1.01 (CI: 0.91 to 1.11)	0.88* (CI: 0.84 to 0.92)	1.09* (CI: 1.02 to 1.16)
	With CMR	1.12 (CI: 0.92 to 1.36)	1.18* (CI: 1.0 to, 1.29)	1.14* (CI: 1.0, 1.30)	1.05 (CI: 0.88 to 1.26)	0.93 (CI: 0.86 to 1.01)	1.16* (CI: 1.03 to 1.30)

* Indicates significance at the 5% level.
a. CI = confidence interval

4. ***MTM programs decreased hospital utilization and costs in diabetes and CHF patients receiving CMRs but not in COPD patients.***

We found that the effect of MTM programs on enrollees' hospital/ER visits and costs varied by disease cohort and CMR receipt. Beneficiaries with CHF and diabetes newly enrolled in MTM consistently had lower risks of hospitalizations and ER visits when receiving CMRs, particularly in the PDP setting (see **Table ES 7** for CHF and **Table ES 8** for diabetes). For example, CHF patients in PDP plans receiving CMRs had lower odds of hospitalization compared with controls (OR: 0.90, 95% CI: 0.86 to 0.94), and this was associated with per-patient hospital cost savings of $526 for the year (95% CI: -$919 to -$133). Similarly, diabetes patients receiving CMRs also had lower odds of hospitalization compared with controls (OR: 0.91, 95% CI: 0.87 to 0.95), with per-patient hospital cost savings of $399 for the year (95% CI: -$651 to -$146). Savings in hospital costs were found only for CHF and diabetes patients receiving CMRs. Patients with COPD did not experience significant cost savings with or without CMR (**Table ES 9**) even though MTM programs did increase adherence to long-acting maintenance drug therapies for COPD. MTM programs were also often associated with decreased ER utilization and costs but with relatively small per patient cost savings as compared to hospital effects. These results suggest that the effects of MTM intervention on health service costs differ by disease cohort or intervention design.

Respondents from the interviewed Part D parent organizations that decreased hospital costs in the quantitative analysis reported that the effect was most likely due to: (i) decreased use of harmful, duplicated or contraindicated medications which prevented future medical complications and adverse events, (ii) increased identification of gaps or problems in medical care, particularly through use of electronic medical records, and (iii) referrals or contact with prescribers for patients actively experiencing drug or medical issues.

MTM programs on average increased Part D costs by $75-181 per patient across all cohorts in the year after enrollment, which may be attributable to improved adherence or other positive drug therapy outcomes. They did not appear to affect the substitution of brand-name drugs for generic equivalents. However, two out of eight Part D parent organizations were notably able to maintain or lower Part D drug costs while improving adherence to evidence-based medications. When one of these organizations (Organization F) was interviewed, the respondents identified several important factors driving these effects from their MTM: (i) a focus on addressing patients' cost barriers to adherence by suggesting lower-cost equivalent options to patients and prescribers, (ii) the inclusion of MTM components focused on identifying cost avoidance opportunities, and (iii) established care coordination (i.e., working relationship)

between the MTM pharmacist and prescribers. The organizations lowering Part D costs were MA-PD plans with integrated health systems and electronic medical records.

We could not conclusively determine why MTM participation among COPD patients improved adherence to evidence-based medications for COPD but did not decrease resource utilization and costs. While long-acting bronchodilator medications have been shown to reduce acute COPD exacerbations and hospitalizations in randomized-controlled trials,[14-16] it is possible that symptoms among patients in the COPD cohort were less easily controlled by such medications in practice.

Table ES 7: Risk-Adjusted Resource Utilization and Cost Outcomes for Individuals with CHF[a] (Odds Ratio or Mean Costs with 95% CI)

Part D Contract Type	*Comparison or Intervention Group*	*N*	*All-Cause Hospitalizations (OR)*	*All-cause ER Visit (OR)*	*Part D Total Drug Costs ($)*	*All-Cause Hospitalization Costs ($)*	*All-Cause ER Costs ($)*
PDP	Comparison	156,441	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	103,080	0.98 * (CI[b]: 0.96 to 1.0)	0.94 * (CI: 0.92 to 0.96)	$156 * (CI: $123 to $189)	$38 (CI: -$141 to $215)	-$11 * (CI: -$20 to -$2)
	With CMR	12,658	0.90 * (CI: 0.86 to 0.94)	0.94 * (CI: 0.90 to 0.98)	$87 * (CI: $7 to $167)	-$526* (CI: -$920 to -$132)	-$13 (CI: -$33 to $8)
MA-PD	Comparison	51,938	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	62,893	1.06 * (CI: 1.03 to 1.09)	N/A	$75* (CI: $27 to $122)	N/A	N/A
	With CMR	11,260	0.96 (CI: 0.91 to 1.02)	N/A	$140* (CI: $56 to $225)	N/A	N/A

* Indicates significance at the 95% confidence level.
a. Emergency room outcomes and hospital costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
b. CI = confidence interval

Table ES 8: Risk-Adjusted Resource Utilization and Cost Outcomes for Individuals with Diabetes (Odds Ratio or Mean Costs with 95% CI)

Part D Contract Type	*Comparison or Intervention Group*	*N*	*All-Cause Hospitalization (Odds Ratio)*	*All-Cause ER Visit (Odds Ratio)*	*Part D Total Non-Diabetes Drug Costs ($)*	*All-Cause Hospitalization Costs ($)*[a]	*All-Cause ER Costs ($)*[a]
PDP	Comparison	133,925	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	149,803	0.97 * (CI[b]: 0.98 to 0.99)	0.96 * (CI: 0.94, 0.98)	$181* (CI: $155 to $206)	$24 (CI: -$98 to $146)	-$13* (CI: -$19 to -$7)
	MTM with CMR	16,545	0.91* (CI: 0.87 to 0.95)	0.91* (CI: 0.87 to 0.96)	$110* (CI: $50 to $169)	-$399* (CI: -$651 to -$147)	-$9 (CI: -$24 to $6)
MA-PD	Comparison	53,912	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	95,299	1.02 (CI: 0.99 to 1.05)	1.01 (CI: 0.98 to 1.04)	$140* (CI: $110 to $170)	N/A	N/A
	MTM with CMR	13,527	0.93* (CI: 0.88 to 0.98)	0.92* (CI: 0.87 to 0.97)	$174* (CI: $118 to $229)	N/A	N/A

* Indicates significance at the 95% confidence level.

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

b. CI = confidence interval

Table ES 9: Risk-Adjusted Resource Utilization and Cost Outcomes for Individuals with COPD (Odds Ratio or Mean Costs with 95% CI)

Part D Contract Type	*Comparison or Intervention Group*	*N*	*All-Cause Hospitalization (Odds Ratio)*	*All-Cause ER Visit (Odds Ratio)*	*Part D Total Non-Diabetes Drug Costs ($)*	*All-Cause Hospitalization Costs ($)[a]*	*All-Cause ER Costs ($)[a]*
PDP	Comparison	184,350	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	110,042	0.98 (CI[b]: 0.96 to 1.00)	0.96 * (CI: 0.94 to 0.97)	$106* (CI: $74 to $138)	$72 (CI: -$87 to $231)	-$11* (CI: -$20 to -$2)
	MTM with CMR	16,372	0.90* (CI: 0.87 to 0.94)	0.89* (CI: 0.86 to 0.93)	$43 (CI: -$28 to $113)	-$250 (CI: -$574 to $75)	-$16 (CI: -$35 to $3)
MA-PD	Comparison	73,623	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	64,637	1.07* (CI: 1.05 to 1.10)	N/A	$97* (CI: $57 to $138)	N/A	N/A
	MTM with CMR	10,575	0.96 (CI: 0.91 to 1.01)	N/A	$95* (CI: $19 to $172)	N/A	N/A

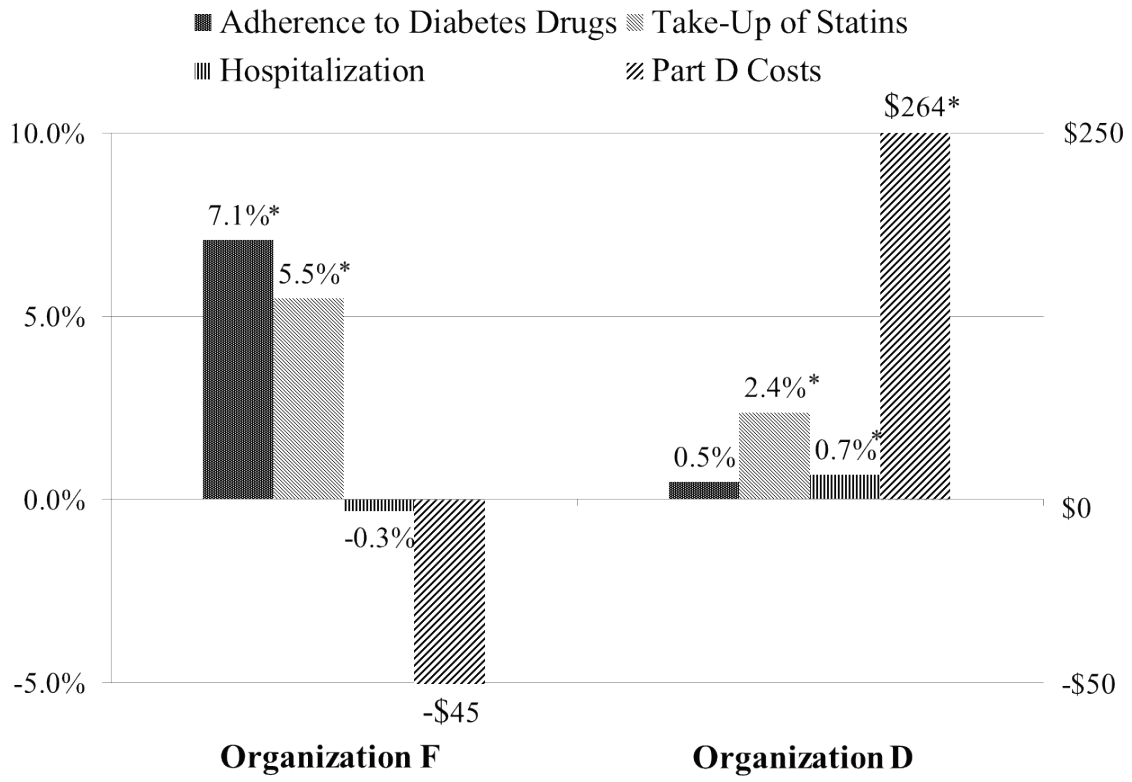
* Indicates significance at the 95% confidence level.
a. Emergency room outcomes and hospital costs were only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
b. CI = confidence interval

5. ***There was substantial variation in outcomes among Part D parent organizations. The best-performing Part D organizations were able to improve medication adherence and quality of prescribing while keeping health care costs (including drugs) from rising.***

Part D parent organizations providing MTM services were associated with a wide variation in outcomes. Using the difference-in-differences estimator approach, we compared outcomes across a set of 5 PDP plans and 8 MA-PD plans. **Figure ES 1** illustrates the variations we observed in outcomes for diabetes patients across the 8 MA-PD plans by providing an example of the differences in effects of receiving MTM with CMRs from two of the organizations. Both Organization F and D had high rates of CMR receipt for MTM enrollees (and large sample sizes). Organization F showed significant improvements in diabetes medication adherence and up-take of statin medications with very strong effect sizes (7.1% average increase in the proportion of days covered [PDC] and 5.5% uptake in statins) whereas Organization D showed little effect on adherence (0.5% average increase in PDC) and a much smaller up-take of statins (2.4%). Diabetes patients in Organization F were associated with a 0.3% decrease in hospitalizations, while those in Organization D were associated with a 0.7% increase (analysis of claims for MA-PDs did not allow calculation of hospital costs). Further, Part D costs decreased by an average of $45 for Organization F patients but increased by $264 for Organization D patients. It is notable that MTM enrollees in Organization F (and several other organizations) did not experience year-over-year Part D cost increases (and some experienced cost savings), which contrasts with the overall growth in average Part D costs demonstrated over time in the aggregate results for Medicare beneficiaries receiving MTM interventions.

Organization F, the higher performing organization in our comparison example, was interviewed as part of our qualitative analysis. The organization's key practices for increasing medication adherence and uptake of evidence-based medications, and keeping Part D costs down are incorporated into the profile of a high-performing MTM program outlined later in item 7. These key practices for this organization included focusing on generics and reducing cost of medications by recognizing patient's financial barriers to adherence, and providing extensive patient education and monitoring of drug regimen quality outcomes. These, along with other practices, are described below.

Figure ES 1: Change in Outcomes for MTM Enrollees with Diabetes in a High Performing (Org F) and Low Performing (Org D) Part D Plan



*Statistically significant at 5% level

6. ***MTM programs appeared to improve enrollees' adherence to drug therapies for targeted chronic medical conditions, but have smaller effects on patient adherence to therapies for non-targeted conditions.***

MTM programs significantly and consistently improved adherence to drug therapies for all medical conditions targeted by MTM programs. However, there were notable differences in the significance and strength of outcomes across disease cohorts within the same Part D parent organizations in the quantitative analysis. Some of these differences, such as for resource use and cost outcomes, can likely be attributed to the medical condition itself and the effectiveness of drug therapies to improve health outcomes (item 4 above). Some of these differences, such as for resource use and cost outcomes, can likely be attributed to the medical condition itself and the effectiveness of drug therapies to improve health outcomes (item 4 above). We observed substantial improvement in medication adherence for MTM enrollees receiving CMRs across all conditions, suggesting that CMR interventions broadly improved medication adherence.

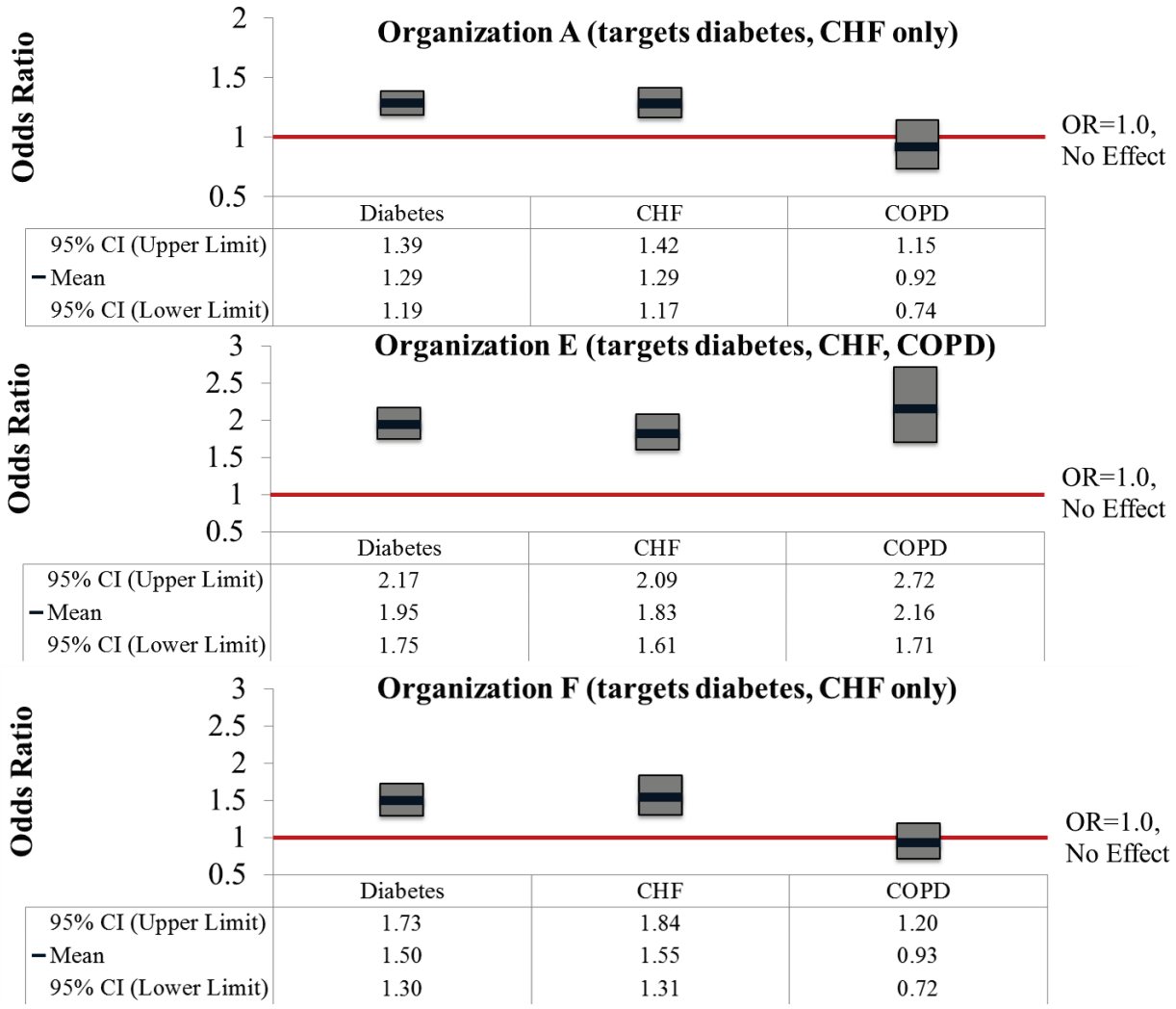
However, our results also suggest that effects of MTM interventions varied by whether the MTM program targeted the chronic condition being treated by the medication or not (see **Figure ES 2**). We observed the greatest improvements in adherence for medications used to treat conditions targeted by MTM programs, with smaller spillover effects on adherence to other medications treating non-targeted conditions.

We have evidence from two analyses supporting the finding of greater adherence effects for drug treatments addressing MTM targeted medical conditions. First, there were multiple overall high-performing Part D parent organizations in the quantitative analysis demonstrating this finding (as shown for Organization A and F in **Figure ES 2** below). Organization F strongly influenced outcomes for CHF and diabetes – both drug therapy and resource utilization– but had no effect on adherence or resource use for COPD patients. During the Part D parent organization interview with Organization F, we learned that this organization did not target patients with COPD during the 2010 enrollment year but did target patients with CHF and diabetes. This differential effect on outcomes was also noted for Organization A, and also supported by our interview with representatives from Organization A who noted that they also did not target patients with COPD in 2010. **Figure ES 2** reports the adherence results for these organizations demonstrating the strong effects on MTM-targeted conditions (CHF and diabetes) and the complete lack of effect on COPD medications. It thus appears that targeting high-risk patients primarily affects adherence to therapies for targeted conditions as opposed to all chronic medications taken by MTM enrollees.

Second, we performed regression analyses for an alternative cohort of COPD patients enrolled in MTM programs to further assess this finding. In the main analysis, we analyzed patients with COPD from all available Part D contracts regardless of whether the contracts targeted COPD as a condition for patient eligibility. However, since only 52% of Part D contracts in 2010 used COPD as a condition for eligibility, we also performed an analysis including only COPD patients enrolled in Part D plans actually targeting COPD. As expected, we observed higher odds of adherence to all assessed medications for COPD patients enrolled in Part D plans targeting COPD in 2010 (the detailed results are reported in **Section 8.4**.). For example, the odds ratio for adherence to long-acting beta-adrenergics (LABAs) in MA-PD patients receiving CMRs rises from 1.11 in all Part D contracts to 1.31 in COPD-targeting contracts (and becomes statistically significant). Similarly, the odds ratio for adherence to the combination regimen of LABA and long-acting anticholinergics (LAACs) increased from 1.20 for all COPD patients to 1.35 for COPD patients enrolled in MTM programs targeting COPD. These results indicate that larger improvements in outcomes, particularly adherence, are achieved for regimens treating medical conditions targeted by MTM programs as opposed to improvements in the same regimens for patients enrolled in MTM programs not targeting these

conditions. However, MTM is intended to be a comprehensive approach to medication management, not condition-specific disease management. Diseases should be utilized for targeting, but not to drive intervention design. Notably, as our study was not specifically designed to determine whether disease targeting itself improved beneficiary outcomes, we were limited in our ability to show whether the observed relationship between condition targeting and adherence was causal or associational.

Figure ES 2: Disease-Specific Adherence Effects for Part D Organizations



	Diabetes	CHF	COPD
95% CI (Upper Limit)	1.39	1.42	1.15
Mean	1.29	1.29	0.92
95% CI (Lower Limit)	1.19	1.17	0.74

	Diabetes	CHF	COPD
95% CI (Upper Limit)	2.17	2.09	2.72
Mean	1.95	1.83	2.16
95% CI (Lower Limit)	1.75	1.61	1.71

	Diabetes	CHF	COPD
95% CI (Upper Limit)	1.73	1.84	1.20
Mean	1.50	1.55	0.93
95% CI (Lower Limit)	1.30	1.31	0.72

7. ***Based on interview responses of high-performing Part D parent organizations, we identified the profile of an effective MTM program to include the following practices:***

(i) Establishing proactive and persistent CMR recruitment efforts

(ii) Targeting and aggressively recruiting patients to complete a CMR based on information on medical events such as recent a hospital discharge in addition to scanning for the usual MTM eligibility criteria

(iii) Coordinating care by utilizing trusted community relationships including networks of community pharmacists to recruit MTM eligible candidates, and utilizing existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients

(iv) Employing intensive patient education efforts aimed at addressing adherence barriers including a comprehensive understanding of the importance of each medication prescribed

(v) Documenting the opportunities that were addressed with the patient for switching to generics or formulary alternatives

(vi) Improving drug adherence by providing a complete list of prescribed medicines

(vii) Addressing financial barriers to adherence such as high drug costs by potentially switching to generics or less expensive formulary alternatives

(viii) Documenting the quality and safety of prescribing as part of the MTM intervention record (e.g. ACEi/ARBs in CHF and diabetes, cardio-selective beta-blockers in CHF, drug-drug interactions, high-risk medications)

(ix) Conducting follow-up, documentation, and resolution of any identified drug safety issues

(x) Using efficient communication methods to convey medication recommendations to prescribers including the use of e-prescribing and electronic medical records

(xi) Leveraging all available data sources (EHR, registries, claims data) to determine whether gaps in medical care are present including preventive care and maintenance care related to the patient's specific medical conditions (e.g. HbA1c and screening for kidney damage in diabetes patients).

Comments

This research used a mixed methods approach to investigate whether and how MTM programs improve health outcomes for Medicare beneficiary with chronic conditions, and found that MTM programs consistently and substantially improved medication adherence and quality of prescribing for evidence-based medications for CHF, COPD and diabetes. Moreover, the effects were strongest among patients receiving CMRs. We also found that there is substantial variation in performance among the Part D parent organizations, but that high-performing MTM programs not only improved drug therapy outcomes but also maintained or lowered rates of hospitalizations, ER visits, and associated costs.

Through our interviews with stakeholders and representatives of Part D parent organizations, we further identified components and strategies used in MTM interventions that appeared to account for the differences in findings across organizations. First, high-performing organizations engaged in multi-pronged, persistent efforts to recruit Medicare beneficiaries to CMRs and often used effective and diverse communication modalities such as person-to-person interactions, phone calls, or community contacts (through trusted community pharmacists), if needed. Many successful organizations targeted high-risk populations for MTM enrollment and CMR completion through data assessment tools such as electronic medical records and e-prescribing systems. Organizations achieving improvements in prescribing quality explicitly focused on and recorded these assessments as part of their MTM documentation. The same was true for organizations that successfully lowered Part D costs and improved the use of generics by targeting and measuring outcomes, and documenting results.

Our research findings have important implications for CMS. First, they demonstrate that MTM programs can achieve substantial and sustained improvements in adherence and quality of prescribing. MTM stakeholders who were interviewed as part of this research certainly believed in MTM program's ability to improve adherence, but comprehensive quantitative evidence of sustained adherence effects had been weak (see **Section 2.1**). In addition to adherence, MTM programs can also improve quality of drug prescribing (the use of evidence-based drug therapies) by specifically measuring the results of these assessments as part of the MTM intervention. Interviews with representatives of Part D organizations also suggested that another factor positively influencing prescribing quality was a trusted working relationship between pharmacists and prescribers and coordination of care, which can be mediated through communication tools such as in integrated health information systems.

Second, the wide variation in Part D parent organization performance on hospital and ER costs, along with the existence of several organizations that were able to lower resource utilization among MTM enrollees present potential opportunities for improving Medicare

beneficiary outcomes. The existence of organizations that positively influenced medical and drug cost outcomes (including preventing expected cost growth) suggests substantial Medicare benefits may be possible from further investigations on how this was accomplished. The research, identification, and dissemination of any identified operational or strategic factors of MTM programs that drive these improvements could improve health outcomes for the Medicare population and positively affect Medicare beneficiary costs.

Third, our analysis provides pertinent information for additional investigations on successful MTM practices including factors such as the targeting of patients with specific disease conditions and effective enrollment strategies. This includes information on: (i) how MTM programs in 2010 targeted and/or prioritized medical conditions and (ii) understanding which patients are most likely to respond positively to MTM interventions. Targeting patients with specific chronic diseases as well as using intervention components targeted at specific drug quality or safety issues appeared to improve patient outcomes. This suggests that CMS guidance on medical conditions for MTM programs could ensure that conditions with the greatest benefit from MTM are prioritized by Part D sponsors. Understanding that MTM resources are limited, and that optimizing adherence to medication therapies for different chronic conditions likely achieves differing levels of medical cost savings, CMS could compare analytic results on the health and cost outcomes of achieving optimal adherence across chronic conditions to help guide and prioritize MTM targeting of Medicare beneficiaries.

The results in this report are limited by several factors. First, we conducted a retrospective data analysis - a method that can be subject to selection bias and confounding from unobserved variables. For example, beneficiaries self-selecting into MTM could influence the results if we were unable to control for these factors with our methodology. Reassuringly, the comparison of MTM enrollees and their control cohort does not suggest substantive differences in demographic and health characteristics between the two groups. Since the comparison group consisted of beneficiaries who were also eligible for MTM according to criteria set out by CMS other than the ones that they were enrolled in, they were very similar to the MTM enrollees in our intervention group. Further, the concern for selection bias could also apply to the MTM with CMR intervention group. This could introduce a confounding "healthy user effect," which refers to individuals' health-preserving behavioral tendencies that globally affect health-promoting or risk-reducing activities (including CMR acceptance). If the healthy user effect was present, those who opted to receive CMRs as part of their MTM programs may have been more likely to engage in other activities to stay healthy which could confound our results.

Second, our research evaluates outcomes only for the first year after MTM program enrollment. The timeline for improved health outcomes such as reduced complications and lower health resource utilization from participating in MTM programs may take longer than a

year to accrue, and only after adherence has improved for some conditions or types of patients. It would be expected that increased adherence to drug treatments for certain diseases, such as diabetes, would take longer than one year to influence health outcomes (given the long time-course for patients with diabetes to develop long-term complications from hyperglycemia). Longer outcome periods for observing health and resource utilization outcomes could thus be considered in future research designs.

Third, limitations in the MTM program data may have biased our estimates, and also produced lower estimates of improvements in some cases. As confirmed by our stakeholder and Part D organization interviews, MTM programs also enroll beneficiaries not meeting Medicare's eligibility guidelines and were not required to report these enrollees to CMS for 2010 (e.g., one organization indicated that they offered MTM with CMR to 25-30% of all Part D patients and TMR-like interventions to another 30%, yet reported only the 5-10% of their MTM enrollees to CMS who met the specified targeting criteria per CMS Part D requirements). This analysis thus does not account for Medicare beneficiaries who were enrolled in MTM by their health plan despite the fact that they did not meet CMS requirements for eligibility. As a result, some members of the comparison group may have received MTM services despite the fact that they did not meet CMS eligibility requirements and were unidentifiable in our data.

Lastly, some of the interviewed Part D organizations had small sample sizes for quantitative data analysis with potentially inadequate power. These results based on small samples should be interpreted cautiously when no effects are reported. In the setting of inadequate power, a lack of statistically significant effect should not be misinterpreted as ruling out a true effect as we may simply not have had enough power with available sample sizes to detect it.

The investigation of MTM effects and their effective components should be further investigated, specifically for other chronic condition cohorts. Additionally, improved data detailing which specific interventions were delivered by MTM programs to Medicare beneficiaries would allow for a more refined quantitative analysis of MTM program effects by intervention. Research would further benefit from data on factors traditionally unobserved, such as the impact of organization structure, specific MTM delivery mechanisms, frequency of MTM, and TMR on health outcomes. Improved and accurate data on these MTM characteristics would allow more sophisticated quantitative data analysis at the level of interventions delivered. For example, more detailed data on care coordination could be used to explore whether care coordination explains the different outcomes observed for MA-PD versus PDP MTM programs.

In summary, this research contributes to the MTM knowledge base by estimating the benefits of MTM for Medicare beneficiaries with COPD, CHF and diabetes, describing the patients who benefited the most from MTM, and outlining which MTM practices are most promising for achieving these positive outcomes. MTM programs are an effective tool for improving the health of complex Medicare beneficiaries through sustained medication adherence and quality of prescribing. Our research shows that drug safety improvements as a result of MTM programs were initially present but appeared fleeting over a longer period of time. MTM programs also appear able to reduce health service costs, although these effects varied across organizations and disease states. More research is needed regarding the mechanisms accounting for the positive health effects achieved by the high-performing MTM programs of Part D organizations.

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1 INTRODUCTION

Acumen, LLC and its partner, Westat, Inc., were contracted by the Centers for Medicare & Medicaid Services (CMS) to conduct a mixed methods study on the impact of medication therapy management (MTM) programs in the Medicare Part D population, focusing on chronically ill populations with strong clinical incentive to maintain drug therapy. In particular, this study focused on high-risk, high-cost beneficiary populations with congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes who stand to benefit significantly from MTM services.

This Final Report summarizes the results of the mixed methods research conducted by Acumen and Westat. It provides information on the effects of MTM on Medicare beneficiaries diagnosed with CHF, COPD and diabetes in 2010. This report also describes mechanisms by which MTM programs may be most effective, and describes the strategies identified in Medicare Prescription Drug Benefit Program (Part D) parent organizations that positively influenced outcomes in their MTM populations.

The remainder of the main report is organized into nine sections. These sections are as follows:

- **Section 2**: Background information on MTM programs
- **Section 3**: Methods for evaluating the impact of MTM programs on outcomes
- **Section 4**: Results for beneficiaries diagnosed with CHF
- **Section 5**: Results for beneficiaries diagnosed with COPD
- **Section 6**: Results for beneficiaries diagnosed with diabetes
- **Section 7**: Findings from stakeholder interviews on MTM practices
- **Section 8**: Results from additional exploratory analyses
- **Section 9**: Synthesis of Part D organization interview findings and quantitative results
- **Section 10**: Discussion of research findings and their implications for CMS.

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.[17] 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.[12,13] 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.[12] 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,[12] 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.[6] 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.[7-9] 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,[10,11] 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) 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'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%.[10] 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.[18] 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.[11] 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.[19] A few other studies conducted outside of the Medicare context reported similar findings, as described in the 2008 Abt Associates report to CMS.[20]

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.[21] 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.[21] 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.[a]

[a] 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.

To promote MTM program consistency starting in program year 2010, CMS outlined stricter guidelines for three requirement categories. They are as follows:[22]

- 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.[22] MTM program

[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.

sponsors were required to provide 2010 information to CMS by February 2011. These data undergo data validation.

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, two-thirds of plans required beneficiaries to have filled at least 8 Part D drugs for beneficiary inclusion in an MTM program. However, a third of plans also targeted beneficiaries who filled fewer Part D covered drugs; the minimum fill requirements for these plans ranged from 2-8 drugs. 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 with written summaries, the content of these reviews varies greatly. CMRs range from providing beneficiaries with basic educational materials to providing concrete, personalized action plans.[22]

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.[11] 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 better addresses 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 purely qualitative 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.[20]

To address these gaps in the understanding of MTM programs, CMS contracted Acumen, partnered with Westat, to build on Abt's previous research. Acumen aimed to identify the impact of Part D MTM programs on Medicare beneficiaries' drug therapies and resource utilization, including hospital and ER visits, while Westat led a complimentary qualitative analysis of promising MTM practices which were most associated with positive effects. We focused on beneficiaries with costly and complex chronic conditions of congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes because they stand to benefit significantly from MTM interventions and their health outcomes are potentially affected even within one year of MTM enrollment.

3 METHODS

We applied a mixed-methods approach to investigate how enrollment in a PDP or MA-PD MTM program influenced outcomes among beneficiaries with CHF, COPD, or diabetes, and to understand how MTM implementation influenced these outcomes. To begin, we performed a retrospective cohort study to investigate the effects of MTM. Next, we used qualitative methods to investigate the potential mechanisms by which MTM could be operating to achieve the observed effects, and to understand the MTM implementation strategies of high-performing Part D parent organizations. To complete our analysis, we synthesized these quantitative and qualitative findings to highlight the Part D parent organization practices that appeared to be associated with positive MTM effects.

The following section provides a logic model illustrating the process by which MTM interventions lead to hypothesized improvement in health and cost outcomes; the quantitative and qualitative methods were built upon the framework of this logic model and are described in the subsequent sections. **Section 3.1** presents the logic model. **Section 3.2** is dedicated to our quantitative methods and is broken into five parts: **Subsection 3.2.1** describes the MTM intervention group selection for the retrospective cohort study, while **Subsection 3.2.2** details the MTM comparison group selection used for our primary analysis technique of OLS regression. Next, **Subsection 3.2.3** describes our outcome measures, and **3.2.4** explains the empirical specifications of this analysis technique. **Subsection 3.2.5** then discusses the subpopulation analyses of Part D parent organizations. **Section 3.3** lists the methods used for our five additional quantitative analyses. **Subsection 3.3.1** describes our methods for comparing the effects of MTM on CHF and COPD at six and twelve months. **Subsection 3.3.2** then explains our analysis of MTM effectiveness in targeting Medicare beneficiaries with drug therapy issues and high resource utilization. After this, **Subsection 3.3.3** explains the methods for the difference-in-differences (DiD) sensitivity analysis. Finally, **Subsection 3.3.4** explores the effectiveness of chronic condition targeting. After this description of the quantitative methods, we outline our qualitative methods in **Section 3.4**, which is broken into two parts: **Subsection 3.4.1** explains the approach to key stakeholder interviews, while **Subsection 3.4.2** discusses selection of Part D Parent Organizations. Finally, **Section 3.5** describes our synthesis of quantitative and qualitative findings to identify best practices for MTM.

3.1 Conceptual Logic Model

The logic model in **Table 3-1** illustrates the process by which potential MTM program interventions may lead to improvements in drug therapy, patient health outcomes, and ultimately health care resource utilization. **Table 3-1** starts by listing potential MTM interventions in the left-hand column. These interventions would be expected to show first-order effects on drug regimen as indicated in the column directly to the right on Intermediate Drug Therapy Outcomes and includes adherence and improvements in the quality of prescribed regimens. These changes in drug regimens for chronic conditions would then be expected to have second-order health effects on patient outcomes and those are described in the column under heading Health Outcomes. Lastly, potential improvements in resource utilization and cost from improved patient health outcomes are indicated under the column heading Resource Use and Cost Outcomes. From this understanding of potential MTM program benefits, relevant definitions in the data for capturing these drug therapy, health resource use and cost outcomes were determined and evaluated in the quantitative data analysis.

Table 3-1: Conceptual Logical Model by MTM Intervention Type

1. Potential MTM Interventions	*2. Intermediate Drug Therapy Outcomes*	*3. Health Outcomes*	*4. Resource Use and Cost Outcomes*
• Provision of health education and medication adherence counseling • Communication with patient's prescriber (e.g., physician) • Identification and discontinuation of contraindicated or high-risk medications • Identification of evidence-based or highly effective therapies not yet prescribed for conditions • Addressing barriers to adherence such as high drug costs	• Improvements in medication adherence • Removal of drug duplications • Removal of drug-drug interactions • Removal of high-risk medications • Removal of medications contraindicated for patient's health condition(s) • Addition of evidence-based medications to drug regimen • Replacement of brand-name medications with generic equivalents	• Improvements in management of chronic conditions • Reduced adverse events related to drugs • Reduced medical complications related to poorly managed chronic conditions	• Reduction in hospitalizations • Reduction in ER visits • Higher use of generics or less costly formulary alternatives • Reduction in drug costs • Reduction in hospital costs • Reduction in ER-related costs

3.2 Main Quantitative Method

In the first phase of the analysis we conducted a retrospective cohort study to compare drug therapy and resource utilization outcomes across a one-year study period for beneficiaries newly enrolled in MTM in 2010 against outcomes experienced by a comparison group. Interim results were measured six months in (reported in **Appendix C**), and final results were measured at the end of the twelve-month study period (reported in Chapters 4, 5, and 6). For this phase, we analyzed MTM recipients and a comparison group using OLS regression. We assessed both all-cause and disease-specific outcomes because MTM programs provide general medication use recommendations for beneficiaries with multiple chronic conditions and therefore have potential to impact CHF, COPD, and diabetes-specific outcomes as well as outcomes related to management of other conditions. To examine the impact of MTM intervention components on beneficiary outcomes, we stratified our primary results by whether or not participants received CMR, and we performed subpopulation analyses comparing the outcomes of beneficiaries in specific large Part D parent organizations. Finally, we tested the sensitivity of our primary OLS regression analysis, using a difference-in-differences (DID) approach.

3.2.1 MTM Intervention Groups

Our initial MTM population included Medicare Part D beneficiaries who were newly enrolled[a] in a Part D MTM program in 2010 (Acumen verified that new MTM enrollees were not enrolled in any Part D contract MTM program in 2009). We included only individuals with a claims-based diagnosis of CHF, COPD, or diabetes in 2009. We identified CHF and COPD using the Part D Hierarchical Condition Categories (RxHCCs)[b] and defined diabetes as at least two fills of oral diabetes medications with no insulin claims during the observation period. Beneficiaries were considered as 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.[c,23] Beneficiaries were also excluded if they resided in a long-term institution for over 90 days in 2010, as MTM programs were not required to offer CMR to these beneficiaries prior to 2013 (beginning in 2013, long-term care settings are no longer exempt from the CMR requirement.)

[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. National Drug Code (NDC) lists were used to identify oral diabetes medications.

[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.

MTM enrollees who were enrolled in standalone Prescription Drug Plans (PDPs) or Medicare Advantage plans (MA-PDs) that submitted MTM eligibility and participation data which did not pass data validation[a] were excluded. Finally, to be assigned to an intervention group, beneficiaries were required to be continuously enrolled in the same Part D contract during the entire study period: for the six-month outcomes the study period was 180 days and for the twelve month outcomes was 365 days. Beneficiaries who met these criteria were included in one of two intervention groups based on whether they received a CMR during that period or not. Please see **Table 3-2** for an illustration of the stepwise implementation of the exclusion criteria to build the final CHF and COPD intervention groups, and see **Table 3-3** 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**. Details on the construction of the intervention group for the six-month outcomes are described along with the results in **Appendix C**.

[a] In 2010, 133 out of 604 contracts submitted MTM files that did not pass data validation.

Table 3-2: Stepwise Implementation of Cohort Selection for Final CHF, COPD, and Diabetes Intervention Groups

Inclusion Criteria	*CHF Intervention Group Selection*			*COPD Intervention Group Selection*			*Diabetes Intervention Group Selection*		
	N	*Remaining from total (%)*	*Remaining from previous step (%)*	*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			2,734,601		
Have CHF, COPD, or diabetes (respectively)[a]	777,839	28.4%	28.4%	772,905	28.3%	28.3%	876,480	32.1%	32.1%
Not new in risk file	774,065	28.3%	99.5%	768,486	28.1%	99.4%	832,394	30.4%	95.0%
Have at least one PDE claim in 2010	771,846	28.2%	99.7%	766,761	28.0%	99.8%	831,627	30.4%	99.9%
Did not have ESRD in 2009[b]	739,431	27.0%	95.8%	751,607	27.5%	98.0%	824,244	30.1%	99.1%
Non-LTI in 2010	646,214	23.6%	87.4%	679,502	24.8%	90.4%	792,457	29.0%	96.1%
Enrolled in contract that passed data validation for MTM section	552,891	20.2%	85.6%	573,056	21.0%	84.3%	678,122	24.8%	85.6%
Enrolled in one MTM program in 2010	535,286	19.6%	96.8%	553,938	20.3%	96.7%	660,658	24.2%	97.4%
Enrolled in a MTM program at least one day in 2010	531,164	19.4%	99.2%	549,911	20.1%	99.3%	657,665	24.0%	99.5%
New to MTM in 2010	288,600	10.6%	54.3%	299,410	10.9%	54.4%	394,111	14.4%	59.9%
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%	392,916	14.4%	99.7%
Continuously enrolled in Part D during study period	236,984	8.7%	82.4%	251,582	9.2%	84.4%	354,580	13.0%	90.2%
Enrolled in the same contract during outcome period	189,891	6.9%	80.1%	201,626	7.4%	80.1%	275,174	10.1%	77.6%

a. Some beneficiaries met criteria for more than one of the studied chronic conditions (CHF, COPD, and/or diabetes) and are thus included in multiple cohorts. In this report, "diabetes" refers to Type II diabetes and excludes Type II diabetics who take insulin.
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 3-3: 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	189,891	23,918	12.6%	165,973	87.4%
COPD	201,626	26,947	13.4%	174,679	86.6%
Diabetes	275,174	30,072	10.9%	245,102	89.1%

3.2.2 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 3-4**), additional steps were required to identify beneficiaries suitable for inclusion in the comparison group.

Table 3-4: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with CHF, COPD, and Diabetes by MTM Eligibility

Demographic Characteristics and Drug Use Patterns	***Individuals with CHF***		***Individuals with COPD***		***Individuals with Diabetes***	
	MTM Eligible	*MTM Ineligible*	*MTM Eligible*	*MTM Ineligible*	*MTM Eligible*	*MTM Ineligible*
N	531,164	1,828,055	549,911	2,311,866	657,665	2,079,895
Average Age (years)	75.3	77.4	72.4	73.5	72.7	73.2
Male (%)	40.9%	43.3%	39.4%	43.8%	40.0%	44.5%
Female (%)	59.1%	56.7%	60.6%	56.2%	60.0%	55.5%
Average Risk Score	1.7	1.4	1.7	1.4	1.5	1.3
Average Number of RxHCCs	9.8	8.1	9.5	7.5	7.8	6.0
Average Number of Any Part D Drugs	18.0	11.3	18.4	11.0	15.8	9.9
Average Number of Maintenance Drugs	12.3	7.5	12.0	6.7	11.1	7.0
Average Part D Cost	$ 6,472.37	$ 2,945.75	$7,016.14	$3,266.74	$6,046.38	$2,460.34

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 used 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, COPD and diabetes 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 3-5** to identify those eligible for MTM.

Table 3-5: 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
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$ multiplied by Days Left in Yr.

Beneficiaries who met the eligibility criteria above were assigned a random index date in 2010 at which point their study periods[a] started. They were then assigned to the final comparison group if they were continuously enrolled in Part D during the study period, and if they were enrolled in the same Part D contract during that study period. **Table 3-6**, **Table 3-7** and **Table 3-8** below demonstrate the results of narrowing the set of beneficiaries to be included in the final CHF, COPD, and diabetes comparison groups, while the six-month comparison groups are detailed in **Appendix C**. Individuals assigned to the comparison group, on average, used similar numbers of prescription medications and had similar severity of health conditions (identified using risk scores) as those in the intervention group in 2010.

[a] The study period was 365 days long for the twelve-month analysis, while it was 180 days long for the six month analysis.

Table 3-6: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with CHF by 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 3-7: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with COPD by 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

Table 3-8: Demographic Characteristics and 2010 Drug Use Patterns for Individuals with Diabetes by Group Assignment

Demographic Characteristics and Drug Use Patterns	*MTM Eligible*	*Not MTM Eligible*	
		Assigned to Comparison Group	*Not Assigned to Comparison Group*
N	657,665	284,497	1,795,398
Average Age (years)	72.7	72.2	73.4
Male (%)	40.0%	39.7%	45.2%
Female (%)	60.0%	60.3%	54.8%
Average Risk Score	1.5	1.5	1.2
Average Number of RxHCCs	7.8	7.7	5.7
Average Number of Any Part D Drugs	15.8	14.8	9.1
Average Number of Maintenance Drugs	11.1	10.1	6.5
Average Part D Cost	$6,046.38	$5,943.60	$1,908.39

We verified that our comparison group selection method did not disproportionately sample beneficiaries from specific types of drug plans. We did so by investigating the distribution of various drug plan benefit packages and MTM selection criteria between patients in the intervention and comparison groups. We found that patients in the intervention and comparison groups were enrolled at similar rates in drug plans which were basic, enhanced with a coverage gap, and enhanced without a coverage gap (**Table 3-9**). Furthermore, we also determined that the selectivity of MTM criteria was similar between plans the intervention and control groups (**Table 3-10**).

Table 3-9: Distribution of Drug Plan Types within the Intervention and Comparison Groups by Coverage Type

Disease Cohort	*Intervention vs. Control Group*	*Part D Contract Type*											
		PDP						*MA-PD*					
		Basic Plan		*Enhanced Plan with Coverage Gap*		*Enhanced Plan without Coverage Gap*		*Basic Plan*		*Enhanced Plan with Coverage Gap*		*Enhanced Plan without Coverage Gap*	
		N	%	N	%	N	%	N	%	N	%	N	%
CHF	*Intervention*	116,587	78%	13,527	9%	19,133	13%	24,479	28%	42,951	50%	18,631	22%
	Comparison	173,345	84%	19,595	9%	13,759	7%	17,419	30%	21,681	38%	18,628	32%
COPD	*Intervention*	125,340	79%	13,214	8%	20,170	13%	23,282	27%	47,179	54%	17,365	20%
	Comparison	213,591	86%	20,320	8%	14,818	6%	26,141	32%	28,799	35%	26,823	33%

Table 3-10: Distribution of Drug Plans Types within the Intervention and Comparison Groups by Selectivity of MTM Program Eligibility Criteria

Selectivity of MTM Eligibility Criteria	*Overall*		*Beneficiaries Enrolled in PDPs*		*Beneficiaries Enrolled in MA-PDs*	
	Participants	**Comparison**	**Participants**	**Comparison**	**Participants**	**Comparison**
N	666,691	654,189	408,500	474,716	258,191	179,473
Minimum Number of Chronic Conditions						
At least 2	24.1%	9.8%	19.7%	8.1%	30.9%	14.4%
At least 3	75.9%	90.2%	80.3%	91.9%	69.1%	85.6%
Chronic Conditions that Apply						
Any	3.5%	4.3%	4.2%	5.3%	2.4%	1.8%
Specific Chronic Diseases Only	96.5%	95.7%	95.8%	94.7%	97.6%	98.2%
Minimum Number of Part D Drugs						
<=5 Part D Drugs	19.4%	7.1%	12.5%	3.2%	30.4%	17.5%
6-7 Part D Drugs	6.5%	6.1%	3.3%	2.4%	11.5%	15.9%
>=8 Part D Drugs	74.1%	86.8%	84.1%	94.5%	58.1%	66.6%
Part D Drugs that Apply						
Any	49.3%	43.6%	58.8%	50.5%	34.2%	25.5%
Chronic / Maintenance Drugs	40.6%	43.2%	34.1%	42.1%	51.1%	46.1%
Disease-specific Drugs	1.8%	5.3%	1.1%	2.4%	2.9%	13.3%
Specific Part D drug classes	8.3%	7.9%	6.1%	5.1%	11.8%	15.2%

3.2.3 Outcomes

For all disease cohorts, the final outcome period was 365 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 outcomes described in **Table 3-11, Table 3-13**, and **Table 3-15**, and resource utilization outcomes described in **Table 3-12**, **Table 3-14**, and **Table 3-16** below for individuals in the intervention and comparison groups.

Table 3-11: Drug Therapy Outcomes Measured During 365-Day Study Period for Individuals with Congestive Heart Failure

DRUG THERAPY OUTCOMES[a]	*DEFINITION*
Adherence Proportion of days covered (PDC) with Evidence-Based Medication for CHF[b]	PDC[24] across all Tier 1 (evidence-based) medications. PDC was calculated as the proportion of days during the 365-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_AppxB 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 ≥ 80%. PDC with Evidence-Based Medication for CHF is defined above.
Quality of Prescribing Use of Evidence-Based Medication for CHF	At least one fill of a Tier 1 medication (ACE inhibitors/ARBs/cardio-selective beta-blockers in the study period.
Drug Safety 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 365-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_AppxB 4**.
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 (HRM)[d]	At least one fill of a drug indicated as a high-risk medication for the elderly, out of the population of individuals ≥ 65 years of age. See the list of high-risk medications maintained by the PQA in **Table_AppxB 5**.

[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 Part D Star Ratings and Display Measures each year.

[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. (**21.** Nau DP. Proportion of Days Covered (PDC) as a Preferred Method for Measuring Medication Adherence.)

[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 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.)

Table 3-12: Resource Utilization Outcomes Measured During 365-Day Study Period for Individuals with Congestive Heart Failure

RESOURCE UTILIZATION OUTCOMES	*DEFINITION*
Hospital and ER Visits	
All-Cause Hospitalization	Occurrence of at least one hospitalization identified using IP claims data.
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. [a]
CHF-Related ER Visit	Occurrence of at least one ER visit, with CHF listed as a primary or other diagnosis on the OP claim. [a]
Medications and Costs	
Number of Medications	Number of unique medication fills. Medications are defined using the therapeutic classification system (TCS).[b]
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_AppxB 1**.
All-Cause Inpatient Costs	Medicare payments recorded on IP claims. [a]
CHF-Related Inpatient Costs	Medicare payments recorded on IP claims with CHF listed as a primary or other diagnosis.[a]
All-Cause ER Costs	Medicare payments recorded on out-patient emergency room (OP ER) claims. [a]
CHF-Related ER Costs	Medicare payments recorded on OP ER claims with CHF listed as a primary or other diagnosis. [a]

[a] This outcome was only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
[b] Drugs are defined at the Medi-Span Generic Product Identifier 10-digit level.

Table 3-13: Drug Therapy Outcomes Measured During 365-Day Study Period for Individuals with Chronic Obstructive Pulmonary Disease[a]

DRUG THERAPY OUTCOMES	*DEFINITION*
Adherence	
PDC to LABA-Only Regimen[b]	Proportion of days covered with long-acting beta-agonists (LABAs). PDC was calculated as the proportion of days during the 365-day study period when an individual possessed any of the LABAs medications. See **Table_AppxB 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 ≥ 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 COPD when their PDC for that regimen is ≥ 80%. PDC to LAAC-Only Regimen is defined above.
Adherent to Combination Regimen	Individuals are defined as adherent to any evidence-based medication for COPD when their PDC for that regimen is ≥ 80%. PDC to PDC to LABA + LAAC Combination Regimen is defined above.
Drug Safety	
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 365-day study period. The list of drug-drug interactions was created by the Pharmacy Quality Alliance and provided in **Table_AppxB 4**.
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 ≥ 65 years of age. See the list of high-risk medications in **Table_AppxB 5**.

[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. (Nau DP. Proportion of Days Covered (PDC) as a Preferred Method for Measuring Medication Adherence.)

[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.)

Table 3-14: Resource Utilization Outcomes Measured During 365-Day Study Period for Individuals with Chronic-Obstructive Pulmonary Disease

RESOURCE UTILIZATION OUTCOMES	*DEFINITION*
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 visit identified using OP claims data. [a]
COPD-Related ER Visit	Occurrence of at least one ER visit, with COPD listed as a primary or other diagnosis on the OP claim. [a]
Medications and Costs	
Number of Medications	Number of unique medication fills. Medications are defined using the therapeutic classification system (TCS). [b]
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. See the list of all COPD-related medications in **Table_AppxB 2**.
All-Cause Inpatient Costs	Medicare payments recorded on IP claims. [a]
CHF-Related Inpatient Costs	Medicare payments recorded on IP claims with COPD listed as a primary or other diagnosis. [a]
All-Cause ER Costs	Medicare payments recorded on out-patient emergency room (OP ER) claims. [a]
CHF-Related ER Costs	Medicare payments recorded on OP ER claims with COPD listed as a primary or other diagnosis. [a]

[a] This outcome was only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
[b] Drugs are defined at the Medi-Span Generic Product Identifier 10-digit level.

Table 3-15: Drug Therapy Outcomes Measured During 365-Day Study Period for Individuals with Diabetes

DRUG THERAPY OUTCOMES	*DEFINITION*
Adherence	
Adherent to any Evidence-Based Medication for Diabetes	Individuals are defined as adherent to any evidence-based medication for diabetes when their PDC[a] for that regimen is ≥ 80%. PDC is calculated the same way as is defined for CHF above. See **Table_AppxB 3** for a list of all diabetes-specific medications included in this analysis.
Adherent to Biguanide Medication for Diabetes	Adherent to biguanide medications for diabetes, defined as PDC ≥ 80%.
Adherent to DPP-IV Medication for Diabetes	Individuals are defined as adherent to DPP-IV medications for diabetes, defined as PDC ≥ 80%.
Adherent to Sulfonylurea Medication for Diabetes	Individuals are defined as adherent to sulfonylurea medications for diabetes, defined as PDC ≥ 80%.
Adherent to Thiazolidinedione Medication for Diabetes	Individuals are defined as adherent to thiazolidinedione medications for diabetes, defined as PDC ≥ 80%.
Quality of Prescribing	
Use of ACE Inhibitor or ARB Medication	At least one fill of an ACE inhibitor or ARB medication during the outcome period.
Use of Statin Medication	At least one fill of a HMG-CoA reductase inhibitor (i.e. statin) medication during the outcome period.

[a] 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.

Table 3-16: Resource Utilization Outcomes Measured During 365-Day Study Period for Individuals with Diabetes

RESOURCE UTILIZATION OUTCOMES	*DEFINITION*
Hospital and ER Visits	
All-Cause Hospitalization	Occurrence of at least one hospitalization identified using IP claims data.
Diabetes-Related Hospitalization	Occurrence of at least one hospitalization with diabetes 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.[a]
Diabetes-Related ER Visit	Occurrence of at least one emergency room (ER) visit, with diabetes listed as a primary or other diagnosis on the OP claim.
Medications and Costs	
Number of Medications	Number of unique medications an individual filled. Medications are defined using the therapeutic classification system (TCS).[b]
Part D Costs	Total payments recorded on Part D claims for all prescription medications not used for treatment of diabetes. Medications used for treatment of diabetes include those listed in **Table_AppxB 3**.
All-Cause Inpatient Costs	Medicare payments recorded on IP claims.
Diabetes -Related Inpatient Costs	Medicare payments recorded on IP claims with diabetes listed as a primary or other diagnosis.
All-Cause ER Costs	Medicare payments recorded on OP ER claims.[b]
Diabetes-Related ER Costs	Medicare payments recorded on OP ER claims with diabetes listed as a primary or other diagnosis.[b]

[a] This outcome was only calculated for individuals enrolled in PDPs, as corresponding data for individuals in MA-PDs were not available.
[b] Drugs are defined at the Medi-Span Generic Product Identifier 10-digit level.

3.2.4 Empirical Specifications

Applying the MTM eligibility algorithm described in **Section 3.2.2** 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 3-11** through **Table 3-16** 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 observation period[a] preceding the start of the study period. Then, we used regression models 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, for the analysis of high-risk medication (HRM) use after twelve months, the 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 365 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 Part D parent organization level estimated the probability of experiencing a given outcome during the study period across all beneficiaries in the study.

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

[a] The observation period was 365 days for the final twelve-month analysis while it was 180 days for the interim analysis of outcomes at six months.

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, and using indicator variables for low-income status (LIS) and Medicaid eligibility; and regional variations, using indicator variables representing Hospital Referral Regions (HRR) stratified into deciles of mean prescription drug and acute care costs. 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 one year 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. We also adjusted for Part D parent organization using indicator variables for each separate organization (fixed effects). Finally, for each outcome, we also adjusted for incidence or level of that outcome in the 365-days preceding each individual's study period: for example, when estimating the association of MTM program participation with medication adherence for individuals with diabetes, we adjusted for each individual's level of adherence in the year 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.

3.2.5 Subpopulation Analyses of Part D Parent Organizations

We also conducted sub-population analyses exploring the outcomes listed above across beneficiaries enrolled in MTM programs offered by PDPs or MA-PDs associated with specific Part D parent organizations. For these analyses, intervention and comparison groups were constructed from those described in **Sections 3.2.1** and **3.2.2** above, restricted to individuals enrolled in MTM programs for each Part D parent organization individually.

Information about the Part D organizations' MTM programs is available in **Table 3-17**. This table lists MTM programs' CMRs and outreach methods, as described in the information they provided to CMS in the MTM Submission Files. Part D organizations showed significant variation on administration of CMRs. Organizations A, B, C, E, and H's MA-PDs reported that they provided CMRs to a low number (less than 25%) of individuals enrolled in their Medicare MTM programs, while Organizations D, F, and G provided CMRs to over 25% of COPD or CHF beneficiaries in their MTM programs. While Organization D provided CMRs to most of its MTM enrollees, its intervention was the least intensive of the group. Organization D's CMR

was conducted by phone only and did 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).

Table 3-17: MTM Program Summary for Selected Part D Organizations in 2010

Part D Organization	*MTM Enrollment*[a]	*CMR Consultation Mode*	*Written Summary of CMR* [b]	*Percent Receiving CMRs* [c]	*Prescriber Outreach Methods*
A[d]	High	Phone	Action plan, recommendations	Low	Phone, fax
B	High	Phone, face-to-face	Action plan, recommendations, personal medication list	Low	Phone, fax, mail
C	Medium	Phone, face–to-face	Action plan, recommendations	Low	Phone, fax, mail
D	Medium	Phone	Personal medication list	High	Fax
E[d]	Low	Phone	Action plan, recommendations, personal medication list	Low	Phone, fax, mail
F[d]	Low	Phone, face-to-face	Recommendations, reconciled medication list, education materials	High	Phone, EMRs, e-mail and mail
G[d]	Low	Phone	Medication action plan, personal medication list, information on assistance programs	High	Mail, phone
H[d]	Low	Phone, face-to-face	Personal medication list, medication action plan, education materials	Low	Mail, phone

[a] For all Part D MTM enrollees annually in 2010: High consists of > 100,000 MTM enrollees; Medium consists of between 40,000 and 100,000 MTM enrollees, and Low consists of < 40,000 MTM enrollees.
[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.
[c] Interviewed as part of the qualitative Part D organization interviews.
[d] CMR rates above 25% are denoted as "high." CMR rates below 25% are denoted as "low."

Source: MTM Program data provided by CMS.

3.3 Additional Quantitative Analyses

We performed additional analyses to investigate, explore and test the robustness of the findings from our main approach. First, we compared the outcomes of MTM intervention at six versus twelve months (**Section 3.3.1**) to assess the timeline of outcome effects. Next, we assessed MTM effectiveness in targeting individuals with high resource utilization and drug therapy problems (**Section 3.3.2**). Third, we conducted a sensitivity analysis of our regression method by analyzing the same outcomes using an alternative approach, the difference-in-differences estimator method (**Section 3.3.3**). Finally, we performed an additional analysis of the effects of MTM on COPD, limiting only to MTM programs that specified that they targeted COPD in 2010 (**Section 3.3.4**).

3.3.1 Comparison between Six-Month and Twelve-Month Outcomes after MTM

To compare the six-month and twelve-month outcomes of MTM, we explored statistically significant differences in drug therapy, resource utilization and cost outcomes for the CHF and COPD cohorts. We identified congruent and incongruent trends in these results, and noted particular outcomes for which the results were robust over time or diminished in effect at twelve months.

3.3.2 Effectiveness of MTM in Targeting High-Risk Individuals

To explore the effectiveness of Part D organizations in targeting their MTM interventions to high-risk individuals, we examined the entire Medicare Part D population with claims data indicating a diagnosis of CHF, COPD, or diabetes, and compared their healthcare utilization and drug therapy characteristics to the baseline characteristics of individuals enrolled in MTM. We then additionally compared the baseline characteristics of these groups to the profile of the subset of MTM enrollees who received CMRs.

3.3.3 Difference-in-Differences Estimator Approach

We conducted an alternative analysis using a difference-in-differences (DiD) estimator method commonly used to reduce biases introduced by time-invariant characteristics such as health-seeking behavior. The DiD estimator compared changes in outcomes among MTM enrollees with the changes in outcomes among matched beneficiaries from the baseline period to the one-year period following MTM enrollment. Unlike in the main analysis (OLS regression), beneficiaries in the comparison groups were selected from the universe of Medicare Part D beneficiaries regardless of their MTM eligibility. These comparison beneficiaries in the DiD analysis were individually matched with MTM enrollees on combinations of demographic and

health characteristics, including the criteria defining MTM eligibility (annual drug costs ≥ $3,000, chronic conditions, number of maintenance medications) using an exact cell matching method. For the analysis of each outcome, controls were also matched with MTM enrollees on that outcome in the baseline period (e.g., hospitalization costs in the pre-enrollment period were matched for the hospital cost outcome). Our approach to the DiD analysis is described in greater detail in **Appendix D**.

3.3.4 Effectiveness of MTM Chronic Condition Targeting

For our main results, we included beneficiaries across all available contracts with each evaluated chronic condition (CHF, COPD or diabetes). However, it is notable that not all Part D plans targeted these conditions for MTM eligibility. Of the contracts evaluated, 96.8% targeted patients with diabetes, 93.7% targeted patients with CHF and 52.8% targeted COPD. Given the large number of contracts not targeting COPD patients, we performed an additional analysis comparing the outcomes for COPD patients enrolled in any MTM program regardless of whether this condition was targeted, and for COPD patients enrolled only in MTM programs targeting this condition. We did this to investigate whether targeting matters for disease-specific outcomes (and by how much) or whether the improvements in adherence and other outcomes with MTM are global across important conditions present in patients enrolled in MTM programs. One interpretation of this analysis is to assess the degree of spillover effects on non-targeted conditions in patients receiving MTM for other reasons. MTM is intended to be a comprehensive approach to medication management, not disease-specific disease management.

3.4 Qualitative Analysis Methods

This section describes the qualitative methods used to investigate MTM practices and outcomes. The qualitative methods – which included interviews with key stakeholders and Part D organizations – supplemented the quantitative analyses by identifying important practices used by MTM programs achieving positive patient outcomes. These interview methods are described in **Sections 3.4.1** and **3.4.2** below.

3.4.1 Approach to Key Stakeholder Interviews

We interviewed 9 key stakeholders to understand how successful MTM programs are implemented and to identify potential synergies with other national healthcare policies. A list of potential stakeholders was developed in consultation with the project's technical expert panel (TEP) and CMS. This list included professional pharmacy associations, health care quality/safety organizations with a focus on prescribing and safe medication use, beneficiary organizations, and health care providers (e.g., pharmacists, primary care providers).

All representatives from these stakeholder organizations were provided anonymity, thus their names and titles were omitted. Additionally, while we list the interviewed organizations, we do not attribute specific responses to the interviewee's organization. The following organizations agreed to participate in the stakeholder interviews: American Pharmacist Association (APhA) Foundation, National Association of Chain Drug Stores (NACDS), The American Society of Health-System Pharmacists (ASHP), the Pharmacy Quality Alliance (PQA), and the American Association of Retired Persons (AARP, a beneficiary organization). To elicit perspectives from providers, we also interviewed one additional major national retail pharmacy chain that has implemented an innovative approach to MTM services, two nationally recognized pharmacists, and one physician.

3.4.2 Overview of Method for Interviewing Part D Organizations

We conducted additional interviews with representatives from five Part D organizations with variations in MTM performance based on the quantitative analyses. We aimed to gather best practices of MTM implementation and to provide a contextual understanding of the major results of the quantitative analyses. Findings from these interviews were used to develop case studies of the selected Part D organizations.

Part D organizations were chosen for interview using beneficiary-level and plan-level MTM data. We selected a heterogeneous set of interviewees in terms of their geographic catchment areas (e.g., national versus regional), Part D enrollment, CMR and TMR completion rates, contract-level MTM program submission data (e.g., details about provider and beneficiary interventions, pharmacy benefits manager, MTM vendor, eligibility criteria), and disease specific-outcomes for beneficiaries with CHF or COPD. Selection of Part D organizations was limited to a minimum total enrollment threshold of 250 Part D enrollees.

Based on the considerations described above, a preliminary list of Part D organizations was presented for discussion with the TEP, which was further narrowed based on input from the TEP and CMS. Some Part D organizations declined to participate in the interviews, and the characteristics of the five organizations that agreed to participate are presented in **Table 3-18**. These organizations also represent a variety of MTM vendors.

Table 3-18: Characteristics of Selected Part D Organizations

Part D Organization	*Total Part D Enrollment**	*Rate of Eligible Part D enrollees (weighted by enrollment)*	*CMR Rate***	*Census Region*	*Type of Plan(s) offered*
Organization A	High	6-10%	Low	National	MA-PD and PDP
Organization E	High	6-10%	Low	National	PDP and MA-PD
Organization F	High	6-10%	High	Multiple	MA-PD
Organization G	Medium	1-5%	High	Northeast	MA-PD
Organization H	Medium	6-10%	Low	South	MA-PD

* High enrollment = above 100,000; Medium enrollment = 20,000-100,000; Low enrollment = below 20,000.
** CMR rates above 25% are denoted as "high." CMR rates below 25% are denoted as "low."

Representatives from the organizations listed in the table above were interviewed from February 2013 through March 2013. These individuals held organizational roles such as Director of Pharmacy Management, Chief of Clinical Pharmacy Call Center, Senior Director of Clinical Pharmacy Programs, Director of Product Development, and Clinical Programs Coordinator. A semi-structured interview protocol was used to conduct the interviews. Interviews were designed to gather standard background information about the administrative policies and procedures for each Part D organization, including a description of MTM services; eligibility requirements; enrollment practices; program-specific evidence of effectiveness; strategies for interacting with patients and providers; and operational issues.

3.5 Synthesis of Quantitative and Qualitative Findings

We evaluated the quantitative outcomes for each of the interviewed Part D parent organizations and identified whether the Part D organization represented a high-performing (i.e., with statistically significant improved effects on evaluated outcomes) plan across the following dimensions: (i) CMR rates, (ii) adherence improvements, (iii) quality of prescribing improvements, (iv) impact on hospital and ER costs, and (v) impact on Part D drug costs. We focused the interview of selected Part D organizations on targeted questions to identify the practices that they employed to achieve these positive results. Similarly, we also reviewed the interview findings and practices of lower performing Part D organizations on some of the above dimensions to confirm that the practices employed by high-preforming Part D organizations were distinct and not also employed by the lower-performing Part D organizations. Those practices uniquely employed by high performing Part D organizations were identified as "best practices" and organized according to each MTM performance dimension. Some best practices also appear to be leveraged to achieve high performance for several dimensions. A final, unique, set of best practices is presented, based on this combined integrated quantitative and qualitative analysis, which appear to reflect the best practices that a hypothetical high-performing Part D organization would employ to maximize their MTM enrollee outcomes.

4 RESULTS: IMPACT OF MTM ON BENEFICIARIES WITH CHF

Beneficiaries with CHF who enrolled in Medicare MTM programs consistently experienced higher odds of medication adherence, greater uptake of evidence-based medications, and higher total prescription drug costs relative to individuals in a comparison group. For individuals in PDPs, receiving MTM with CMR was associated with lower odds of all-cause and CHF-related hospitalizations and lower all-cause hospitalization costs during the 365-day outcome period, relative to the comparison group. 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 Part D 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** and **4.4** then summarize the risk-adjusted results for drug therapy, resource utilization and costs of our overall PDP, overall MA-PD, and Part D 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, 156,441 were assigned to the comparison group, 103,080[a] to the intervention group for individuals in MTM programs who did not receive a CMR ("MTM without CMR"), and 12,658[b] to the intervention group for individuals in MTM programs who did receive a CMR ("MTM with CMR"). For those enrolled in MA-PDs, 51,938 were assigned to the comparison group, 62,893[c] to the MTM without CMR intervention group, and 11,260[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), 10.9% of those in PDPs, and 15.1% 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

[a] Of these, 6,184 opted out during the measurement period. All individuals who opted out were included in the analysis, based on the intention-to-treat analytical approach.
[b] Of these, 29 opted out during the measurement period.
[c] Of these, 6,397 opted out during the measurement period.
[d] Of these, 77 opted out during the measurement period.

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 difference in the proportion of individuals in the MTM intervention groups that were taking a high number of maintenance drugs preceding MTM enrollment relative to the comparison group suggests 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 disabled, 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 Part D 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 in Study Cohorts by PDP and MA-PD Setting

Demographic and Health Characteristics	*Beneficiaries Enrolled in PDPs*			*Beneficiaries Enrolled in MA-PDs*		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	156,441	103,080	12,658	51,938	62,893	11,260
% in MTM Receiving CMR			8.1%			21.7%
Gender						
Male	36.7%	40.3%	31.8%	40.9%	45.2%	47.7%
Female	63.3%	59.7%	68.2%	59.1%	54.8%	52.3%
Age						
≤65	16.7%	13.8%	25.2%	12.5%	11.9%	8.0%
66-75	28.7%	31.8%	33.4%	32.6%	35.1%	35.8%
76-85	34.8%	36.8%	30.7%	38.0%	38.3%	41.9%
> 85	19.8%	17.6%	10.7%	16.9%	14.6%	14.3%
Race						
White	81.8%	82.5%	74.8%	79.2%	79.1%	79.8%
Black	12.6%	11.3%	19.0%	13.9%	13.3%	11.6%
Hispanic	2.5%	2.6%	3.5%	3.4%	4.0%	3.5%
Other or Unknown	3.1%	3.6%	2.7%	3.4%	3.7%	5.2%
SES						
LIS Eligible	52.1%	44.1%	71.1%	37.0%	36.7%	22.4%
General Health Status in Observation Period						
Less than or equal to 8 Maintenance Drugs	20.8%	17.4%	8.2%	26.3%	20.6%	15.5%
9-10 Maintenance Drugs	27.0%	22.4%	17.4%	29.3%	23.4%	21.9%

Demographic and Health Characteristics	*Beneficiaries Enrolled in PDPs*			*Beneficiaries Enrolled in MA-PDs*		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
General Health Status in Observation Period						
11-12 Maintenance Drugs	22.4%	22.1%	22.0%	21.4%	23.0%	24.4%
Greater than 12 Maintenance Drugs	29.8%	38.0%	52.4%	23.0%	33.0%	38.2%
Disabled	18.5%	15.6%	27.9%	14.6%	14.0%	9.8%
Specific Health Conditions						
Diabetes	46.5%	63.2%	69.8%	44.6%	66.4%	66.1%
Dyslipidemia	73.1%	78.8%	77.3%	74.2%	83.0%	85.1%
Rheumatoid Arthritis	5.9%	4.4%	6.4%	6.0%	4.0%	3.9%
AMI & Unstable Angina	67.1%	70.3%	67.7%	64.9%	71.4%	68.2%
Stroke & Cerebral Hemorrhage	26.1%	25.6%	23.2%	24.3%	24.2%	20.9%
Vascular Disease	33.7%	32.6%	32.5%	35.7%	35.9%	36.7%
Asthma & COPD	51.2%	46.0%	58.6%	54.9%	44.8%	45.4%

4.2 Baseline Demographic and Health Characteristics of MTM Enrollees and Controls

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 one year 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. Beneficiaries targeted by MTM programs experienced higher rates of adverse drug regimens preceding enrollment. They were also more likely to have drug-drug interactions, use high-risk medications, and use medications contraindicated for CHF in their medication regimens in the observation period before enrolling in MTM. Further analysis of MTM effectiveness in targeting high-risk enrollees is provided in **Section 8.2**.

MTM enrollees were also more likely to experience all-cause and CHF-related hospitalizations in the observation period. The proportion of individuals experiencing a hospitalization due to any cause in the one year preceding the outcome period ranged from 48.5% (comparison group) to 50.7% (MTM with or without CMR) for those in PDPs, and slightly lower at 39.1% (comparison group) to 45.3% (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 $1,213 more in inpatient costs than those in the comparison group, in the one-year period before they received any 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. 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 91.6% and 93.1% of individuals who received MTM (in PDPs and MA-PDs, respectively) already adherent to evidence-based medications in the one-year preceding MTM enrollment.

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 accept the offer to receive a CMR, they were also slightly less likely to experience a hospitalization in the observation period and incurred lower hospitalization costs prior to enrolling in MTM. In particular, individuals enrolled in PDPs who received a CMR incurred approximately $632 less in all-cause hospitalizations and $305 less in CHF-related hospitalizations during the one-year 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	156,441	103,080	12,658	51,938	62,893	11,260
Drug Therapy						
Quality of Prescribing						
Use of Evidence-Based Medication for CHF	84.9%	91.6%	92.4%	84.7%	93.1%	94.6%
Adherence						
Adherent to Any Evidence-Based Medications for CHF	84.1%	85.8%	87.6%	84.6%	85.7%	90.6%
Drug Safety						
At Least One Drug-Drug Interaction	15.7%	17.9%	20.0%	12.8%	14.6%	12.7%
Use of at Least One High Risk Medication	48.0%	50.4%	54.4%	41.0%	44.7%	39.8%
Use of at Least One Medication Contraindicated for CHF	22.4%	24.7%	35.4%	22.1%	19.5%	17.6%
Resource Utilization: Hospital and ER Visits						
Any (All-Cause) Hospitalization	48.5%	50.7%	50.7%	39.1%	45.3%	42.7%
Any CHF-Related Hospitalization	27.4%	32.2%	31.9%	20.6%	28.7%	29.2%
Any (All-Cause) ER Visit	43.9%	41.3%	48.0%	---	---	---
Any CHF-Related ER Visit	12.3%	12.7%	16.3%	---	---	---
Resource Utilization: Medications and Costs (Average)						
Number of Medications	17.17	17.47	20.02	15.72	16.15	16.69
Generic Substitution Ratio	87.2%	88.2%	90.0%	88.5%	88.9%	87.7%
Part D Costs for Non-CHF Drugs	$5,141.53	$4,269.41	$5,944.11	$4,478.70	$3,298.49	$3,246.23
All-Cause Hospitalization Costs	$9,278.27	$10,491.43	$9,858.94	---	---	---
CHF-Related Hospitalization Costs	$4,316.55	$5,602.01	$5,297.37	---	---	---
Resource Utilization: Medications and Costs (Average)						
All-Cause ER Costs	$444.35	$407.78	$520.09	---	---	---
CHF-Related ER Costs	$103.89	$110.71	$141.52	---	---	---

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 MTM Effects on Drug Therapy Outcomes for CHF Patients

The association between MTM, drug adherence, and quality of prescribing for CHF was positive for the PDP and MA-PD cohorts; further, the magnitude of that association 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 adherence and evidence-based medication use, while those results were less consistent for individuals in MTM programs who did not receive a CMR. However, our overall analysis did not show a positive effect of MTM on drug safety outcomes. MTM recipients were less likely than members of the comparison group to discontinue use of high-risk and contraindicated medications in the 365-day outcome period. The following two sections provide the risk-adjusted results for overall PDP and MA-PD groups and stratified by Part D organization.

4.3.1 Drug Therapy Outcomes

MTM programs provided by PDPs and MA-PDs showed similar impacts on enrollees for quality of prescribing and adherence to evidence-based medications. In contrast to outcomes for quality of prescribing and adherence, the association was not as consistently positive for drug safety outcomes, as follows:

- **Discontinue use of High-Risk Medications (HRM):** Among treatment groups who filled at least one HRM during the 365 day period prior to the index date, beneficiaries in MA-PDs who received MTM without CMR showed lower odds of discontinuing high-risk medications. The other groups studied in both PDPs and MA-PDs did not have significantly different odds of discontinuing use of high-risk medications if they received MTM, compared to their respective comparison groups.

- **Discontinue use of Contraindicated Medications:** Individuals in PDPs who received MTM services were less likely to discontinue use of contraindicated medications relative to the PDP comparison group (MTM without CMR, OR=0.81, MTM with CMR, OR=0.63). However, individuals in MA-PDs who were enrolled in MTM programs had higher odds (MTM without CMR: OR=1.09, MTM with CMR, OR=1.16) of discontinuing contraindicated medications by the end of the study period, compared to the MA-PD comparison group. Thus, for recipients of MTM with CMR in PDP plans who were taking contraindicated medications at enrollment, the odds of discontinuing these medications were 37% lower than for members of the comparison group who were taking contraindicated medications over the same initial period. However, for MTM recipients with CMRs in MA-PD plans, the odds of discontinuing their contraindicated meds were 16% higher relative to the comparison group.

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 after they received MTM without CMR (PDP: OR=1.18; MA-PD: OR=1.29). Those receiving CMRs as part of their MA-PD MTM programs also had higher odds of uptake of evidence-based medications (OR=1.36), however the difference was not significant for CMR recipients in PDPs. Additionally, MTM was associated with increased odds of adherence to evidence-based medications for CHF within both PDPs and MA-PDS. The magnitude of this increase ranged from OR=1.11 for individuals in MA-PDs who did not receive CMR to OR=1.40 for individuals in MA-PDs who did receive CMR.

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

Part D Contract Type	*Intervention Group*	*N*	*Take Up of Evidence-Based Medication for CHF*	*Adherent to Evidence-Based Medications for CHF*	*Remove Drug-Drug Interaction*	*Discontinue Use of High Risk Medications*	*Discontinue use of Medication Contraindicated for CHF*
PDP	Comparison	156,441	---	---	---	---	---
	MTM without CMR	103,080	1.18* (1.10 , 1.26)	1.12 * (1.08 , 1.15)	0.96 (0.90 , 1.02)	0.98 (0.95 , 1.00)	0.81* (0.78 , 0.84)
	With CMR	12,658	1.01 (0.88 , 1.26)	1.28* (1.19 , 1.37)	0.87 (0.76 , 1.00)	1.04 (0.97 , 1.11)	0.63* (0.58 , 0.67)
MA-PD	Comparison	51,938	---	---	---	---	---
	MTM without CMR	62,893	1.29 * (1.16 , 1.44)	1.11 * (1.06 , 1.16)	1.01 (0.91 , 1.11)	0.88 * (0.84 , 0.92)	1.09 * (1.02, 1.16)
	With CMR	11,260	1.36 * (1.09 , 1.71)	1.40 * (1.29 , 1.52)	1.05 (0.88 , 1.26)	0.93 (0.86 , 1.01)	1.16 * (1.03, 1.30)

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

4.3.2 Drug Therapy Outcomes by Part D Organization

After stratifying the analyses by Part D organization and adjusting for all covariates, the estimated effects of MTM on quality of prescribing and adherence to evidence-based medications for CHF were positive for several Part D organizations.

- PDP results are shown in **Table 4-4** and can be summarized as follows:
    - **Adherence:** 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 Part D organization's comparison group (OR=1.41, 2.01, and 1.83, respectively). **Organizations A, B, D,** and **E's** enrollees showed higher odds (OR=3.15, 1.17, 1.49, and 2.29, respectively) on this metric if they were enrolled in an MTM program and did receive a CMR.
    - **Quality of Prescribing: Organizations A, C, D** and **E's** MTM enrollees who did not receive a CMR had higher odds of uptake of an evidence-based medication regimen for CHF during the outcome period (OR=1.79, 1.46, 2.17, and 2.02, respectively) relative to their comparison groups. For their corresponding MTM with CMR groups, only **Organizations A, C** and **D** showed significant differences from the comparison group (OR=2.15, 2.17, and 1.54, respectively), but the lack of significant differences for other Part D organizations could be due to imprecise estimates resulting from the relatively small number of individuals in their MTM programs who received CMRs.
- MA-PD results are shown in and **Table 4-5** and can be summarized as follows:
    - **Adherence:** MTM recipients who received CMRs in **Organizations A, C, D,** and **F** were more likely to be adherent to evidence-based medications for CHF relative to the comparison group (ORs=3.45, 1.53, 1.53, and 1.55 respectively). MTM recipients in **Organizations A** and **E** who did not receive CMRs were also more likely to be adherent (ORs=1.29 and 3.41, respectively).
    - **Quality of Prescribing:** Individuals who received MTM without a CMR enrolled in **Organization A, C, E,** and **F's** MTM programs had higher odds of filling an evidence-based medication for CHF during the outcome period (ORs = 1.62, 1.54, 2.74, and 1.46, respectively), relative to the comparison group. For individuals who received a CMR, the odds ratios for evidence-based medication use were also significantly higher for **Organizations A, C,** and **F** (OR = 1.65, 1.78, and 1.71, respectively).

- **Drug Safety:** Individuals who received MTM with a CMR enrolled in **Organization F's** MTM program had lower odds of a drug-drug interaction (OR=0.70) and lower odds of using a medication contraindicated for CHF (OR=0.66).

Table 4-4: Risk-Adjusted Drug Therapy Outcomes for Individuals with CHF by PDP Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*N*	*Take-up of Evidence-Based Medication for CHF*	*Adherent to 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	17,655	1.79 * (1.69 , 1.89)	1.41 * (1.32 , 1.51)	1.21 (1.08 , 1.35)	1.08 * (1.01 , 1.14)	0.79 * (0.73 , 0.85)
	With CMR	167	2.15* (1.28 , 3.60)	3.15 * (1.70 , 5.83)	2.43 * (1.30 , 4.55)	0.79 (0.50 , 1.26)	0.53 (0.25 , 1.12)
Organization B	MTM without CMR	15,850	0.94* (0.88 , 0.99)	1.03 (0.96 , 1.20)	1.02 (0.91 , 1.13)	1.01 (0.96 , 1.10)	2.00 * (1.89 , 2.12)
	With CMR	4,048	1.00 (0.90 , 1.11)	1.17 * (1.04 , 1.32)	1.02 (0.86 , 1.21)	1.06 * (0.97 , 1.16)	2.28 * (2.09 , 2.50)
Organization C	MTM without CMR	14,736	1.46 * (1.30 , 1.65)	1.12 (0.96 , 1.32)	0.96 (0.69 , 1.35)	0.90 (0.80 , 1.03)	0.86 (0.73 , 1.02)
	With CMR	339	2.17 * (1.53 , 3.08)	1.04 (0.71 , 1.52)	1.62 (0.80 , 3.28)	0.76 (0.53 , 1.09)	1.02 (0.75 , 1.76)
Organization D	MTM without CMR	335	2.17 * (1.47 , 3.21)	2.01 * (1.34 , 3.02)	0.96 (0.56 , 1.68)	1.91 (1.41 , 2.58)	0.79 (0.53 , 1.16)
	With CMR	6,791	1.54 * (1.38 , 1.71)	1.49 * (1.31 , 1.69)	1.01 (0.80 , 1.29)	1.17 * (1.04 , 1.32)	0.98 (0.88 , 1.11)
Organization E	MTM without CMR	5,226	2.02 * (1.79 , 2.28)	1.83 * (1.61 , 2.09)	1.16 (0.92 , 1.47)	1.04 (0.93 , 1.16)	1.06 (0.94 , 1.21)
	With CMR	97	1.80 (0.90 , 3.59)	2.29 * (1.08 , 4.83)	1.49 (0.52 , 4.26)	0.76 (0.42 , 1.36)	2.36* (1.34 , 4.15)

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

a. For each PDP Parent Organization, the number of individuals in the CHF comparison group was as follows- Organization A: 52,036, Organization B: 36,478, Organization C: 2,620, Organization D: 7,765, and Organization E: 6,723.

Table 4-5: Risk-Adjusted Drug Therapy Outcomes for Individuals in with CHF by MA-PD Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*N*	*Take-up of Evidence-Based Medication for CHF*	*Adherent to 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	13,207	1.62 * (1.50 , 1.75)	1.29 * (1.17 , 1.42)	1.07 (0.89 , 1.29)	1.21 * (1.11 , 1.32)	0.75 * (0.68 , 0.82)
	With CMR	179	1.65 * (1.04 , 2.62)	3.45 * (1.81 , 6.60)	0.58 (0.23 , 1.50)	0.91 (0.58 , 1.44)	0.89 (0.52 , 1.53)
Organization B	MTM without CMR	330	0.71 (0.47 , 1.06)	1.06 (0.69 , 1.63)	0.57 (0.24 , 1.37)	0.73 (0.51 , 1.06)	1.90* (1.27 , 2.84)
	With CMR	140	1.16 (0.62 , 2.16)	0.94 (0.51 , 1.73)	0.92 (0.33 , 2.61)	0.80 (0.47 , 1.36)	2.77 * (1.66 , 4.63)
Organization C	MTM without CMR	11,983	1.54 * (1.35 , 1.75)	1.13 (0.95 , 1.35)	1.24 (0.81 , 1.90)	1.21* (1.04 , 1.40)	0.84* (0.72 , 0.99)
	With CMR	521	1.78 * (1.34 , 2.37)	1.53 * (1.07 , 2.19)	0.94 (0.47 , 1.92)	1.13 (0.84 , 1.51)	0.71 (0.49 , 1.02)
Organization D	MTM without CMR	35	0.82 (0.32 , 2.06)	1.82 (0.53 , 6.30)	7.67* (1.26 , 46.572)	1.08 (0.39 , 3.04)	0.23 (0.03 , 2.45)
	With CMR	651	1.17 (0.88 , 1.54)	1.53 * (1.08 , 2.17)	1.42 (0.68, 2.97)	0.97 (0.70 , 1.33)	1.01 (0.69 , 1.47)
Organization E	MTM without CMR	534	2.74 * (1.77 , 4.26)	3.41 * (2.12 , 5.46)	0.76 (0.30 , 1.97)	1.20 (0.81 , 1.79)	1.18 (0.75 , 1.67)
	With CMR	18	3.22 (0.51 , 20.49)	2.54 (0.29 , 22.18)	2.34 (0.12 , 45.77)	2.63 (0.70 , 9.84)	0.60 (0.12 , 3.03)
Organization F	MTM without CMR	4,003	1.46 * (1.27 , 1.65)	1.15 (0.97 , 1.37)	0.80 (0.56 , 1.15)	1.30* (1.06 , 1.60)	0.86 (0.69, 1.08)
	With CMR	5,897	1.71 * (1.52 , 1.92)	1.55 * (1.31 , 1.84)	0.70 * (0.50 , 0.99)	0.95 (0.78 , 1.16)	0.66 * (0.54 , 0.81)

* Indicates significance at the p<0.05 level.

a. For each MA-PD Parent Organization, the number of individuals in the CHF comparison group was as follows - Organization A: 13,640, Organization B: 1,193, Organization C: 2,208, Organization D: 1,861, Organization E: 659, and Organization F: 4,164.

4.4 MTM Effects on Resource Utilization Outcomes for CHF Patients

Results at the overall PDP and MA-PD levels suggested that individuals who received a CMR were consistently less likely than individuals in the comparison group to experience hospitalizations and ER visits and accrue associated costs during the outcome period. Those results were less consistent for individuals in MTM programs who did not receive a CMR, and were also inconsistent at the Part D organization level. The following three sections provide the adjusted results for overall PDP and MA-PD groups and stratified by Part D organization. **Section 4.4.1** provides overall results for hospital and ER visits, while **Section 4.4.2** presents overall results for medications and costs, and **Section 4.4.3** lists results stratified by Part D Organization.

4.4.1 Resource Utilization Outcomes: Hospital and ER Visits

The association between MTM and risk-adjusted resource utilization outcomes was inconsistent. After adjusting for covariates, odds of all-cause hospitalizations in PDPs were slightly lower among MTM recipients with and without CMR than for the comparison group; however, all-cause hospitalization odds were slightly higher for MTM recipients in MA-PDs who did not receive CMR than for the comparison group (see **Table 4-6**). Individuals who received MTM showed increases in their total number of medications, and inconsistent results for their medication, hospital, and ER costs.

While we observed fewer hospitalizations among beneficiaries enrolled in PDP MTM programs, there is little evidence that these reductions were due to fewer CHF-related hospitalizations, which accounted 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=1.04) compared to the comparison group, while those who received CMRs had lower odds of experiencing such a hospitalization (OR=0.95).

For PDPs, the odds of any all-cause ER visit were slightly lower for individuals who received MTM, with and without CMR. ER visits could not be measured for MA-PDs.

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

Part D Contract Type	*Intervention Group*	*N*	*Any (All-Cause) Hospitalization*	*Any CHF-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any CHF-Related ER Visit*
PDP	Comparison	156,441	---	---	---	---
	MTM without CMR	103,080	0.98 * (0.96 , 1.0)	1.04 * (1.01 , 1.06)	0.94 * (0.92 , 0.96)	1.03 (1.0 , 1.05)
	With CMR	12,658	0.90 * (0.86 , 0.94)	0.95 * (0.90 , 1.0)	0.94 * (0.90 , 0.98)	1.01 (0.95 , 1.07)
MA-PD	Comparison	51,938	---	---	---	---
	MTM without CMR	62,893	1.06 * (1.03 , 1.09)	1.17 * (1.13 , 1.21)	---	---
	With CMR	11,260	0.96 (0.91 , 1.02)	1.03 (0.97 , 1.09)	---	---

* 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 Resource Utilization Outcomes: Medications and Costs

After adjusting for covariates, individuals in PDP MTM programs – regardless of receipt of CMRs – took a greater number of medications, and showed inconsistent changes in medication, hospital, and ER costs. PDP medication results are in **Table 4-7** while PDP cost results are in **Table 4-8** and can be summarized as follows:

- **Number of Medications:** After adjusting for individuals' drug utilization during the one year preceding the index date, as well as other risk factors, individuals in PDPs who received MTM with and without CMR took a larger total number of medications in the outcome period.
- **Non-CHF Part D Costs:** Individuals enrolled in MTM programs also had higher adjusted non-CHF Part D costs in the outcome period.
- **Generic Substitution:** MTM without CMR was associated with a higher generic substitution ratio for CHF drugs, but a lower generic substitution ratio for non-CHF drugs.
- **All-Cause Hospital Costs:** Those enrolled in MTM programs who received a CMR had lower all-cause inpatient costs; $526 lower than the comparison group (or approximately $44 per enrollee per month in savings relative to their predicted costs without a MTM intervention).
- **All-Cause ER Costs:** Individuals with CMRs had all-cause ER costs of $11 less than the comparison group over the observation period, translating to ER-related cost savings of slightly less than $1 per member per month.
- **CHF-Related Hospitalization Costs:** For CHF participants who did not receive CMR, CHF-related hospitalization costs were $226 higher than those of the comparison group.

Medication results for individuals in the MA-PD MTM programs are also shown in **Table 4-7** while cost results are shown in **Table 4-8**. These can be summarized as follows:

- **Number of Medications:** Individuals who received MTM without CMR filled a lower total number of medications relative to the comparison group.
- **Generic Substitution Ratio:** Individuals who received MTM with and without CMR had higher rates of generic substitution for CHF drugs than the comparison group, but MTM enrollees had lower rates of generic substitution for non-CHF drugs.

- **Non-CHF Part D Costs:** MTM enrollees had higher adjusted Part D costs than the comparison group.

Table 4-7: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Medications (OLS Estimate with 95% CI)[a]

Part D Contract Type	*Intervention Group*	*N*	*Total Number of Medications*	*Generic Substitution Ratio for CHF Drugs*	*Generic Substitution Ratio for Non-CHF Drugs*
PDP	Comparison	156,441	---	---	---
	MTM without CMR	103,080	0.05 * (0.02 , 0.08)	0.002 * (0.002 , 0.003)	-.002 * (-.003 , -.001)
	With CMR	12,658	0.26 * (0.19 , 0.32)	0.001 (-0.000 , 0.002)	0.000 (-.002 , 0.002)
MA-PD	Comparison	51,938	---		---
	MTM without CMR	62,893	-0.08 * (-.11 , -.05)	0.001 * (0.000 , 0.002)	-0.005 * (-0.006 , -0.004)
	MTM With CMR	11,260	-0.03 (-0.09 , 0.04)	0.005 * (0.003 , 0.006)	-0.010 * (-0.013 , -0.008)

* 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.

Table 4-8: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Costs (OLS Estimate with 95% CI)[a]

Part D Contract Type	*Intervention Group*	*N*	*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*
PDP	Comparison	156,441	---	---	---	---	---
	MTM without CMR	103,080	$156.04 * (122.6 , 189.47)	$37.62 (-140.73 , 215.96)	$225.78* (77.36 , 374.19)	-$11.30* (-20.38 , -2.21)	-$0.07 (-5.84 , 5.71)
	With CMR	12,658	$87.05 * (7.33 , 166.78)	-$526.19* (-919.71 , -132.66)	-$222.08 (-525.99 , 81.82)	-$12.66 (-33.61 , 8.30)	-$3.17 (-14.59 , 8.25)
MA-PD	Comparison	51,938	---	---	---	---	---
	MTM without CMR	62,893	$74.77 * (27.43 , 122.11)	---	---	---	---
	MTM With CMR	11,260	$140.52 * (55.79 , 225.25)	---	---	---	---

* 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.

4.4.3 Resource Utilization Outcomes by Part D Organization

This section shows risk-adjusted resource utilization results for the studied Part D parent organizations. After stratifying the analyses by Part D organization and adjusting for all covariates, specific PDP Part D Organizations showed a positive association between MTM and reduced hospitalizations and ER visits.

- PDP results are shown in **Table 4-9** and can be summarized as follows:
    - **ER Visits: Organization A's** MTM without CMR recipients had lower odds of all-cause ER visits than the comparison group.
    - **Hospitalizations: Organization B**'s MTM program enrollees who received CMR had lower odds of all-cause hospitalizations.
    - **Generic Substitution:** Individuals in **Organizations A, B, and C** who did not receive CMR demonstrated higher rates of generic substitution of CHF drugs relative to their comparison groups, translating to 3%, 1%, and 10% increases in generic substitution, respectively. Individuals in **Organizations B** and **D** who received CMR also demonstrated higher rates of generic substitution of CHF drugs which translated to 2% and 3% increases in generic substitution over their comparison groups. MTM recipients in **Organization B** also showed greater rates of generic substitution of non-CHF drugs, equivalent to an increase of 7% for those who did not receive CMR and an increase of 11% for those who did receive CMR, relative to the comparison group.
- Results for MA-PDs are shown in **Table 4-10** and can be summarized as follows:
    - **Hospitalizations:** Those in **Organization A** receiving MTM with a CMR had lower odds of all-cause hospitalization. **Organization E's** MTM program enrollees without CMR also had significantly lower odds of all-cause hospitalization than the comparison group.
    - **Generic Substitution:** Individuals in **Organizations A** and **C** who did not receive CMRs demonstrated higher rates of generic substitution of CHF drugs relative to their comparison groups, translating to a 1% and 4% increase in generic substitution respectively.

- Individuals in **Organizations C** and **F** who did receive CMRs also demonstrated higher rates of generic substitution of CHF drugs, translating to 5% and 9% greater generic substitution respectively.

Table 4-9: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital and ER Visits, Generics, and Costs by PDP Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*N*	*Any (All-Cause) Hospitalization*	*Any (All-Cause) ER Visit*	*Generic Substitution Ratio for CHF Drugs*	*Generic Substitution Ratio for Non-CHF Drugs*	*Part D Total Drug Costs for Non-CHF Drugs*	*All-Cause Hospitalization Costs*	*All-Cause ER Costs*
Organization A	MTM without CMR	17,655	1.06 * (1.02 , 1.10)	0.95 * (0.91 , 0.98)	0.003 * (0.001 , 0.004)	-0.016 * (-0.019 , -0.014)	$238.04 * (166.81 , 309.27)	$305.81 (-110.86 , 722.47)	-$15.56 (-34.06 , 2.95)
	With CMR[b]	167	0.72 (0.52 , 1.01)	1.07 (0.77 , 1.49)	0.005 (-0.006 , 0.016)	-0.007 (-0.025 , 0.010)	-$99.58 (-698.49 , 499.33)	-$3160.05* (-4984.39, -1335.72)	-$27.60 (-143.44 , 88.24)
Organization B	MTM without CMR	15,850	0.97 (0.93 , 1.01)	0.84 * (0.80 , 0.87)	0.001 * (0.000 , 0.002)	0.007 * (0.005 , 0.009)	$100.25 * (31.17 , 169.32)	$351.15 (-46.88 , 749.19)	-$21.74 (-45.35 , 1.88)
	With CMR	4,048	0.87 * (0.82 , 0.94)	0.94 (0.88 , 1.01)	0.002 * (0.000 , 0.004)	0.011 * (0.008 , 0.014)	$109.53 (-8.87 , 227.94)	-$223.61 (-864.68 , 417.47)	-$5.36 (-39.99 , 29.27)
Organization C	MTM without CMR	14,736	1.01 (0.92 , 1.12)	1.10 (1.0 , 1.21)	0.010 * (0.007 , 0.013)	-0.002 (-0.007 , 0.002)	$274.54 * (110.74 , 438.33)	$705.58 (-95.61 , 1506.76)	$26.08 (-8.30 , 60.46)
	With CMR	339	0.88 (0.68 , 1.14)	1.0 (0.77 , 1.29)	0.007 (-0.000 , 0.015)	0.006 (-0.006 , 0.019)	$119.06 (-310.47 , 548.59)	$558.96 (-1372.64 , 2490.56)	$31.78 (-63.17 , 126.73)
Organization D	MTM without CMR	335	1.04 (0.81 , 1.32)	0.90 (0.71 , 1.15)	0.006 (-0.000 , 0.013)	-0.009 (-0.019 , 0.001)	$392.11 (-120.96 , 905.19)	$80.93 (-2429.21 , 2591.07)	$27.60 (-99.13 , 154.33)
	With CMR	6,791	0.98 (0.91 , 1.06)	0.85 * (0.79, 0.92)	0.003 * (0.001 , 0.005)	-0.011 * (-0.014 , -0.008)	$9.60 (-157.67 , 176.88)	-$180.41 (-982.77 , 621.95)	-$36.71 (-83.26 , 9.84)
Organization E	MTM without CMR	5,226	0.90 * (0.83 , 0.98)	0.93 (0.85 , 1.01)	0.000 (-0.002 , 0.001)	-0.003 * (-0.007 , -0.000)	$330.50 * (162.16 , 498.84)	-$892.53 (-1788.28 , 3.21)	-$15.10 (-57.92 , 27.72)
	With CMR	97	0.83 (0.53 , 1.30)	0.70 (0.45 , 1.10)	-0.003 (-0.014 , 0.008)	-0.013 (-0.031 , 0.004)	$295.18 (-603.55 , 1193.91)	-$4575.8* (-7984.47 , -1167.12)	$46.62 (-206.82 , 300.06)

* Indicates significance at the 5% level.

a. For each PDP Parent Organization, the number of individuals in the CHF comparison group was as follows- Organization A: 52,036, Organization B: 36,478, Organization C: 2,620, Organization D: 7,765, and Organization E: 6,723.

Table 4-10: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital Visits, Generics, and Costs by MA-PD Part D Organization (Odds Ratio with 95% CI)[a]

Part D Organization	*Intervention Group*[b]	*N*	*Any (All-Cause) Hospitalization*	*Generic Substitution Ratio for CHF Drugs*	*Generic Substitution Ratio for Non-CHF Drugs*	*Part D Total Drug Costs for Non-CHF Drugs*
Organization A	MTM without CMR	13,207	1.06 (0.99 , 1.12)	0.001 * (0.000 , 0.003)	-0.013 * (-0.016 , -0.010)	-$50.45 (-151.19 , 50.29)
	With CMR	179	0.69 * (0.48 , 0.97)	0.003 (-0.004 , 0.011)	-0.021 * (-0.038 , -0.004)	-344.95 (-905.61 , 215.72)
Organization B	MTM without CMR	330	1.10 (0.82 , 1.47)	0.000 (-0.007 , 0.006)	0.006 (-0.005 , 0.018)	-$161.56 (-602.81 , 279.69)
	With CMR	140	0.82 (0.53 , 1.26)	-0.004 (-0.014 , 0.005)	0.000 (-0.016 , 0.017)	$313.21 (-314.03 , 940.45)
Organization C	MTM without CMR	11,983	1.28 * (1.14 , 1.43)	0.004 * (0.001 , 0.006)	-0.005 (-0.010 , 0.000)	$67.54 (-89.50 , 224.59)
	With CMR	521	1.31 * (1.04 , 1.64)	0.005 * (0.000 , 0.010)	-0.007 (-0.017 , 0.003)	$3.85 (-311.85 , 319.56)
Organization D	MTM without CMR	35	1.61 (0.75 , 3.45)	0.004 (-0.013 , 0.023)	-0.02 (-0.06 , 0.02)	$601.82 (-730.11 , 1933.75)
	With CMR	651	0.99 (0.79 , 1.2)	0.001 (-0.004 , 0.006)	-0.014 * (-.024 , -.003)	$85.61 (-287.73 , 458.95)
Organization E	MTM without CMR	534	0.76 * (0.57 , 0.10)	0.001 (-0.004 , 0.007)	-0.001 (-0.012 , 0.008)	-$236.33 (-657.73 , 185.08)
	With CMR	18	0.36 (0.11 , 1.23)	0.003 (-0.020 , 0.026)	0.020 (-0.020 , 0.062)	-$128.28 (-1777.90 , 1521.33)
Organization F	MTM without CMR	4,003	1.14 * (1.0 , 1.26)	0.003 (-0.000 , 0.007)	-0.024 * (-0.030 , -0.019)	-$169.08 (-338.35 , 0.20)
	With CMR	5,897	1.04 (0.94 , 1.14)	0.009 * (0.005 , 0.012)	-0.026 * (-0.031 , -0.021)	$30.83 (-126.21 , 187.87)

* 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.

b. For each MA-PD Parent Organization, the number of individuals in the CHF comparison group was as follows - Organization A: 13,640, Organization B: 1,193, Organization C: 2,208, Organization D: 1,861, Organization E: 659, and Organization F: 4,164.

5 RESULTS: IMPACT OF MTM ON BENEFICIARIES WITH COPD

Beneficiaries with COPD who enrolled in MTM programs consistently experienced higher quality prescription drug therapies relative to the comparison group, but these outcomes did not consistently correspond to reductions in hospital and ER visits or associated costs during the one year outcome period. 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 Part D 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** and **5.4** then summarize the risk-adjusted results for drug therapies, resource utilization, and costs of our overall PDP, overall MA-PD, and Part D 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, 2,734,601 (10.9%) had COPD. Out of those individuals with COPD who were enrolled in PDPs, 184,350 were assigned to the comparison group, 110,042[a] to the MTM without CMR intervention group, and 16,372[b] to the MTM with CMR intervention group. For those enrolled in MA-PDs, 73,623 were assigned to the comparison group, 64,637[c] to the MTM without CMR intervention group, and 10,575[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), 13.0% of those in PDPs and 14.1% 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 prior to MTM enrollment as 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

[a] Of these, 6,401 opted out during the measurement period. All individuals who opted out were included in the analysis, based on the intention-to-treat analytical approach.
[b] Of these, 41 opted out during the measurement period.
[c] Of these, 6,445 opted out during the measurement period.
[d] Of these, 68 opted out during the measurement period.

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 (pre-MTM enrollment). The intervention and comparison groups for each of these Part D 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 in Study Cohorts by PDP and MA-PD Setting

Demographic and Health Characteristics	*Beneficiaries Enrolled in PDPs*			*Beneficiaries Enrolled in MA-PDs*		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	184,350	110,042	16,372	73,623	64,637	10,575
% in MTM Receiving CMR			8.9%			14.4%
Gender						
Male	35.3%	38.2%	30.8%	37.6%	43.3%	45.4%
Female	64.7%	61.8%	69.2%	62.4%	56.7%	54.6%
Age						
≤65	24.9%	23.1%	34.2%	17.9%	15.6%	10.1%
66-75	33.0%	35.7%	34.7%	37.3%	40.9%	38.8%
76-85	29.9%	30.7%	24.6%	34.0%	34.2%	40.1%
>85	12.2%	10.4%	6.5%	10.7%	9.2%	10.9%
Race						
White	86.1%	85.6%	81.4%	83.7%	84.4%	84.0%
Black	9.1%	9.1%	13.7%	10.1%	9.8%	9.3%
Hispanic	2.1%	2.1%	2.6%	2.9%	3.0%	2.9%
Other or Unknown	2.7%	3.2%	2.3%	3.2%	2.8%	3.8%
SES						
LIS Eligible	56.1%	54.1%	77.0%	41.7%	38.9%	25.0%
General Health Status in Observation Period						
≤8 Maintenance Drugs	28.7%	23.5%	11.5%	34.7%	30.3%	22.5%
9-10 Maintenance Drugs	25.9%	21.9%	19.1%	27.9%	22.8%	22.3%
11-12 Maintenance Drugs	19.7%	19.8%	21.9%	18.8%	19.3%	22.5%
>12 Maintenance Drugs	25.7%	34.9%	47.4%	18.6%	27.6%	32.7%
Disabled	27.1%	25.4%	37.1%	20.4%	18.0%	12.2%
Specific Health Conditions						
Diabetes	41.4%	52.6%	56.7%	38.5%	56.6%	56.1%
Dyslipidemia	37.9%	37.9%	40.2%	33.8%	38.2%	40.9%
Rheumatoid Arthritis	53.8%	53.9%	53.0%	56.4%	54.4%	53.0%
Specific Health Conditions						
AMI & Unstable Angina	70.0%	73.7%	72.0%	70.0%	78.9%	80.5%
Stroke & Cerebral Hemorrhage	6.8%	4.8%	6.7%	6.6%	4.3%	4.2%

Demographic and Health Characteristics	*Beneficiaries Enrolled in PDPs*			*Beneficiaries Enrolled in MA-PDs*		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
Specific Health Conditions						
Hypertension & Heart Failure	49.9%	51.7%	50.2%	44.6%	51.9%	50.6%
Vascular Disease	21.7%	20.6%	18.8%	19.2%	20.3%	18.0%

5.2 Baseline Demographic and Health Characteristics of MTM Enrollees and Controls

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 one year preceding their study periods, i.e. prior to enrolling in MTM. 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 intervention group who eventually enrolled in MTM programs and chose to receive a CMR were more likely to be adherent to their evidence-based COPD medications prior to MTM enrollment as 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 – before enrolling in MTM were also more likely to choose to receive a CMR once they enrolled in an MTM program (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 safety problems including drug-drug interactions and use of high-risk medications in the observation period prior to MTM enrollment. Further, they were more likely to experience all-cause and COPD-related hospitalizations in that period. The proportion of individuals experiencing a hospitalization due to any cause in the one year preceding the outcome period ranged from 44.4% (comparison group) to 46.1% (MTM without CMR) for those in PDPs, and slightly lower at 33.8% (comparison group) to 39.0% (MTM without CMR) for those in MA-PDs. These differences imply that MTM programs were generally effective in targeting individuals who had issues with their complex medication regimens preceding MTM enrollment. Additional analysis of differences between MTM enrollees and the overall Medicare Part D population is discussed in **Section 8.2**.

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

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	184,350	110,042	16,372	73,623	64,637	10,575
Drug Therapy						
Adherence						
Adherent to LABAs	16.1%	16.7%	22.0%	18.4%	13.5%	14.9%
Adherent to LAACs	23.3%	20.9%	23.4%	24.3%	17.9%	21.0%
Adherent to LABA + LAAC Combination Regimen	10.7%	10.9%	14.0%	12.1%	8.2%	8.7%
Drug Safety						
At Least One Drug-Drug Interaction	12.9%	15.0%	17.3%	10.2%	12.2%	11.0%
Use of at Least One High Risk Medication	46.0%	47.0%	53.1%	38.6%	40.2%	35.8%
Resource Utilization: Hospital and ER Visits						
Any (All-Cause) Hospitalization	44.4%	46.1%	46.0%	33.8%	39.0%	35.8%
Any COPD-Related Hospitalization	29.4%	31.9%	33.6%	21.8%	25.2%	23.8%
Any (All-Cause) ER Visit	44.1%	42.3%	47.6%	---	---	---
Any COPD-Related ER Visit	18.0%	18.4%	22.6%	---	---	---
Resource Utilization: Medications and Costs (Average)[a]						
Number of Medications	17.36	17.86	20.33	15.76	15.96	16.45
Generic Substitution Ratio	66.9%	69.4%	69.9%	70.1%	72.5%	74.5%
Part D Costs for Non-COPD Drugs	$6,380.38	$5,662.91	$7,197.64	$5,103.86	$4,230.15	$4,090.44
All-Cause Hospitalization Costs	$7,837.56	$8,548.15	$7,904.05	---	---	---
COPD-Related Hospitalization Costs	$3,884.81	$4,483.00	$4,588.34	---	---	---
All-Cause ER Costs	$452.13	$419.90	$495.04	---	---	---
COPD-Related ER Costs	$151.31	$157.85	$192.22	---	---	---

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 MTM Effects on Drug Therapy Outcomes for COPD Patients

The empirical association between MTM and medication adherence was generally positive, particularly for the PDP cohorts; further, the magnitude of that impact was usually greater for individuals receiving MTM with CMR compared to those who did not receive CMRs. In other words, PDP results 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. By contrast, there was no evidence of a positive association between MTM enrollment and drug safety outcomes. The following two sections provide the risk-adjusted results for overall PDP and MA-PD groups and stratified by Part D organization.

5.3.1 Drug Therapy Outcomes

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 association of MTM with improved adherence to a combination regimen increased for participants with CMRs. However, in most cases 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. Additionally, there was no positive association between MTM enrollment and either drug safety outcome of interest. There was also no significant association between MTM enrollment and removing drug-drug interactions, and individuals who received MTM with CMR in PDPs were slightly less likely to discontinue high-risk medications.

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

Part D Contract Type	*Intervention Group*	*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*
PDP	Comparison	184,350	---	---	---	---	---
	MTM without CMR	110,042	1.22 * (1.16 , 1.29)	1.14 * (1.05 , 1.24)	1.26 * (1.18 , 1.35)	0.96 (0.90 , 1.04)	1.00 (0.97 , 1.03)
	With CMR	16,372	1.26 * (1.14 , 1.40)	1.36 * (1.12 , 1.65)	1.43 * (1.26 , 1.62)	0.92 (0.79 , 1.07)	1.06 (0.99 , 1.13)
MA-PD	Comparison	73,623	---	---	---	---	---
	MTM without CMR	64,637	1.06 (0.98 , 1.15)	1.06 (0.95 , 1.18)	1.11 * (1.01 , 1.23)	1.03 (0.91 , 1.16)	0.94 * (0.90 , 0.98)
	With CMR	10,575	1.11 (0.95 , 1.29)	1.01 (0.83 , 1.24)	1.20 (1.00 , 1.44)	1.11 (0.89 , 1.38)	1.00 (0.92 , 1.09)

* Indicates significance at the 5% level.

5.3.2 Drug Therapy Outcomes by Part D Organization

After stratifying the analyses by Part D organization and adjusting for all covariates, the association between MTM and adherence was consistently positive.

- PDPs results are shown in **Table 5-4** and can be summarized as follows:
    - **Quality of Prescribing: Organization B** and **E's** MTM enrollees with and without CMR improved their adherence to evidence-based medications for COPD (LABA-only, LAAC-only, and/or combination therapy regimens) during the outcome period, relative to their comparison groups. **Organization D**'s MTM enrollees with CMR also improved their adherence to the LABA-only and LAAC-only regiments. MTM enrollees in **Organization E** showed the highest odds of adherence relative to the comparison group for all medication regimens (MTM without CMR: OR= 2.15-3.11, depending on the regimen in question; MTM with CMR: OR=4.76-4.89.)
- MA-PDs results are shown in **Table 5-5** and can be summarized as follows:
    - **Quality of Prescribing:** MTM enrollees in **Organizations A, D, and E** improved their LABA-only, LAAC-only, and/or combination therapy regimens for COPD during the outcome period, relative to their comparison groups.
    - **Drug Safety:** MTM enrollees in **Organization F** who received CMR experienced lower-odds of high-risk medication use (OR=0.81) relative to their comparison groups.

Table 5-4: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD by PDP Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*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	1.07	0.78 *	1.20	1.31 *	1.03
		(0.89 , 1.28)	(0.62 , 1.0)	(0.95 , 1.50)	(1.14 , 1.51)	(0.97 , 1.10)
	With CMR	1.05	2.13	1.76	2.94 *	0.67
		(0.20 , 5.65)	(0.51 , 8.96)	(0.29 , 10.58)	(1.25 , 6.91)	(0.38 , 1.18)
Organization B	MTM without CMR	1.43 *	1.12	1.37 *	1.03	1.01
		(1.265 , 1.61)	(0.93 , 1.36)	(1.19 , 1.58)	(0.92 , 1.16)	(0.96 , 1.06)
	With CMR	1.31 *	1.23	1.67 *	1.01 *	1.00
		(1.12 , 1.54)	(0.86 , 1.75)	(1.39 , 2.01)	(0.84 , 1.20)	(0.93 , 1.09)
Organization C	MTM without CMR	0.78	0.94	0.84	1.23	0.83*
		(0.59 , 1.03)	(0.66 , 1.35)	(0.56 , 1.27)	(0.85 , 1.79)	(0.75 , 0.93)
	With CMR	0.52	0.99	0.46	1.82	0.65*
		(0.17, 1.56)	(0.30 , 3.25)	(0.06 , 3.48)	(0.72 , 4.58)	(0.44 , 0.96)
Organization D	MTM without CMR	1.32	1.84	1.00	1.16	1.97 *
		(0.72 , 2.41)	(0.75, 4.50)	(0.45 , 2.21)	(0.64 , 2.11)	(1.46 , 2.65)
	With CMR	1.50 *	1.80 *	1.27	1.02	1.16 *
		(1.20 , 1.88)	(1.25 , 2.58)	(0.96 , 1.69)	(0.78 , 1.33)	(1.04 , 1.31)
Organization E	MTM without CMR	2.16 *	2.79 *	3.11 *	0.98	1.08
		(1.71 , 2.72)	(1.80 , 4.32)	(2.31 , 4.18)	(0.74 , 1.29)	(0.97 , 1.21)
	With CMR	4.76 *	5.70	4.89 *	1.31	0.72
		(1.30 , 17.40)	(0.09 , 342.29)	(1.67 , 14.37)	(0.41 , 4.19)	(0.39 , 1.32)

* Indicates significance at the 5% level.

a. For each PDP Parent Organization, the number of individuals in the COPD comparison group was as follows- Organization A: 68,455, Organization B: 33,777, Organization C: 4,842, Organization D: 9,552, and Organization E: 9,475.

Table 5-5: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD by MA-PD Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*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	0.92	1.05	0.99	1.0	1.15 *
		(0.74 , 1.15)	(0.79 , 1.41)	(0.75 , 1.29)	(0.80 , 1.24)	(1.05 , 1.26)
	With CMR	0.61	5.80 *	4.63 *	0.71	0.79
		(0.11 , 3.50)	(1.37 , 24.51)	(1.52 , 14.09)	(0.22 , 2.32)	(0.46 , 1.34)
Organization B	MTM without CMR	1.80	1.00	0.01	0.63	0.96
		(0.60 , 5.34)	(1.00 , 1.00)	(0.01 , 0.01)	(0.24, 1.65)	(0.70 , 1.31)
	With CMR	2.17	0.00	0.00	2.14	0.95
		(0.64 , 7.36)	(0.00,0.00)	(0.00,0.00)	(0.63 , 7.21)	(0.62 , 1.44)
Organization C	MTM without CMR	1.18	0.88	1.02	1.25	1.06
		(0.90 , 1.55)	(0.57 , 1.36)	(0.70 , 1.49)	(0.82 , 1.90)	(0.94 , 1.19)
	With CMR	1.23	1.1	2.79*	1.31	0.97
		(0.60 , 2.54)	(0.37 , 3.26)	(1.04 , 7.50)	(0.63 , 2.72)	(0.74 , 1.26)
Organization D	MTM without CMR	17.29	0.03	1.00	5.63	1.08
		(0.50 , 594.26)	(0.00 , 24.87)	(1.00 , 1.00)	(0.52 , 61.09)	(0.36 , 3.3)
	With CMR	0.89	430.28 *	2.50*	0.95	1.30*
		(0.35 , 2.31)	(5.06 , 36583.42)	(1.05 , 5.95)	(0.41 , 2.22)	(0.95 , 1.77)
Organization E	MTM without CMR	2.92 *	0.00	0.00	0.91	1.52*
		(1.21 , 7.04)	(0.00,0.00)	(0.00, 0.00)	(0.32 , 2.60)	(1.04 , 2.22)
	With CMR	85.03 *	1.00	1.00	5.97	1.00
		(4.55 , 1587.86)	(1.00 , 1.00)	(1.00 , 1.00)	(0.40 , 89.65)	(0.27 , 3.67)
Organization F	MTM without CMR	0.91	0.80	0.95	1.13	1.25*
		(0.69 , 1.20)	(0.56 , 1.14)	(0.66 , 1.35)	(0.73 , 1.75)	(0.02 , 1.53)
	With CMR	0.929	0.76	0.81	0.78	0.81*
		(0.72 , 1.20)	(0.55 , 1.04)	(0.59 , 1.11)	(0.52 , 1.19)	(0.66 , 0.98)

* Indicates significance at the 5% level.

a. For each PDP Parent Organization, the number of individuals in the COPD comparison group was as follows- Organization A: 68,455, Organization B: 33,777, Organization C: 4,842, Organization D: 9,552, and Organization E: 9,475.

5.4 MTM Effects on Resource Utilization Outcomes for COPD Patients

Across all PDP and MA-PD cohorts, individuals enrolled in MTM programs had higher rates of hospitalization and ER use during the one year 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 suggest that individuals who received MTM interventions – regardless of receipt of CMR – had consistently reduced odds of experiencing hospitalizations and ER visits. Similarly, MTM recipients showed only slight differences in their cost outcomes compared to the PDP comparison group. Results were varied at the Part D organization level. The following three sections provide the risk-adjusted results for overall PDP and MA-PD groups and stratified by Part D organization. **Section 5.4.1** provides overall results for hospital and ER visits, while **Section 5.4.2** discusses the overall results for medications and costs, and **Section 5.4.3** presents Part D organization results.

5.4.1 Resource Utilization Outcomes: Hospital and ER Visits

During the outcome period, individuals in PDP and MA-PD MTM programs showed inconsistent trends in their rates of hospitalizations and ER visits relative to the comparison group. Rates of all-cause hospitalization and ER visits were sometimes lower for MTM enrollees; however, rates of COPD-related hospitalizations and ER visits were higher (see **Table 5-6**.)

As an example of the inconsistent direction of association between MTM and resource utilization, beneficiaries enrolled in PDP MTM programs who received a CMR had lower odds of all cause hospitalization (OR=0.90), and all-cause ER visits (OR=0.89); however, they experienced higher odds of a COPD-related ER visit (OR=1.09) relative to the comparison group. Individuals enrolled in MA-PDs who received CMRs had lower odds of COPD-related hospitalizations (OR=0.91); however, those enrolled in MTM who did not receive a CMR had higher odds of both COPD-related hospitalizations and all-cause hospitalizations (ORs = 1.07 and 1.06, respectively).

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

Part D Contract Type	*Intervention Group*	*N*	*Any (All-Cause) Hospitalization*	*Any COPD-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any COPD-Related ER Visit*
PDP	Comparison	184,350	---	---	---	---
	MTM without CMR	110,042	0.98 (0.96, 1.00)	1.03 * (1.01 , 1.05)	0.96 * (0.94 , 0.97)	1.03 * (1.0 , 1.06)
	With CMR	16,372	0.90 * (0.87 , 0.94)	1.04 (0.99 , 1.08)	0.89 * (0.86 , 0.93)	1.09 * (1.04 , 1.15)
MA-PD	Comparison	73,623	---	---	---	---
	MTM without CMR	64,637	1.07 * (1.05 , 1.10)	1.06 * (1.03 , 1.10)	---	---
	With CMR	10,575	0.96 (0.91 , 1.01)	0.91 * (0.86 , 0.97)	---	---

* 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 Resource Utilization Outcomes: Medications and Costs

After adjusting for covariates, individuals in PDP MTM programs – regardless of receipt of CMRs – showed increases in their non-COPD Part D costs, and inconsistent differences in their hospital and ER costs compared to the PDP comparison group. PDP medication results are shown in **Table 5-7** while PDP costs results are shown in **Table 5-8**. These PDP outcomes can be summarized as follows:

- **Number of Medications:** Individuals enrolled in PDPs took more medications if they were enrolled in an MTM program, regardless of receipt of a CMR.
- **Generic Substitution Ratio:** Those enrolled in MTM programs had lower average generic substitution ratios. Please note that individuals in both 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 without CMR accrued higher overall Part D costs of $106 over the twelve-month outcome period.
- **ER Costs:** Individuals in MTM without CMR cost $11 less in ER visits relative to the comparison group during the outcome period.

Medication-related results for individuals in MA-PD MTM programs are also shown in **Table 5-7** while cost results are shown in **Table 5-8.** MA-PD results can be summarized as follows:

- **Number of Medications:** Individuals enrolled in MA-PDs took more medications if they were enrolled in MTM without CMR, but took fewer medications if they were enrolled in an MTM program and received a CMR.
- **Generic Substitution Ratio:** Those enrolled in MTM programs had higher average generic substitution ratios for non-COPD drugs (0.06% more fills of generic drugs with CMR and .04% more fills without CMR over the twelve-month outcome period) relative to the comparison group. 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 with and without CMR accrued higher non-COPD Part D total prescription drug costs relative to the comparison group.

Table 5-7: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Medications (OLS Estimate with 95% CI)[a]

Part D Contract Type	*Comparison or Intervention Group Assignment*	*N*	*Total Number of Medications*	*Generic Substitution Ratio for COPD Drugs*	*Generic Substitution Ratio for Non-COPD Drugs*
PDP	Comparison	184,350	---	---	---
	MTM without CMR	110,042	0.12 * (0.09 , 0.14)	-.001 * (-0.002 , -0.000)	0.000 (-0.001 , 0.000)
	With CMR	16,372	0.36 * (0.30 , 0.42)	-0.001 (-0.003 , 0.000)	0.000 (-0.001 , 0.003)
MA-PD	Comparison	73,623	---	---	---
	MTM without CMR	64,637	-0.07 * (-0.11 , -0.04)	-0.001 (-.002 , 0.000)	0.004 * (0.002 , 0.005)
	With CMR	10,575	0.06 * (0.00 , 0.12)	0.000 (-.002 , 0.002)	0.006 * (0.003 , 0.009)

* 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.

Table 5-8: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Costs (OLS Estimate with 95% CI)[a]

Part D Contract Type	*Intervention Group*	*N*	*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*
PDP	Comparison	184,350	---	---	---	---	---
	MTM without CMR	110,042	$106.45 * (74.41 , 138.48)	$72.14 (-86.74 , 231.01)	$83.79 (-34.79, 202.36)	-$11.26* (-20.03 , -2.5)	$1.06 (-5.04 , 7.15)
	With CMR	16,372	$42.55 (-28.12 , 113.22)	-$249.70 (-574.03 , 74.62)	$200.21 (-55.81, 456.23)	-16.21 (-35.37 , 2.96)	$12.81 (-.14 , 25.76)
MA-PD	Comparison	73,623	---	---	---	---	---
	MTM without CMR	64,637	$97.34 * (56.50 , 138.19)	---	---	---	---
	With CMR	10,575	$95.45 * (18.88 , 172.02)	---	---	---	---

*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.

5.4.3 Resource Utilization Outcomes by Part D Organization

After stratifying the analyses by Part D organization and adjusting for all covariates, some positive hospital and ER visit, and medication and cost outcomes arose for specific Part D parent organizations.

- Results for PDPs are shown in **Table 5-9** and can be summarized as follows:
    - **Hospitalizations:** Individuals in **Organization A** who did not receive CMR had lower rates of COPD-related hospitalizations, while individuals who did receive CMR had lower rates of all-cause hospitalization. **Organization E**'s MTM programs without CMR had lower rates of all-cause and COPD-specific hospital visits.
    - **ER Visits:** Individuals in **Organization A** and **E**'s MTM programs without CMR had lower odds of COPD-related ER visits relative to the comparison group.
    - **Generic Substitution:** Individuals in **Organization C** demonstrated higher rates of generic substitution relative to their comparison groups, translating to a 2.5% increase in generic substitution among individuals without CMRs and 3.0% for individuals who received CMRs.
    - **Non-COPD Part D Costs:** Those enrolled in **Organization C**'s MTM programs had lower Part D costs for non-COPD medications.
    - **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** and **E**'s MTM programs who received CMRs cost $3,761 and $4,683 less than the comparison group on all-cause hospitalizations, respectively. CMR recipients in **Organization A** accrued $124 less in all-cause ER costs over the twelve-month observation period.
- Results for MA-PDs are shown in **Table 5-10** and can be summarized as follows:
    - **Hospitalizations:** Those enrolled in **Organization F**'s MTM programs with and without CMR had lower odds of COPD-specific hospitalizations relative to the comparison group.
    - **Generic Substitution:** Individuals in **Organization C** who did not receive a CMR showed a higher rate of generic substitution of 1.7%.

Table 5-9: Risk-Adjusted Resource Utilization for Individuals with COPD: Hospital and ER Visits for PDP Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group* [a]	*N*	*Any (All-Cause) Hospitalization*	*Any (All-Cause) ER Visit*	*Generic Substitution Ratio for COPD Drugs*	*Generic Substitution Ratio for Non-COPD Drugs*	*Total Part D Costs for Non-COPD Drugs*	*All-Cause Hospitalization Costs*	*All-Cause ER Costs*
Organization A	MTM without CMR	11,491	1.04 (0.99 , 1.09)	1.01 (0.97 , 1.06)	0.001 (-0.001 , 0.004)	-0.004 * (-0.008 , -0.002)	$217.34 * (135.12 , 299.56)	$532.91* (109.4 , 956.43)	-$7.87 (-26.87 , 11.13)
	With CMR	118	0.65 * (0.43 , 0.98)	1.04 (0.70 , 1.55)	0.004 (-0.021 , 0.030)	0.004 (-0.003 , 0.006)	$144.89 (-571.83 , 861.61)	-$3761.73* (-5659.58 , -1863.89)	-$124.12* (-212.03 , -36.22)
Organization B	MTM without CMR	24,526	0.95 * (0.92 , 0.99)	0.87 * (0.84 , 0.90)	-0.001 (-0.003 , 0.001)	-0.002 * (-0.004 , -0.000)	$50.33 (-11.24 , 111.90)	$86.72 (-248.08 , 421.52)	-$25.24* (-45.28 , -5.2)
	With CMR	6,454	0.87 * (0.82 , 0.93)	0.85 * (0.80 , 0.90)	-0.001 (-0.004 , 0.001)	0.000 (-.002 , 0.003)	-$8.57 (-107.52 , 90.38)	-$401.39 (-897.6 , 94.83)	-$29.18* (-58.25 , -.11)
Organization C	MTM without CMR	14,167	1.15 * (1.06 , 1.24)	1.11 * (1.03 , 1.20)	-0.001 (-.005 , 0.003)	0.025 * (0.019 , 0.032)	-$294.54 * (-413.00 , -176.07)	$718.20* (123.72 , 1312.68)	$17.39 (-11.56 , 46.35)
	With CMR	291	0.83 (0.63 , 1.09)	0.92 (0.70 , 1.20)	-0.014 (-0.031 , 0.002)	0.030 * (0.009 , 0.052)	-$483.75 * (-890.88 , -76.62)	-$493.83 (-2227.71 ,1240.05)	$0.53 (-101.99 , 103.06)
Organization D	MTM without CMR	413	1.15 (0.92, 1.43)	1.19 (0.95 , 1.49)	-0.001 (-0.012 , 0.010)	0.010 (-0.001 , 0.022)	$270.89 (-183.48 , 725.25)	$2807.72* (310.35 , 5305.09)	$16.90 (-90.870 , 124.68)
	With CMR	8,187	0.98 (0.91 , 1.05)	0.81 * (0.75 , 0.87)	0.000 (-0.003 , 0.004)	-0.002 (-0.006 , 0.002)	$79.51 (-70.35 , 229.37)	$783.37* (146.16 , 1420.58)	-$36.95 (-78.790 , 4.89)
Organization E	MTM without CMR	4,895	0.87 * (0.80 , 0.95)	0.94 (0.86 , 1.02)	0.003 (-0.000 , 0.007)	0.002 (-0.002 , 0.007)	$420.20* (279.25 , 561.15)	-$529.65 (-1300.89 , 241.59)	$3.55 (-38.28 , 45.37)
	With CMR	101	0.66 (0.43 , 1.03)	1.01 (0.66 , 1.55)	0.001 (-0.022 , 0.024)	-.034* (-0.060 , -0.009)	$524.21 (-236.48 , 1284.91)	-$4683.35* (-6561.28 , -2805.43)	$6.83 (-215.83 , 229.48)

* Indicates significance at the 5% level.

a. For each PDP Parent Organization, the number of individuals in the COPD comparison group was as follows- Organization A: 68,455, Organization B: 33,777, Organization C: 4,842, Organization D: 9,552, and Organization E: 9,475.

Table 5-10: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Hospital Visits for MA-PD Part D Organization (Odds Ratio with 95% CI)[a]

Part D Organization	*Intervention Type*[b]	*N*	*Any (All-Cause) Hospitalization*	*Generic Substitution Ratio for COPD Drugs*	*Generic Substitution Ratio for Non-COPD Drugs*	*Part D Total Drug Costs for Non-COPD Drugs*
Organization A	MTM without CMR	10,212	1.12 * (1.06 , 1.19)	0.000 (-0.003 , 0.002)	-0.002 (-0.006 , 0.001)	30.16 (-61.80 , 122.12)
	With CMR	132	0.82 (0.56 , 1.23)	-0.002 (-0.025 , 0.019)	0.003 (-0.024 , 0.030)	192.53 (-423.70 , 808.77)
Organization B	MTM without CMR	522	1.25 (0.97 , 1.61)	0.002 (-0.010 , 0.014)	-0.006 (-0.021 , 0.007)	-322.90 (-688.17 , 42.37)
	With CMR	230	1.20 (0.85 , 1.69)	-0.001 (-0.017 , 0.013)	0.001 (-0.016 , 0.020)	-200.47 (-695.13 , 294.19)
Organization C	MTM without CMR	14,834	1.23 * (1.13 , 1.35)	-0.003 (-0.008 , 0.001)	0.017 * (0.011 , 0.023)	299.91 * (195.06 , 404.76)
	With CMR	654	1.09 (0.89 , 1.33)	0.001 (-0.011 , 0.014)	0.009 (-0.006 , 0.024)	218.37 (-26.16 , 462.91)
Organization D	MTM without CMR	30	1.27 (0.56 , 2.86)	-0.006 (-0.052 , 0.039)	0.028 (-0.027 , 0.083)	263.77 (-1180.60 , 1708.14)
	With CMR	701	1.07 (0.86 , 1.32)	0.007 (-0.004 , 0.020)	0.003 (-0.012 , 0.018)	232.59 (-133.51 , 598.67)
Organization E	MTM without CMR	495	1.06 (0.81 , 1.38)	-0.003 (-0.020 , 0.013)	0.002 (-0.013 , 0.019)	372.29 (-38.04 , 782.62)
	With CMR	22	0.67 (0.23 , 1.93)	-0.014 (-0.077 , 0.048)	-0.017 (-0.078 , 0.042)	376.41 (-1183.16 , 1935.98)
Organization F	MTM without CMR	3,214	1.11 * (1.00 , 1.23)	-0.003 * (-0.006 , -0.000)	0.000 (-0.004 , 0.005)	78.19 (-52.00 , 208.39)
	With CMR	4,721	0.96 (0.88 , 1.05)	-0.002 (-0.004 , 0.000)	0.001 (-0.003 , 0.005)	109.00 (-6.74 , 224.75)

* 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.

b. For each MA-PD Parent Organization, the number of individuals in the comparison group for the COPD cohort were as follows- Organization A: 23,206, Organization B: 1,243, Organization C: 4,339, Organization D: 1,968, Organization E: 1,072, and Organization F: 8,007.

6 RESULTS: IMPACT OF MTM ON BENEFICIARIES WITH DIABETES

Beneficiaries with diabetes who enrolled in MTM programs consistently demonstrated improvements to adherence and quality of their prescription drug therapies relative to the comparison group, and individuals receiving MTM with CMR also experienced consistent reductions in hospitalizations. Relative to the comparison group, individuals who were enrolled in PDP MTM programs with CMR saved $399 in all-cause hospital costs in the outcome period, $363 of which were attributed to diabetes-related hospitalizations. Additionally, MTM enrollees experienced consistent increases in Part D drug costs with improved adherence and drug therapy improvements. This section provides the results of the retrospective cohort study comparing risk-adjusted outcomes among beneficiaries with diabetes 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 Part D organizations. **Sections 6.1** and **6.2** 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 6.3** and **6.4** then summarize the risk-adjusted results for drug therapy and resource utilization from the overall and Part D parent organization analyses.

6.1 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, 3,783,682 (12.7%) had diabetes. Out of those individuals with diabetes who were enrolled in PDPs, 133,925 were assigned to the comparison group, 149,803[a] to the MTM without CMR intervention group, and 16,545[b] to the MTM with CMR intervention group. For those enrolled in MA-PDs, 53,912 were assigned to the comparison group, 95,299[c] to the MTM without CMR intervention group, and 13,527[d] to the MTM with CMR intervention group. In other words, for beneficiaries with diabetes 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), 9.9% of those in PDPs and 12.4% of those in MA-PDs received a CMR.

As shown in **Table 6-1,** the intervention and comparison groups for beneficiaries enrolled in PDPs varied in terms of distributions of age, race, socio-economic status, and rates of disability as a reason for Medicare enrollment. However, all three groups (comparison, MTM

[a] Of these, 10,172 opted out during the measurement period. All individuals who opted out were included in the analysis, based on the intention-to-treat analytical approach.
[b] Of these, 39 opted out during the measurement period.
[c] Of these, 8,073 opted out during the measurement period.
[d] Of these, 71 opted out during the measurement period.

without CMR, and MTM with CMR) tended to have a relatively similar prevalence of claims for most health conditions in the pre-MTM enrollment observation period, excluding asthma & COPD. In comparison to all PDP groups, those in the MA-PD groups tended to have comparable rates of claims for specific health conditions preceding MTM enrollment but took fewer maintenance drugs at baseline.

Table 6-1: Demographic and Health Characteristics of Individuals with Diabetes in Study Cohorts by PDP and MA-PD Setting

Demographic and Health Characteristics	*Beneficiaries Enrolled in PDPs*			*Beneficiaries Enrolled in MA-PDs*		
	Comparison	*MTM without CMR*	*MTM with CMR*	*Comparison*	*MTM without CMR*	*MTM with CMR*
N	133,925	149,803	16,545	53,912	95,299	13,527
% in MTM Receiving CMR			9.9%			12.4%
Gender						
Male	39.1%	40.6%	31.2%	42.2%	43.6%	46.7%
Female	60.9%	59.4%	68.8%	57.8%	56.4%	53.3%
Age						
≤65	22.2%	16.5%	28.6%	14.7%	13.2%	8.9%
66-75	37.6%	40.1%	36.1%	43.9%	45.8%	45.5%
76-85	30.5%	33.4%	27.8%	33.4%	33.4%	37.6%
>85	9.7%	10.0%	7.6%	8.0%	7.6%	8.0%
Race						
White	77.3%	80.7%	76.3%	72.2%	76.5%	75.1%
Black	13.7%	10.6%	16.2%	16.5%	12.9%	12.4%
Hispanic	3.7%	3.0%	3.9%	4.6%	5.0%	4.2%
Other or Unknown	5.3%	5.7%	3.6%	6.6%	5.6%	8.3%
SES						
LIS Eligible	56.4%	42.8%	68.0%	36.5%	36.1%	22.5%
General Health Status in Observation Period						
≤8 Maintenance Drugs	29.0%	29.7%	16.8%	33.0%	34.7%	27.6%
9-10 Maintenance Drugs	34.0%	27.9%	26.6%	35.7%	27.8%	28.1%
11-12 Maintenance Drugs	19.4%	20.5%	24.0%	18.2%	19.7%	22.4%
>12 Maintenance Drugs	17.6%	21.9%	32.6%	13.1%	17.8%	22.0%
Disabled	24.3%	18.3%	31.0%	16.7%	15.3%	10.7%
Specific Health Conditions						
Hypertension & Heart Failure	91.0%	90.9%	91.7%	91.3%	92.2%	94.2%
Dyslipidemia	77.0%	79.2%	76.3%	79.2%	82.6%	85.6%
Rheumatoid Arthritis	3.9%	3.2%	5.2%	3.9%	2.8%	2.9%
Specific Health Conditions						
AMI & Unstable Angina	39.4%	40.7%	39.5%	36.9%	39.6%	40.7%
Stroke & Cerebral Hemorrhage	16.6%	16.7%	15.4%	15.8%	15.4%	15.1%
Vascular Disease	20.9%	20.1%	20.3%	22.7%	22.0%	23.1%
Asthma & COPD	29.0%	25.9%	33.9%	31.2%	25.6%	27.9%

6.2 Baseline Demographic and Health Characteristics of MTM Enrollees and Controls

Table 6-2 below provides baseline rates of drug therapy outcomes, use of the hospital and ER, and healthcare costs among the PDP and MA-PD intervention and comparison groups in the 12 months preceding their study periods. It displays unadjusted outcomes in the one-year observation period and shows how individuals in the intervention groups differed from the comparison groups before any MTM services were rendered.

Differences across the intervention and comparison groups provide insights into MTM programs' abilities to identify beneficiaries with poor outcomes. MTM enrollees had higher rates of hospital and ER use and correspondingly higher costs during the baseline period. Such differences imply that MTM programs effectively targeted individuals who were having difficulty managing their health conditions prior to MTM enrollment. A discussion of differences between MTM enrollees and the overall Medicare Part D population is discussed in **Section 8.2**. **Table 6-2** also illustrates the differences in medication adherence between future MTM enrollees and the comparison group. Individuals in the PDP and MA-PD intervention groups were more likely to be adherent to medication regimens and to take other recommended medications such as ACEi/ARBs and statins before they received MTM services, and this effect was particularly pronounced for individuals who received CMRs. This illustrates the "healthy user effect:" individuals who were already inclined to be adherent to their medications, for example, were those who chose to receive a CMR once they enrolled in an MTM program.

Table 6-2: 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	133,925	149,803	16,545	53,912	95,299	13,527
Drug Therapy						
Adherence						
Adherent to Diabetes Medications	83.2%	85.0%	87.2%	83.5%	84.1%	88.5%
Adherent to Biguanides Medications	73.4%	76.2%	78.4%	73.1%	74.1%	78.9%
Adherent to DPP-IV Inhibitors Medications	72.7%	74.8%	80.3%	68.0%	66.1%	69.3%
Adherent to Sulfonylureas Medications	76.7%	78.7%	81.1%	76.4%	77.3%	80.8%
Adherent to Thiazolidinediones Medications	72.1%	73.4%	77.6%	68.1%	68.9%	74.8%
Quality of Prescribing						
Use of ACE Inhibitor or ARB Medication	62.0%	67.5%	68.7%	64.7%	70.9%	78.2%
Use of Statin Medication	71.6%	81.8%	76.5%	74.7%	84.7%	87.3%

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*
Resource Utilization: Hospital and ER Visits						
Any (All-Cause) Hospitalization	27.0%	27.8%	29.1%	21.1%	22.8%	22.2%
Any Diabetes-Related Hospitalization	23.5%	24.0%	24.8%	18.6%	20.0%	19.4%
Any (All-Cause) ER Visit	32.5%	29.7%	35.9%	---	---	---
Any Diabetes-Related ER Visit	22.1%	19.6%	24.4%	---	---	---
Resource Utilization: Medications and Costs (Average)						
Number of Medications	14.9	14.8	16.9	13.9	13.6	14.2
Generic Use Ratio for Non-Diabetes Drugs	91.6%	92.0%	93.2%	92.5%	93.3%	91.5%
Part D Costs for Non-Diabetes Drugs	$5,020	$4,479	$5,864	$4,152	$3,567	$3,560
All-Cause Hospitalization Costs	$3,903	$4,300	$4,144	---	---	---
Diabetes-Related Hospitalization Costs	$2,863	$3,062	$2,897	---	---	---
All-Cause ER Costs	$261	$233	$298	---	---	---
Diabetes-Related ER Costs	$168	$148	$190	---	---	---

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.

6.3 MTM Effects on Drug Therapy Outcomes for Diabetes Patients

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 Part D organization.

6.3.1 Drug Therapy Outcomes

As shown in **Table 6-3**, beneficiaries in PDPs and MA-PDs were more likely to be adherent to their diabetes medications if they participated in an MTM program. These increases were generally greater with the added effect of CMR. MA-PD MTM programs were also associated with improved quality of prescribing as evidenced by fills of ACEi/ARB and statin medications. PDP MTM programs were not associated with increased ACEi/ARB use but were associated with increased statin use among individuals who received MTM without CMR. In MA-PDs, the strength of the association between MTM and quality of prescribing also increased with CMR.

Table 6-3: Risk-Adjusted Drug Therapy Outcomes for Individuals with Diabetes (Odds Ratio with 95% CI)

Part D Contract Type	*Intervention Group*	*N*	*Adherent to Diabetes Medication*	*Adherent to Biguanides Medications*	*Adherent to DPP-IV Inhibitors Medications*	*Adherent to Sulfonylureas Medications*	*Adherent to Thiazolidinediones Medications*	*Use of ACE Inhibitor or ARB Medication*	*Use of Statin Medication*
PDP	Comparison	133,925	---	---	---	---	---	---	---
	MTM without CMR	149,803	1.15* (1.12, 1.18)	1.12* (1.09 , 1.15)	1.14* (1.06 , 1.21)	1.09* (1.06 , 1.12)	1.12* (1.07 , 1.16)	1.03 (0.99, 1.07)	1.10* (1.05, 1.16)
	With CMR	16,545	1.33* (1.25, 1.41)	1.27* (1.19 , 1.36)	1.32* (1.12 , 1.55)	1.22* (1.13 , 1.31)	1.31* (1.19 , 1.45)	0.99 (0.90, 1.08)	1.01 (0.91, 1.13)
MA-PD	Comparison	53,912	---	---	---	---	---	---	---
	MTM without CMR	95,299	1.17* (1.13, 1.21)	1.11* (1.07 , 1.15)	1.19* (1.07 , 1.31)	1.08* (1.04 , 1.13)	1.09* (1.03 , 1.15)	1.07* (1.01, 1.12)	1.12* (1.05, 1.20)
	With CMR	13,527	1.35* (1.27, 1.45)	1.20* (1.12 , 1.29)	1.19 (.96 , 1.48)	1.28* (1.19 , 1.38)	1.16* (1.04 , 1.29)	1.24* (1.12, 1.38)	1.33* (1.16, 1.52)

* Indicates significance at the 5% level.

6.3.2 Drug Therapy Outcomes by Part D Organization

After stratifying the analyses by Part D organization and adjusting for all covariates, the estimated impacts of MTM on drug therapy outcomes were consistently positive across Part D organizations for adherence, and some organizations also showed positive associations between MTM and quality of prescribing.

- Results for PDPs are shown in **Table 6-4** and can be summarized as follows:
    - **Adherence:** MTM program participants – whether or not they received CMRs – were more likely to be adherent to their diabetes medications than the comparison group, across all Part D organizations.
    - **Quality of Prescribing: Organization C** significantly improved quality of prescribing with regard to ACEi/ARB medications and statins.
- Results for MA-PDs are shown in and **Table 6-5** and can be summarized as follows:
    - **Adherence:** MTM participants in **Organizations A** and **F** were more likely to be adherent to their medications, regardless of receipt of CMR; participants in **Organization E** who did not receive a CMR were also more likely to be adherent.
    - **Quality of Prescribing: Organization F** also significantly improved use of ACEi/ARBs and statins, with the impact on these outcomes generally increasing with the added effect of CMRs. One may infer that **Organization F**'s impact on use of ACEi/ARBs and statins may have driven the estimates for these outcomes at the overall MA-PD level reported in **Section 6.3.1** above.

Table 6-4: Risk-Adjusted Medication Adherence for Individuals with Diabetes by PDP Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*N*	*Adherent to Diabetes Medication*	*Adherent to Biguanides Medications*	*Adherent to DPP-IV Inhibitors Medications*	*Adherent to Sulfonylureas Medications*	*Adherent to Thiazolidin-ediones Medications*	*Use of ACE Inhibitor or ARB Medication*	*Use of Statin Medication*
Organization A	MTM without CMR	31,812	1.32* (1.25, 1.38)	1.15* (1.09 , 1.22)	1.09 (.94 , 1.26)	1.15 * (1.08 , 1.23)	1.06 (0.97 , 1.17)	1.07 (0.98 , 1.16)	1.15* (1.02 , 1.31)
	With CMR	346	2.32* (1.59, 3.38)	1.32 (0.93 , 1.88)	1.26 (0.46 , 3.45)	1.94* (1.25 , 3.01)	1.67 (0.84 , 3.34)	1.03 (0.56 , 1.89)	2.10 (0.74 , 5.94)
Organization B	MTM without CMR	20,542	1.09* (1.03, 1.15)	1.10 * (1.03 , 1.17)	1.07 (0.92 , 1.24)	1.06 (0.98 , 1.14)	1.06 (0.96 , 1.16)	1.04 (0.96 , 1.13)	0.98 (0.88 , 1.08)
	With CMR	5,041	1.07 (0.97, 1.18)	1.09 (0.98 , 1.21)	1.23 (0.92 , 1.65)	1.04 (0.92 , 1.18)	1.16 (0.98 , 1.38)	0.98 (0.85 , 1.13)	1.00 (0.86 , 1.16)
Organization C	MTM without CMR	19,203	1.13* (1.00, 1.28)	0.97 (0.84 , 1.12)	0.46 (0.20 , 1.04)	0.92 (0.78 , 1.08)	0.78* (0.62 , 0.97)	1.30* (1.08 , 1.56)	1.90* (1.49 , 2.43)
	With CMR	454	1.49* (1.10, 2.03)	1.36 (0.96 , 1.93)	0.73 (0.10 , 5.49)	1.16 (0.79 , 1.69)	1.45 (0.75 , 2.78)	1.50 (0.98 , 2.29)	2.15* (1.24, 3.71)
Organization D	MTM without CMR	398	1.64* (1.19, 2.26)	2.18* (1.50 , 3.15)	0.87 (0.31 , 2.46)	1.59* (1.06 , 2.37)	1.14 (0.69 , 1.86)	0.94 (0.56 , 1.60)	0.88 (0.46 , 1.68)
	With CMR	8,777	1.56* (1.40, 1.73)	1.42* (1.25 , 1.60)	1.39* (1.03 , 1.87)	1.43* (1.25 , 1.64)	1.30* (1.10 , 1.55)	0.90 (0.76 , 1.06)	0.77* (0.62, 0.96)
Organization E	MTM without CMR	6,675	1.95* (1.75, 2.17)	1.81* (1.62 , 2.03)	2.04* (1.48 , 2.82)	1.44 * (1.27 , 1.63)	1.69 * (1.44 , 1.99)	0.91 (0.76 , 1.08)	0.89 (0.73 , 1.08)
	With CMR	125	2.50* (1.33, 4.69)	3.07 * (1.62 , 5.80)	5.14 (0.98 , 27.02)	1.75 (0.90 , 3.36)	2.66 (0.92 , 7.71)	1.98 (0.97 , 4.06)	0.71 (0.24 , 2.16)

* Indicates significance at the 5% level.

a. For each PDP Parent Organization, the number of individuals in the comparison group for the diabetes analysis was as follows- Organization A: 35,781, Organization B: 36,248, Organization C: 2,590, Organization D: 6,868, and Organization E: 8,787.

Table 6-5: Risk-Adjusted Drug Therapy Outcomes for Individuals with Diabetes by MA-PD Part D Organization (Odds Ratio with 95% CI)

Part D Organization	*Intervention Group*[a]	*N*	*Adherent to Diabetes Medication*	*Adherent to Biguanides Medications*	*Adherent to DPP-IV Inhibitors Medications*	*Adherent to Sulfonylureas Medications*	*Adherent to Thiazolidinediones Medications*	*Use of ACE Inhibitor or ARB Medication*	*Use of Statin Medication*
Organization A	MTM without CMR	19,599	1.29* (1.20, 1.39)	1.17* (1.08 , 1.27)	1.14 (0.90 , 1.46)	1.12* (1.02 , 1.23)	0.99 (0.86 , 1.12)	1.09 (0.96 , 1.22)	1.08 (0.91 , 1.27)
	With CMR	283	1.78* (1.20 , 2.63)	1.94* (1.28, 2.93)	1.21 (0.31 , 4.78)	1.37 (0.87 , 2.16)	1.02 (0.49 , 2.12)	1.40 (0.83 , 2.37)	1.74 (0.79 , 3.80)
Organization B	MTM without CMR	498	0.80 (0.58 , 1.11)	0.90 (0.62 , 1.29)	603.63 (0.80 , 454388.70)	1.28 (0.82 , 2.00)	1.11 (0.51 , 2.43)	0.98 (0.60 , 1.63)	0.89 (0.42 , 1.87)
	With CMR	222	0.97 (0.63 , 1.51)	0.80 (0.50 , 1.29)	3085.36 (0.16 , 58200.00)	1.26 (0.73 , 2.18)	3.87* (1.17 , 12.87)	0.61 (0.28 , 1.35)	1.71 (0.69 , 4.22)
Organization C	MTM without CMR	17,726	1.09 (0.95 , 1.24)	0.89 (0.77 , 1.03)	0.46 (0.16 , 1.33)	1.06 (0.90 , 1.25)	0.85 (0.65 , 1.11)	1.09 (0.91 , 1.30)	1.20 (0.95 , 1.52)
	With CMR	713	1.22 (0.94 , 1.59)	0.88 (0.66 , 1.16)	0.09 * (0.01 , 0.94)	1.23 (0.89 , 1.70)	1.28 (0.78 , 2.13)	1.40 (0.99 , 1.99)	1.54 (0.98 , 2.41)
Organization D	MTM without CMR[b]	41	4.04 (0.88, 18.57)	1.88 (0.52 , 6.73)	---	4.20 (0.72 , 24.56)	4.28 (0.47 , 38.52)	1.41 (0.24 , 8.21)	1.091 (0.11 , 10.71)
	With CMR	1,117	1.17 (0.92 , 1.48)	1.29 (0.99 , 1.68)	0.93 (0.45 , 1.93)	1.06 (0.79 , 1.41)	1.29 (0.85 , 1.95)	0.68 (0.43, 1.07)	0.84 (0.45 , 1.57)
Organization E	MTM without CMR	740	1.79* (1.30 , 2.46)	1.92* (1.36 , 2.71)	3.54 (0.08 , 156.13)	1.30 (0.90 , 1.88)	2.0* (1.08 , 3.69)	0.66 (0.38 , 1.18)	0.84 (0.38 , 1.84)
	With CMR	29	1.01 (0.35 , 2.90)	1.23 (0.38 , 4.01)	---	2.18 (0.54 , 8.75)	1.14 (0.12 , 10.80)	15.45 (0.31 , 776.45)	---
Organization F	MTM without CMR	4,356	1.24* (1.07 , 1.44)	1.07 (0.91 , 1.26)	166.78 (0.97 , 28739.31)	0.98 (0.84 , 1.15)	0.99 (0.76 , 1.30)	1.40* (1.04 , 1.90)	1.12 (0.77 , 1.63)
	With CMR	5,912	1.50* (1.30 , 1.73)	1.19* (1.02 , 1.38)	45.66 (0.39 , 5287.99)	1.21* (1.04 , 1.41)	1.00 (0.78 , 1.29)	2.06 * (1.57 , 2.69)	2.25 * (1.60 , 3.17)

* Indicates significance at the 5% level.

a. For each MA-PD Parent Organization, the number of individuals in the comparison group for the diabetes analysis was as follows- Organization A: 13,831, Organization B: 1,251, Organization C: 2,196, Organization D: 2,064, Organization E: 983, and Organization F: 3,945.

6.4 MTM Effects on Resource Utilization Outcomes for Diabetes Patients

Across both PDP and MA-PD cohorts, diabetic patients enrolled in MTM programs generally had higher rates of preceding hospitalization and ER use during the year preceding the outcome period (see **Table 6-2**). After adjusting for covariates including prior hospitalizations, results suggested that individuals who received MTM services were less likely to experience adverse events in the year after MTM enrollment. However, across cohorts, individuals enrolled in MTM programs did not generally fill fewer medications or more generic equivalents. Further, they did not generally have lower costs in the Part D, hospital, or ER settings.

The following three sections provide the overall risk adjusted results for MTM enrollees and stratified by Part D organization. **Section 6.4.1** presents overall results for hospital and ER visits, while **Section 6.4.2** presents overall results for medications and costs, stratified by Part D contract type. Finally, **Section 6.4.3** discusses these results stratified by Part D organization.

6.4.1 Resource Utilization Outcomes: Hospital and ER Visits

As shown in **Table 6-6**, beneficiaries in PDPs and MA-PDs were generally less likely to experience adverse events if they participated in an MTM program. PDP MTM programs were associated with significant reductions in enrollees' risk of all-cause and diabetes-related hospitalization, with a greater risk reduction for those who received a CMR; further, they were also associated with significant reductions in the risk of ER visits for those who participated in MTM but did not receive a CMR. MA-PD MTM programs were also associated with reduced risk of hospitalization for their participants who received a CMR.

Table 6-6: Risk-Adjusted Resource Utilization for Individuals with Diabetes: Hospital and ER Visits (Odds Ratio with 95% CI)[a]

Part D Contract Type	*Intervention Group*	*N*	*Any (All-Cause) Hospitalization*	*Any Diabetes-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any Diabetes-Related ER Visit*
PDP	Comparison	133,925	---	---	---	---
	MTM without CMR	149,803	0.97* (0.98 , 0.99)	0.96* (0.94 , 0.98)	0.93* (0.92 , 0.95)	0.95* (0.93 , 0.97)
	With CMR	16,545	0.91 * (0.87 , 0.95)	0.91* (0.87 , 0.96)	0.96 (0.92 , 1.00)	1.00 (0.96 , 1.05)
MA-PD	Comparison	53,912	---	---	---	---
	MTM without CMR	95,299	1.02 (0.99, 1.05)	1.01 (0.98 , 1.04)	---	---
	With CMR	13,527	0.93 * (0.88, 0.98)	0.92* (0.87 , 0.97)	---	---

* 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.

6.4.2 Resource Utilization Outcomes: Medications and Costs

After adjusting for covariates, individuals in PDP and MA-PD MTM programs – regardless of receipt of CMRs – tended to show slight differences in the number of medications they took compared to their respective comparison groups. Medication results are shown in **Table 6-7** and can be summarized as follows:

- **Number of Medications:** Individuals enrolled in PDPs and MA-PDs took smaller numbers of both diabetes and non-diabetes medications if they were enrolled in an MTM program, regardless of receipt of a CMR.
- **Generic Substitution:** Those enrolled in MTM programs had lower average generic substitution ratios (for non-diabetes medications, this was 0.1-0.2% fewer fills of generic drugs over the one-year 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 6-2**).

Cost results are shown in **Table 6-8**. Part D costs generally went up for MTM recipients. However, individuals who received MTM with CMR showed some reductions in hospital costs, and individuals who received MTM without CMR showed reductions in ER costs relative to the comparison group:

- **Non-Diabetes Part D Costs:** Individuals enrolled in MTM programs had higher Part D costs relative to the comparison group for non-diabetes drugs. Across the PDP and MA-PD cohorts, participants accrued about $110 to $181 more in non-diabetes Part D costs over the one-year outcome period relative to the comparison group.
- **Hospital Costs:** Relative to the comparison group, individuals who were enrolled in PDP MTM programs with CMR saved about $399 in all-cause hospital costs in the outcome period, $363 of which were attributed to diabetes-related hospitalizations.
- **Emergency Room Costs:** Those who received MTM without a CMR showed a reduction in all-cause ER costs of $13 relative to the comparison group; $8 of these savings were attributable to savings for diabetes-related ER costs.

Table 6-7: Risk-Adjusted Resource Utilization Outcomes for Individuals with Diabetes: Medications (OLS Estimate with 95% CI)

Part D Contract Type	*Intervention Group*	*N*	*Total Number of Medications*	*Generic Substitution for Diabetes Medications*	*Generic Substitution for Non-Diabetes Medications*
PDP	Comparison	133,925	---	---	---
	MTM without CMR	149,803	0.096* (.075 , .117)	-0.000* (-.000 , -.000)	-0.001* (-.001 , -.000)
	MTM with CMR	16,545	0.215* (0.165 , 0.266)	-0.000 (-0.000 , 0.000)	-0.001 (-0.002 , 0.000)
MA-PD	Comparison	53,912	---	---	---
	MTM without CMR	95,299	0.059* (0.032 , 0.086)	0.000 (-0.000 , 0.000)	-0.002* (-0.003 , -0.001)
	MTM with CMR	13,527	0.245* (0.195 , 0.294)	0.000 (-0.000 , 0.000)	-.002 * (-0.003 , -0.001)

* Indicates significance at the 5% level.

Table 6-8: Risk-Adjusted Resource Utilization Outcomes for Individuals with Diabetes: Costs (OLS Estimate with 95% CI)[a]

Part D Contract Type	*Intervention Group*	*N*	*Part D Total Drug Costs for Non-Diabetes Drugs*	*All-Cause Hospitalization Costs*	*Diabetes-Related Hospitalization Costs*	*All-Cause ER Costs*	*Diabetes-Related ER Costs*
PDP	Comparison	133,925	---	---	---	---	---
	MTM without CMR	149,803	$181.00* (155.84 , 206.54)	$24.04 (-98.23 , 146.32)	-$28.85 (-125.79 , 68.09)	-$12.87* (-18.9 , -6.85)	-$7.85* (-12.93 , -2.77)
	MTM with CMR	16,545	$109.70* (50.16 , 169.25)	-$398.98* (-651.21 , -146.75)	-$363.45* (-562.00 , -164.91)	-$8.76 (-23.65 , 6.12)	-$3.27 (-15.37 , 8.84)
MA-PD	Comparison	53,912	---	---	---	---	---
	MTM without CMR	95,299	$140.36* (110.21 , 170.51)	---	---	---	---
	MTM with CMR	13,527	$173.79* (118.35 , 229.22)	---	---	---	---

* 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.

6.4.3 Resource Utilization Outcomes by Part D Organization

After stratifying the analyses by Part D organization and adjusting for all covariates, some patterns in hospital and ER visit outcomes arose for specific Part D organizations; certain MTM programs were consistently associated with a reduced risk of hospitalizations and ER visits.

- Results for PDPs are shown in **Table 6-9** and can be summarized as follows:
    - **Hospitalizations:** MTM participants in **Organizations A** and **B** who did not receive CMR experienced a reduced risk of all-cause hospitalizations (OR=0.92 for both organizations). **Organization E**'s participants who received MTM without CMR also experienced a lower rate of hospitalizations (OR=0.89). Individuals who received MTM with CMR also showed reduced odds of hospital and ER visits relative to the comparison group. In **Organization B,** receiving MTM with CMR was associated with an OR of 0.88 for hospitalizations. In **Organization A**, receiving MTM with CMR was associated with an OR of .65 for hospitalizations. Thus, for recipients of MTM with CMR in **Organization A**'s PDP plan, the odds of hospitalization were 45% lower than for members of the comparison group.
    - **ER Visits:** MTM participants in **Organizations A**, **B**, and **E** who did not receive CMR reduced their odds of all-cause ER visits (OR=0.91 and 0.83, and 0.90 respectively).
    - **Generic Substitution: Organizations C's** MTM enrollees increased had slightly higher use of generic drugs (0.5% and 0.8% more fills of generic medications over the one-year outcome period). Please note that individuals in the comparison and intervention groups were using mostly generic medications at baseline (see **Table 6-2**).
    - **Hospital and ER Costs**: Individuals who were enrolled in **Organization A**'s PDP MTM program cost about $1,697 less for all-cause hospitalizations and $1,023 less for diabetes-specific hospitalizations over the one-year outcome period if they received a CMR. **Organization B**'s MTM participants who did not receive CMR accrued about $30 in ER-related savings.
- MA-PD results are shown in **Table 6-10** and can be summarized as follows:
    - **Hospitalizations:** The two MA-PD Part D organizations with MTM programs that reduced enrollees' hospital use were **Organizations A** and **E**. Participants in

these programs who received a CMR experienced a significant reduction in this risk (OR=0.66 and 0.89, respectively).

Table 6-9: Risk-Adjusted Resource Utilization for Individuals with Diabetes: Hospital and ER Visits by PDP Part D Organization (Odds Ratio with 95% CI)[a]

Part D Organization	*Intervention Type*	*N*	*Any (All-Cause) Hospitalization*	*Any (All-Cause) ER Visit*	*Generic Substitution Ratio for Diabetes Medications*	*Generic Substitution Ratio for Non-Diabetes Medications*	*Part D Total Drug Cost for Non-Diabetes Drugs*	*All-Cause Hospitalization Costs*	*All-Cause ER Costs*
Organization A	MTM without CMR	31,812	0.92* (0.89 , 0.96)	0.91* (0.87 , 0.95)	0.000 (-0.000 , 0.000)	-0.002* (-0.003 , -0.001)	$136.61* (85.38 , 187.84)	-$133.83 (-385.62 , 117.96)	-$14.13* (-26.16 , -2.10)
	With CMR	346	0.65* (0.49 , 0.85)	0.96 (0.75 , 1.23)	0.000 (-0.005 , 0.004)	0.003 (-0.004, 0.012)	$37.51 (-289.67 , 364.69)	-$1697.58* (-2656.47 , -738.69)	-$25.41 (-83.09 , 32.27)
Organization B	MTM without CMR	20,542	0.92* (0.88 , 0.96)	0.83* (0.79 , 0.86)	0.000 (-0.000 , 0.000)	0.000 (-0.000 , 0.001)	$176.20* (120.33, 232.08)	$258.31 (-32.68 , 549.30)	-$47.88* (-63.99 , -31.77)
	With CMR	5,041	0.88* (0.82 , 0.95)	0.90* (0.84 , 0.96)	0.000 (-0.000 , 0.000)	0.001 (-0.000 , 0.002)	$63.09 (-29.49 , 155.67)	-$191.39 (-608.17 , 225.38)	-$39.98* (-63.92 , -16.04)
Organization C	MTM without CMR	19,203	1.23* (1.10 , 1.37)	1.11* (1.00 , 1.23)	0.000 (-0.000 , 0.002)	0.005* (0.001 , 0.008)	$201.76* (80.87 , 322.66)	$398.78 (-160.90 , 958.47)	$20.93 (-5.87 , 47.72)
	With CMR	454	0.83 (0.64 , 1.09)	1.09 (0.86 , 1.39)	0.000 (-0.003 , 0.003)	0.008* (0.000 , 0.016)	$107.23 (-179.07 , 393.53)	-$690.92 (-1868.87 , 487.03)	-$2.93 (-57.92 , 52.06)
Organization D	MTM without CMR	398	1.11 (0.88 , 1.42)	1.07 (0.85 , 1.35)	0.000 (-0.003 , 0.003)	0.001 (-0.004 , 0.007)	$342.88* (20.89 , 664.86)	-$265.43 (-1474.21 , 943.34)	-$18.01 (-95.45 , 59.42)
	With CMR	8,777	1.05 (0.96 , 1.14)	0.93 (0.86 , 1.01)	0.000 (-0.000 , 0.001)	0.001 (-.000 , .003)	$83.22 (-26.57 , 193.00)	$271.72 (-255.08 , 798.53)	$6.11 (-26.11 , 38.32)

Part D Organization	*Intervention Type*	*N*	*Any (All-Cause) Hospitalization*	*Any (All-Cause) ER Visit*	*Generic Substitution Ratio for Diabetes Medications*	*Generic Substitution Ratio for Non-Diabetes Medications*	*Part D Total Drug Cost for Non-Diabetes Drugs*	*All-Cause Hospitalization Costs*	*All-Cause ER Costs*
Organization E	MTM without CMR	6,675	0.89 * (0.81 , 0.96)	0.90* (0.83 , 0.98)	0.000 (-0.000 , 0.000)	0.000 (-0.001 , 0.002)	$390.46* (289.48 , 491.44)	-$580.13 (-1161.99 , 1.74)	-$24.72 (-51.53 , 2.08)
	With CMR	125	0.96 (0.62 , 1.47)	0.78 (0.52 , 1.18)	0.000 (-0.002 , 0.002)	0.005 (-0.004 , 0.015)	$618.051* (79.820 , 1156.282)	-$1286.98 (-3754.30 , 1180.34)	-$76.05 (-176.18 , 24.08)

* Indicates significance at the 5% level.

a. For each Parent Organization, the number of individuals in the comparison group was as follows- Organization A: 35,781, Organization B: 36,248, Organization C: 2,590, Organization D: 6,868, Organization E: 8,787

Table 6-10: Risk-Adjusted Resource Utilization Outcomes for Individuals with Diabetes: Hospital Visits for MA-PD Part D Organizations (Odds Ratio with 95% CI)[a]

Part D Organization	*Intervention Group*[b]	*N*	*Any (All-Cause) Hospitalization*	*Generic Substitution Ratio for Diabetes Medications*	*Generic Substitution Ratio for Non-Diabetes Medications*	*Part D Total Drug Cost for Non-Diabetes Drugs*
Organization A	MTM without CMR	19,599	0.94 (0.88 , 1.01)	0.000 (-0.000 , 0.000)	-0.001 (-0.002 , 0.000)	$147.24* (77.13 , 217.34)
	With CMR	283	0.66* (0.48 , 0.92)	0.000 (-0.002 , 0.001)	0.005 (-0.000 , 0.013)	$145.18 (-192.80 , 483.13)
Organization B	MTM without CMR	498	1.13 (0.83 , 1.55)	0.001 (-0.000 , 0.004)	0.002 (-0.004 , 0.008)	$175.91 (-50.92 , 402.75)
	With CMR	222	0.95 (0.63 , 1.44)	0.000 (-0.003 , 0.003)	-0.001 (-0.010 , 0.006)	$158.74 (-146.68 464.17
Organization C	MTM without CMR	17,726	1.33 * (1.16 , 1.52)	0.000 (-0.001 , 0.001)	0.002* (0.000 , 0.005)	$258.34* (151.17 , 365.50)
	With CMR	713	1.19 (0.94 , 1.51)	0.000 (-0.003 , 0.001)	0.001 (-0.003 , 0.006)	$228.88* (27.85 , 429.92)
Organization D	MTM without CMR[b]	41	0.82 (0.37 , 1.81)	0.000 (-0.013 , 0.012)	-0.001 (-0.023 , 0.020)	$1,008.70* (117.57 , 1899.83)
	With CMR	1,117	0.91 (0.74 , 1.13)	-0.001 (-0.004 , 0.001)	-0.001 (-0.007 , 0.003)	$140.08 (-84.55 , 364.71)
Organization E	MTM without CMR	740	0.99 (0.77 , 1.28)	0.000 (-0.000 , 0.002)	0.001 (-0.003 , 0.006)	$439.10* (213.60 , 664.61)
	With CMR[b]	29	0.41 (0.13 , 1.30)	0.000 (-0.006 , 0.006)	0.002 (-0.015 , 0.021)	$569.30 (-287.16 , 1425.76)
Organization F	MTM without CMR	4,356	1.02 (0.90 , 1.15)	0.001* (0.000 , 0.002)	-0.008* (-0.012 , -0.005)	$18.70 (-112.44 , 149.83)
	With CMR	5,912	0.89* (0.79 , 1.00)	0.000 (-0.000 , 0.001)	-0.004* (-0.007 , -0.001)	$67.10 (-55.25 , 189.45)

* 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.

b. For each Parent Organization, the number of individuals in the comparison group was as follows- Organization A: 13,831, Organization B: 1,251, Organization C: 2,196, Organization D: 2,064, Organization E: 983, Organization F: 3,945

7 RESULTS: POTENTIAL MECHANISMS FOR MTM SUCCESS

Interviews with nine key stakeholders focused on identifying effective MTM program strategies and potential synergies with other national healthcare policies. These findings are summarized in the following subsections. Key findings from these interviews related to eligibility criteria (**Section 7.1**), provision of CMRs (**Section 7.2, 7.3,** and **7.4**), care coordination (**Section 7.5**), use of healthcare IT and integration with other data (**Section 7.6, 7.7**), quality measurement models (**Section 7.8**), and new healthcare payment (**Section 7.9**).

7.1 Develop Comprehensive MTM Eligibility Criteria

All stakeholders believed that MTM services are most effective for medically complex patients. Most stakeholders stated that the current Part D eligibility criteria (i.e., diagnosis of 2-3 chronic diseases, at least $3,000 in drug costs, minimum threshold of 2-8 prescriptions) were useful in identifying most patients who could benefit from MTM services. Stakeholders also suggested additional indications of medically complex patients, including recent hospital discharge or related process measures, disease progression as suggested by claims data, and use of specific drugs (e.g., Coumadin, anti-psychotics). One stakeholder cited a retail pharmacy that is currently using care transitions as a trigger for a CMR. CMS may also look to studies of care coordination for medically complex patients for examples of process measures and tools used to identify transitions in care, such as hospital discharge.

Stakeholders also suggested that the current eligibility criteria exclude some patients who could benefit from MTM services, such as those with poor medication adherence. A patient who has trouble adhering to her medication regimen may not fill enough prescriptions to reach the threshold of $3,000 in annual drug costs. To avoid such missed opportunities, CMS may look to incorporate additional process measures, such as timeliness of medication refills among patients with complex medical conditions, as part of the eligibility criteria for MTM services.

7.2 Build Beneficiary Awareness of MTM Services

Part D organizations face challenges when building general awareness of MTM services. As some stakeholders noted, most beneficiaries do not expect to have problems with their medications and do not actively seek out MTM services. Therefore, Part D vendors have the burden of educating beneficiaries about the rationale for MTM services and also providing education about their specific MTM benefits. Some stakeholders suggested that broader advertising efforts in medical offices and at pharmacies may help build awareness of MTM services among Part D beneficiaries. One stakeholder from a provider organization also noted that MTM marketing must be "patient-friendly" and suggested that current advertising efforts may be ineffective in conveying important information about MTM services. CMS may

consider evaluating advertisements and other outreach materials to ensure that the beneficiaries gain a proper understanding of MTM services.

7.3 Optimize Patient Targeting and Engagement in a CMR

As demonstrated through the quantitative analyses, patients who receive CMRs are more likely to reap the benefits from MTM programs; however, patient participation in CMRs remains low. Indeed, all stakeholders cited low patient engagement as a common and persistent challenge faced by MTM Programs.

Many stakeholders, including health care providers and professional associations, noted that access to robust data systems with patient-specific information was a key component in effective patient identification and targeting. One health care provider stated that Part D vendors that have large databases and refined algorithms to identify and target patients for MTM have a significant competitive advantage. Large retail pharmacies are more likely to partner with MTM vendors and gain access to these data systems. Multiple stakeholders expressed concern but did not offer solutions regarding the implications for small, community pharmacists who are interested in providing CMRs for their local clientele, but may not have access to sophisticated data systems. The perceived value of information systems is discussed further in **Section 7.6** "Use of Health IT and Clinical Information Systems" below.

Some stakeholders also suggested that the relationship between the beneficiary and the entity offering the CMR mediated the likelihood that the patient would participate in the CMR. Currently, Part D vendors are responsible for recruiting beneficiaries to participate in a CMR and recruitment is often done by mailed invitation, computer-automated phone call (i.e., interactive voice response), typical phone call, or a combination of methods. However, many stakeholders suggested that individuals who share an existing, trusted relationship with the beneficiary (e.g. health care provider, local pharmacist), may be better suited to CMR recruitment. Stakeholders suggested that beneficiaries may perceive their providers as being concerned about health care quality and may be more likely to agree to participate in a CMR.

7.4 Adopt Effective Methods for Performing a CMR

Little is known about the best practices for Part D CMR implementation. Stakeholders cited examples of effective MTM programs (within Medicare Part D or not) as models for CMR implementation and provided expert opinion about effective implementation practices. Responses addressed the following aspects of CMR implementation:

- Who should perform the CMR?

Healthcare providers and stakeholders from professionals associations and quality/safety organizations suggested that an existing, trusted relationship between the patient and the person providing the CMR is crucial. Many stakeholders felt that patients were more likely to participate in CMRs offered by trusted partners in their health care, such as local physicians, nurses, or pharmacists.

- What modes of communication are effective with a CMR?

Stakeholders from professional associations, quality/safety organizations, and health care providers felt that person-to-person communication (e.g., phone, in-person) facilitated an effective CMR. One stakeholder noted that the Pharmacy Quality Alliance (PQA) is currently engaged in a project comparing face-to-face and telephonic models for MTM. Acumen confirmed by referencing the PQA website that this study of 230 MTM patients was being conducted with the Illinois Medication Therapy Management Collaborative and the results were not available at the time of this report.

Stakeholders also cited anecdotal evidence that in-person CMRs should be the preferred method. For example, one health care provider stated that patients were more likely to be truthful about their medications and adherence when face-to-face with the person completing the CMR. Multiple stakeholders also cited retail pharmacies as models of in-person CMRs by a pharmacist. One retail pharmacy has redesigned a limited number of locations to place the pharmacist in the center of the store and facilitate in-person communication with patients. Another retail pharmacy has identified pharmacists who enjoyed patient consultations and had these pharmacists travel from store-to-store to meet with patients about their medication history and to work with them on a more ongoing basis.

- What is the optimal duration of a CMR?

Many stakeholders reported that a high-quality CMR takes approximately 45-60 minutes, with consultation accounting for half the time and administrative duty accounting for the second half. One stakeholder reported that members of her organization often reported time was a limitation to performing a CMR: “Reimbursement rates are too low and time is too limited to do CMRs.” A stakeholder from a provider organization cited a retail pharmacy chain that revised its CMR workflow to leverage pharmacy technicians to perform other activities outside of the actual CMR, where appropriate, and make the CMR process more cost-effective from a provider perspective.

- What tools can support a good CMR?

Many health care providers and professional associations suggested that the effectiveness of CMRs was mediated by the amount of clinical data available to the CMR provider. Stakeholders cited the information systems of integrated health care systems and large Part D vendors as resources that support the implementation of CMRs. Information systems are discussed further in **Section 7.6** "Use of Health IT and Clinical Information Systems" below.

7.5 Facilitate Coordination between MTM and Health Care Providers

Many health care providers felt that MTM programs with a clear workflow for coordination between the MTM provider and the patient's health care provider (e.g., primary care physician) were more likely to produce benefits for the patient. The communication loop between the MTM and health care provider was viewed as critical because the information that the MTM provider collects at the point of the interview is often information that the health care provider does not know.

One stakeholder cited an employer-sponsored MTM program as an example of effective coordination. In this program, MTM providers document the CMR in a SOAP note format (Subjective, Objective, Assessment, Plan) in the patient chart. Another stakeholder cited CMS' PACE program (which does not have Part D MTM programs), which builds on existing professional relationships. "In the PACE program, there is a clinical pharmacist on site who knows the patients in some depth. When the pharmacist makes a therapeutic change to a regimen, that pharmacist knows the patient, knows their circumstances, and knows the physician. They may say, '[Physician], you might want to consider not using this medicine, or using a different class of medicine, or using a different medicine from this class." Many stakeholders also noted that MTM-health care provider coordination was an area where health IT could be a useful tool, and they look forward to leveraging health information exchange as it becomes more widely available.

7.6 Use of Health IT and Clinical Information Systems

Health IT is diverse set of tools that can be used to improve health care processes and outcomes. One stakeholder noted that many MTM providers currently use electronic prescribing (e-prescribing) systems, which link providers, pharmacies, and pharmacy benefits managers and are used to transmit prescription information and pharmacy claims data. Nearly every pharmacy and provider office in the country is equipped with an e-prescribing system. However, health care providers suggested that the quality of CMRs may be improved if MTM providers had access to more robust disease state information beyond what is available in most e-prescribing products. Stakeholders suggested that this information could be offered to MTM providers by:

1) enhancing existing e-prescribing platforms to include health claims data; 2) integrating health care delivery systems to give MTM providers access to the electronic health records; 3) leveraging patient portals with patient-entered health information; and 4) leveraging health information exchanges to gather disease state information from disparate health care organizations.

Some large MTM vendors are actively enhancing their information systems with claims data. Stakeholders reported that these MTM vendors have developed databases and algorithms to aggregate claims data and identify patients who are eligible for MTM services. These information systems provide a significant competitive advantage over community pharmacists and other local MTM providers who do not have access to this information and cannot identify eligible patients as effectively. Given that many stakeholders believed community pharmacists were well positioned to engage patients for CMRs due to their existing relationships, it will be important to monitor the effect of information systems on CMR rates and CMR quality among community pharmacists compared to large MTM organizations.

7.7 Advance the Integration of MTM Services with Other Aspects of Healthcare Reform

Many stakeholders hypothesized that MTM could integrate well with newer models of healthcare including accountable care organizations (ACOs) and patient-centered medical homes (PCMHs), given that these programs are designed to improve health care quality and reduce costs. Stakeholders emphasized the importance of understanding implementation details such as payment models, organization of care teams, and division of labor, because there is potential for conflicting incentives and overlap of services. For example, ACO reimbursement is tied to overall health care quality and cost for a given patient, and as such, the ACO has an incentive to ensure that their patients are adhering to their medications, potentially increasing drug costs but reducing the risk of high hospitalization costs. However, standalone Part D plans are at risk for drug costs only and do not have an incentive to identify adherence problems. Another example of potential conflict is that, in PCMHs, a health care provider (e.g., physician, nurse, care manager) is responsible for medication reconciliation at every visit. This creates the potential for overlap of services with MTM organizations and CMRs. Some stakeholders suggested addressing these potential issues through policy changes or research to identify ways to align services offered by various programs. Some stakeholders suggested it would be beneficial to have MTM providers working very closely with case managers, physicians, and behavioral specialists to think about adherence and behavioral issues in relation to medication management of conditions.

7.8 Support Development of MTM Quality Measures

Many stakeholders noted that there is a current lack of consensus on appropriate Part D MTM measures and that the Pharmacy Quality Alliance (PQA) is sponsoring a workgroup that may address this issue. The PQA workgroup is focusing on the development of process measures and the impact of drug-related problems. One stakeholder stated, "There has been a struggle to create a performance measure that is truly outcomes-based. The standardized formatting now required by CMS can lend an opportunity to use standard data elements to determine process-oriented measures; for example, identifying the percent of MTM encounters that led to the resolution of a drug related program."

7.9 Modify Payment Structures to Incentivize Medication Management

Stakeholders from beneficiary and provider organizations suggested that payment structures and financial incentives could be used as a policy lever to motivate the Part D organizations, health care providers, and pharmacists to achieve various outcomes. Three stakeholders suggested that the financial incentives of standalone Part D plans are not aligned to address medication adherence. One stakeholder stated, "Approximately 2/3 of Medicare enrollees select the standalone plan… [because] standalone plans are structured to keep drug costs down, immediately there is a major conflict with helping people get more medication [if non-adherent], even though doing so will ultimately lead to the most benefit, minimize the risk, and avoid downstream unnecessary medical visits and hospitalizations." Plans that are responsible for a beneficiary's broader health care needs, such as Medicare Advantage drug plans or private insurers, may be more effective at addressing medication adherence issues.

8 RESULTS: ADDITIONAL QUANTITATIVE ANALYSES

This section reports additional quantitative analyses that supplement our primary quantitative and qualitative findings reported in Chapters 4, 5, 6 and 7. **Section 8.1** discusses the differences in MTM effects for the six-month outcomes as compared to our main outcome period of twelve months. **Section 8.2** describes MTM program effectiveness in targeting high-risk beneficiaries by comparing drug therapy and resource utilization characteristics among the overall Medicare Part D population, MTM enrollees, and MTM enrollees who received CMRs. **Section 8.3** summarizes the findings of the DiD estimator method and compares them with the results from the main OLS regression method. **Section 8.4** provides a comparison of results between the main COPD analysis (including COPD patients across all plans) and those in plans specifically targeting COPD.

8.1 Comparison between Six-Month and Twelve-Month Outcomes

A comparison of the effects of MTM on six-month and twelve-month drug therapy outcomes is notable for the persistence of positive adherence effects across both periods. However, the effects of MTM on drug safety (discontinuation of high-risk medications and contraindicated medications) were divergent for these periods. At six months, there were improvements in the safety of prescribed drug regimens for patients with CHF and COPD (only cohorts tested), but these effects had dissipated or reversed for the 12 month outcomes. Furthermore, the Part D drug costs savings suggested at six months were seen to revert for the twelve month outcome results where MTM programs were associated with higher drug costs for most Part D organizations. While hospital and ER visits and their associated costs were reduced for CMR recipients in both the CHF and COPD cohorts in the six-month outcome results, the effects were only evident in the CHF cohort for the twelve-month outcomes.

The results for the divergent drug safety outcomes for the six-month and twelve-month outcomes in patients with CHF are reported in **Table 8-1**. In addition, all outcomes at six months are detailed in **Appendix C**.

Table 8-1: Drug Safety Outcomes at 6 and 12 Months after MTM Enrollment in Individuals with CHF (Odds Ratio with 95% Confidence Interval)

Part D Contract Type	*Intervention Group*	*6 Months*			*12 Months*		
		Remove Drug-Drug Interactions	*Discontinue High-Risk Medication Use*	*Discontinue Contraindicated Medications*	*Remove Drug-Drug Interactions*	*Discontinue High-Risk Medication Use*	*Discontinue Contraindicated Medications*
PDP	Comparison	N/A	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	1.05 (CI: 0.99 to 1.12)	1.04* (CI: 1.01 to 1.07)	0.88* (CI: .85, .91)	0.96 (CI: 0.90 to 1.02)	0.98 (CI: 0.95 to 1.00)	0.81* (CI: 0.78 to 0.84)
	With CMR	0.95 (CI: 0.82 to 1.11)	1.04 (CI: 0.97 to 1.11)	0.64* (CI: 0.60, .69)	0.87 (CI: 0.76 to 1.00)	1.04 (CI: 0.97 to 1.11)	0.63* (CI: 0.58 to 0.67)
MA-PD	Comparison	N/A	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	1.14* (CI: 1.02 to 1.27)	0.95* (CI: 0.91 to 1.0)	1.11* (CI: 1.04, 1.18)	1.01 (CI: 0.91 to 1.11)	0.88* (CI: 0.84 to 0.92)	1.09* (CI: 1.02 to 1.16)
	With CMR	1.12 (CI: 0.92 to 1.36)	1.18* (CI: 1.00 to, 1.29)	1.140* (CI: 1.0, 1.30)	1.05 (CI: 0.88 to 1.26)	0.93 (CI: 0.86 to 1.01)	1.16* (CI: 1.03 to 1.30)

*Indicates statistical significance at the 5% level.

8.2 MTM Effectiveness at Targeting Individuals with Preceding Medication Issues and High Health Care Resource Utilization

MTM enrollees were higher-risk prior to MTM enrollment than the average Part D Medicare beneficiary in that they had more medication issues and healthcare resource utilization in the pre-enrollment period. For patients in PDP plans, CMR recipients were even higher-risk on these characteristics preceding MTM enrollment than the average for all MTM enrollees (**Table 8-2**) in the pre-enrollment period. Evidence of medication issues was seen in MTM enrollees' more common use of high-risk medications, and higher resource utilization in the form of drug costs, hospital and ER visits, and associated costs. Within PDPs, MTM enrollees receiving CMRs were even more likely to use high-risk medications, be hospitalized, and visit the emergency room, and they also accrued higher Part D drug costs compared to the MTM population in general. By contrast, CMR recipients in MA-PD plans were less likely to use high-risk medications and were approximately the same as other MTM enrollees in their hospitalizations, number of medications, and Part D costs.

Table 8-2: MTM Effectiveness at Targeting High-Risk Individuals

Baseline Period High-risk Characteristics	***Medicare Beneficiaries with CHF, COPD or Diabetes***					
	Enrolled in PDPs			***Enrolled in MA-PDs***		
	All Part D	*MTM Enrollees*	*MTM with CMR*	*All Part D*	*MTM Enrollees*	*MTM with CMR*
N	2,276,205	304,602	32,492	1,455,474	194,488	26,470
Drug Therapy						
Use of at Least One High Risk Medication	34.4%	46.4%	51.5%	28.7%	40.4%	36.0%
Resource Utilization: Hospital and ER visits						
Any(All-cause) Hospitalization	27.0%	36.6%	38.0%	19.2%	30.8%	30.4%
Any(All-cause) ER visits	29.5%	35.9%	41.8%	---	---	---
Resource Utilization: Medication and costs						
Number of Medications	11.32	16.20	18.51	10.02	14.67	15.26
Part D costs for All Part D Drugs	$3,426.57	$5,939.17	$7,477.25	$2,429.70	$4,595.84	$4,542.43
All-Cause Hospitalization Costs	$4,265.81	$6,428.99	$6,243.12	---	---	---
All-Cause ER Costs	$238.14	$320.73	$395.53	---	---	---

8.3 Comparison with Difference-in-Differences Estimator Results

We observed similar associations between MTM enrollment and drug therapy outcomes at twelve months for the full cohort of MTM beneficiaries in the difference-in-differences (DiD) analysis as in the main ordinary least square (OLS) regression approach. However, the results for health service utilization differed in the direction of the effect in some cases. The differences in the comparison groups and methods used in the two analyses may have contributed to the inconsistency in these cases. The detailed results by disease cohort for the main analysis are presented in **Sections 4**, **5** and **6** in the main body of the report, while detailed DiD analysis results are presented starting in **Section D.2** of the appendix.

The different methods used to estimate outcomes necessitated the use of a slightly different set of explanatory variables between the two approaches. In the main regression analysis, the model was able to accommodate more regressors (explanatory covariates) as well as Part D organization fixed effects. The addition of all of these covariates was not possible with the DiD estimator approach given that this method used cell-matching on the set of covariates for identifying control patients at the cell-level (as defined by unique combinations of the set of characteristics).

The DiD estimator approach was thus limited by the imperative to match all available MTM enrollees in the data so as to avoid bias from dropped participants that could not be matched to control beneficiaries. The DiD estimator approach also did not consider Part D organization influences on outcomes as done with the fixed effects approach in the main regression approach. If the Part D organization also influences the health outcomes being evaluated in unobserved ways, the main OLS regression analysis would be preferred as it asks what the effects of MTM would be given stability in patient enrollment in Part D organizations (and does not assume these can be easily influenced). The DiD estimator method, though, is advantageous in that many more control beneficiaries are matched to MTM enrollees which decreases variance in the estimates, and outcomes can be measured for smaller numbers of participants where they cannot be in the OLS regression model. This last characteristic of the DiD allows its use for Part D organization-specific analyses when small numbers of enrollees prevent the regression models from working.

Results for medications adherence and quality of prescribing outcomes were consistent between the two methods for all three chronic condition cohorts. In the CHF cohort, we observed increases in take-up of and adherence to evidence-based CHF medications, increases in number of medications and total Part D drug costs, and no positive effects on removal of drug-drug interaction and discontinuation of high-risk and contraindicated medications among MTM beneficiaries in both analyses. For the diabetes cohort, we observed similar increases in adherence to oral diabetes medications and take-up of ACEi/ARBs and statins, and increase in

total Part D costs, and generic substitution ratio for non-diabetes drugs in both analyses. For the COPD cohort, we observed consistent improvements in adherence to all COPD medication regimens across cohorts, a positive effect on the removal of drug-drug interactions for MA-PD enrollees receiving MTM with CMR, increases in number of medications and total drug costs, and no change in generic substitution ratios for COPD or non-COPD medications in the DiD analysis. The medication adherence and quality of prescribing results were similar for the COPD cohort in the main analysis, but the number of medications and total drug costs decreased, and the generic substitution ratio for medications used increased for MTM beneficiaries with COPD in the main analysis.

The results from the two analyses diverged from each other for hospitalizations and ER visits, which were significant in a few cases. In the main analysis, MTM beneficiaries with CHF experienced inconsistent but decreased odds of all-cause hospitalizations, and consistently showed decreased odds of all-cause ER visits. However, MTM beneficiaries with CHF experienced consistent increases in the percentage of all-cause hospitalizations and mixed effects on ER visits in the DiD analysis. For the diabetes cohort, while the main analysis suggested consistently decreased odds of hospitalizations and ER visits among MTM beneficiaries, the DiD analysis suggested an increase in hospitalizations and mixed effects on ER visits. MTM beneficiaries with diabetes in both analyses had lower average hospitalization costs. For the COPD cohort, MTM beneficiaries consistently increased their all-cause and COPD-related hospitalizations, decreased their ER visits, and consistently increased their COPD-related ER visits in the DiD analysis. The main analysis results for the COPD cohort differed slightly: MTM beneficiaries experienced mixed effects on all-cause and COPD-related hospitalizations, decreases in odds of all-cause ER visits, and mixed effects on COPD-related ER visits.

The observed differences in results (generally lesser effects on hospitalization and costs in the DiD models) were likely due to differences in the methods used and/or the comparison groups between the two methods. In particular, these outcomes of hospitalization and its costs could be substantially affected by Part D organizations and regional propensities to hospitalization (though hospital costs were price-standardized) that were controlled for more rigorously in the main regression approach. Reassuringly, the effects on the drug therapy outcomes were very consistent between the two approaches.

8.4 Effectiveness of MTM Chronic Condition Targeting

MTM is intended to be a comprehensive, rather than disease-specific, approach. However, MTM programs that specifically target COPD patients were associated with larger improvements in drug therapy outcomes among enrollees with COPD compared with aggregated results of all MTM programs regardless of COPD targeting; by contrast, effects on resource utilization outcomes were similar for the two cohorts. When we restricted our main regression analysis to only beneficiaries enrolled in MTM programs targeting COPD, we observed larger improvements in odds of adherence to COPD medications, and better drug safety outcomes. While the 12-month aggregated results for all MTM programs suggested that MTM enrollees had lower odds of removing drug-drug interactions and discontinuing high-risk medications than controls in both the PDP and MA-PD cohorts, MTM programs targeting COPD patients were not associated with significant differences from controls in drug safety outcomes, except for MA-PD enrollees in the MTM with CMR sub-cohort. However, we observed similar increases in COPD-related hospitalizations and COPD-related ER visits, and similar decreases in all-cause hospitalizations and all-cause ER visits among PDP enrollees in this analysis as in the analysis conducted on the full cohort of COPD patients who participated in all MTM programs regardless of COPD targeting. **Table 8-3** and **Table 8-4** provide detailed drug therapy and resource utilization outcome results for COPD patients enrolled in MTM programs specifically targeting COPD patients in 2010.

Table 8-3: Drug Therapy Outcomes of MTM Beneficiaries with COPD by Regimen and Part D Setting (Odds Ratio with 95% Confidence Interval)

Part D Setting	*Intervention Group*	*N*	*Adherent to LABA-Only Regimen, Odds Ratio*	*Adherent to LAAC-Only Regimen, Odds Ratio*	*Adherent to Combination Regimen, Odds Ratio*	*Remove Drug-Drug Interaction, Odds Ratio*	*Discontinue Use of High Risk Medications, Odds Ratio*
PDP	Comparison	87,490	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	74,503	1.27* (1.18 , 1.36)	1.23* (1.11 , 1.37)	1.33* (1.23 , 1.44)	0.96 (0.88 to 1.50)	1.00 (0.96, 1.04)
	With CMR	15,791	1.30* (1.17 , 1.45)	1.36* (1.11 , 1.67)	1.48* (1.31 , 1.69)	0.95 (0.81, 1.11)	1.05 (0.98, 1.12)
MA-PD	Comparison	20,387	N/A	N/A	N/A	N/A	N/A
	MTM without CMR	26,584	1.11 (0.98 , 1.26)	1.13 (0.93 , 1.37)	1.23* (1.03 , 1.43)	1.08 (0.87 to 1.33)	0.96 (0.90, 1.03)
	With CMR	4,926	1.31* (1.06 , 1.62)	1.05 (0.76 , 1.45)	1.35* (1.02 , 1.78)	1.18 (0.86, 1.64)	0.88* (0.79, 0.99)

*Indicates statistical significance at the 5% level.

Table 8-4: Hospital and ER Utilization Outcomes of MTM Beneficiaries with COPD by Part D Setting (Odds Ratio with 95% Confidence Interval)

Part D Setting	*Intervention Group*	*N*	*All-Cause Hospitalization*	*COPD-Related Hospitalization*	*All-Cause ER Visit*	*COPD-Related ER Visit*
PDP	Comparison	87,490	N/A	N/A	N/A	N/A
	MTM without CMR	74,503	0.98* (0.95 ,1.00)	1.07* (1.05 , 1.10)	0.93* (0.91 , 0.95)	1.04* (1.01 , 1.07)
	With CMR	15,791	0.91* (0.88 , 0.95)	1.06* (1.02 , 1.11)	0.89* (0.85 , 0.93)	1.10* (1.05 , 1.16)
MA-PD	Comparison	20,387	N/A	N/A	N/A	N/A
	MTM without CMR	26,584	1.08* (1.03, 1.13)	1.13* (1.07, 1.19)	N/A	N/A
	With CMR	4,926	1.02 (0.95, 1.11)	1.03 (0.94, 1.12)	N/A	N/A

*Indicates statistical significance at the 5% level.

9 QUALITATIVE RESEARCH FINDINGS AND SYNTHESIS FOR PART D ORGANIZATIONS

We conducted semi-structured interviews with a small number of selected Part D organizations. We completed 5 interviews and summarize our findings in this section. We begin in **Section 9.1** by describing the overall findings from the Part D organization interviews. In **Section 9.2**, we review the quantitative analysis findings on the performance of each interviewed Part D organization. **Section 9.3** synthesizes the interview findings aimed at identifying important factors driving the high-performing areas of each organization and reviews key practices and success factors for achieving high performance by MTM programs.

9.1 Part D Organization Interview Findings

Interviews with individual Part D organizations provided insight into the processes that organizations used to administer their Part D MTM programs. Even within CMS parameters, Part D organizations varied in their definitions of MTM eligibility, the approaches they used to conduct MTM, and the scope and emphasis of those MTM services. They also varied in the type of information available to pharmacists before or during MTM interventions, ranging from only pharmacy claims for PDPs to full EHR data for some integrated delivery systems. These variations were associated with high or low performance across Part D organizations' MTM programs – as identified through the quantitative analyses – and are summarized in the sections 9.3 and 9.4 below.

9.1.1 Variations in Program Operations

The Part D organizations we interviewed represented a mixture of PDPs and MA-PDs with various geographic catchment areas. A summary of their MTM program operations is presented in **Table 9-1** below. For all of their MTM programs, a pharmacist provided the MTM services (i.e., CMR and TMR), though some organizations used pharmacist technicians or other staff to provide support for MTM-related activities such outreach to eligible members and appointment scheduling; Organization E also used pharmacy residents and students to provide MTM services, who were supervised by licensed pharmacists. Organizations H and E were two of the few organizations to offer ongoing training to pharmacists, providing training sessions to discuss new clinical guidelines. Organization E also was the only organization interviewed that required all pharmacists to have MTM certification.

Table 9-1: Program Operations by Part D Organization

Program Operations	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Type of Plan	MA-PD and PDP	MA-PD and PDP	MA-PD	MA-PD	MA-PD
Program Administrator	Vendor	Combination of in-house and vendor; also contracts with a local university's school of pharmacy for MTM services	In-house	Vendor, though MTM services are provided through a combination of in-house, community-based pharmacists, and vendor	Vendor, though MTM services are provided through a combination of community-based pharmacists and in-house pharmacists
MTM Provider Type	Pharmacist	Pharmacist, pharmacy resident or pharmacy student	Pharmacist	Pharmacist	Pharmacist
Additional MTM Provider Training/Certification Required	None	MTM certification for all pharmacists	None	None	Not required, but ongoing training offered
Date of MTM Program Implementation	2006	2006	2006	2006	Unknown
Census Region	National	National	Multiple (South and West)	Northeast	South
Integrated Delivery System	No	No	Yes	Yes	No
Notable Changes Since 2010	None; same MTM vendor used prior to 2010; no other changes	Changes to the number of MA-PD and PDP contracts	None	Contract with current vendor since 2010	Contract with current vendor began in January 2013

9.1.2 Variations in MTM Eligibility Criteria

Within CMS-defined eligibility parameters, Part D organizations varied with regard to their targeted disease states. Eligibility criteria across organizations are provided in **Table 9-2** below. All required that beneficiaries have at least 2 or 3 disease diagnoses. Organizations indicated that these decisions were based on the expectation that an MTM program had the potential to be more effective or have a greater impact on these diseases based on previous trends, perceptions, and/or research.

At least two organizations considered the burden of the MTM program when determining the targeted disease states. For one organization (Organization F) this meant deciding not to include a disease if it would result in too many members becoming eligible for the MTM program. Organization F also noted that it targeted diseases that did not overlap with other specialty management programs. For another (Organization G), the disease states were chosen in an effort to target between 5 and 10 percent of its entire Part D population. Organization H relied on an analysis of claims data prior to defining the enrollment parameters so that the disease states and criteria could be optimally defined based on this information. Please note it is against CMS guidance to restrict MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for MTM programs.

Table 9-2: MTM Eligibility Criteria

Eligibility Criteria	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Diseases	3 or more of the following: • Diabetes • Hypertension • Heart Failure • Dyslipidemia • Rheumatoid Arthritis (added in 2013)	3 or more chronic conditions; conditions not specified and identified using RxHCC codes	3 or more of the following: • Osteoporosis • Rheumatoid Arthritis • Diabetes • Dyslipidemia • Hypertension • Coronary artery disease • Stroke • COPD (added in 2012)	2 or more of the following: • Diabetes • Hypertension • Chronic heart failure • Dyslipidemia • Osteoporosis	3 or more of the following : • Osteoporosis • Rheumatoid arthritis • Chronic heart failure • Diabetes • Dyslipidemia • Hypertension • Depression • Asthma • COPD • HIV/AIDS (non-core disease)
Medications	8 or more chronic Part D medications; no specificity regarding drug classes	7 or more chronic Part D medications; no specificity regarding drug classes and medications identified based on First Data Bank classifications for chronic medications	5 or more covered Part D drugs from within the following specific Part D drug classes: • Antihyperlipidemics • Antihypertensives • Osteoporosis agents • Insulins • Oral Hypoglycemics • Disease-Modifying Anti-Rheumatic Drugs • Bronchodilators • Inhaled corticosteroids	6 or more covered Part D drugs from the following classes of targeted mediations: • ACE-Inhibitors • Alpha blockers • Angiotensin II receptor blockers • Antihyperlipidemics • Antihypertensives • Beta-blockers • Calcium channel blockers • Diuretics • Insulins • Oral hypoglycemic • Digoxin • Bisphosphonates	8 or more chronic Part D medications; no specificity regarding drug classes

Eligibility Criteria	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Cost Threshold	Calculated based on quarterly claims analysis	Calculated based on quarterly claims analysis	Calculated based on two methods: • Drug spend of $3144 or more for covered Part D drugs in previous 12 months • High likelihood for meeting cost threshold based on quarterly formula (applied to beneficiaries with less than 12 months of prescription history)	Calculated based on quarterly claims analysis	Calculated based on claims data from the past 120 days
Notable Changes Since 2010	• Rheumatoid Arthritis added in 2013 • Prior to 2013, member was required to have 3 of 4 other chronic conditions	• None	• COPD added in 2012 • Targeted disease states changed after 2010 to reduce duplication with other specialist programs (including removal of heart failure)	Unknown	Unknown

9.1.3 Variations in MTM Enrollment Practices

To identify eligible beneficiaries, most organizations used some form of claims-based analysis, performed either in-house or through their MTM vendor. However, the frequency of analysis differed across the organizations. Characteristics of the enrollment strategies used by the interviewed Part D organizations are summarized in **Table 9-3**. Some organizations had a more unique or robust approach for identifying eligible beneficiaries. For example, Organization F used a combination of prescription claims data, in-house medical records, and regional disease state registries, which it believed allows for more accurate targeting and identification of eligible members. Some MA-PD organizations also utilized medical claims data in addition to pharmacy claims data to identify eligible members, maintaining that this tactic provided more complete and accurate information to determine member eligibility. After these identification processes, most organizations also used a workflow whereby a pharmacist reviewed the "queue" of identified beneficiaries to confirm that they met eligibility criteria. Organizations also varied in terms of their outreach to eligible beneficiaries after identifying them for enrollment.

Table 9-3: MTM Enrollment Strategies

Enrollment Practices	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Identification of Eligible Beneficiaries	Done by MTM vendor using Part D claims data (for PDP members) and a combination of Part D and medical claims for MA-PD members	Done by vendor using Part D claims data (for PDP members) and a combination of Part D and medical claims for MA-PD members	Done automatically through in-house service using prescription claims data, in-house medical records, and regional disease state registries	Done by MTM vendor using Part D claims data	Done by MTM vendor using Part D claims data
Frequency of eligible beneficiary identification	Quarterly	Quarterly	Quarterly	Quarterly	Daily
Outreach Mechanism	Mailed welcome letter	3 phone calls followed by an IVR call	Mailed welcome letter	Mailed welcome letter	Mailed welcome letter
Follow-up Processes	3 IVR calls	Mailed welcome letter followed by another letter inserted with explanation of benefits Quarterly newsletter sent	1 IVR call and then follow-up calls by a pharmacist technician	3 follow-up calls by a pharmacist and then another letter	3 follow-up calls by pharmacist and then letter with MAP and PML
Notable Changes Since 2010	Extensive changes made to materials and follow-up processes	Beneficiaries first received a welcome letter and then follow up phone calls; the order of this communication has since changed as described above	Increased emphasis on using simple language in communication with members	Previously, eligible beneficiaries were identified on a monthly basis (vs. quarterly); the welcome letter was introduced in 2013	Unknown

9.1.4 Variations in Comprehensive Medical Reviews (CMRs)

There was variation across the Part D organizations with regard to the mechanisms used to deliver CMRs. Differences across organizations are presented in **Table 9-4**. Some organizations conducted all CMRs by telephone, others used only face-to-face interactions through community-based pharmacists, and others employed a combination of these two approaches. Organizations that offered face-to-face CMRs did so through contracts with community-based pharmacists, and these organizations indicated that this approach was beneficial because it leverages the existing relationships between beneficiaries and their pharmacists.

The information available to the pharmacist at the time of the CMR was another important feature emphasized by the Part D organizations. Though organizations with MA-PDs and PDPs indicated that the CMR process was the same for all beneficiaries, organizations with PDPs reported relying primarily on pharmacy claims information to conduct the CMR, while organizations with MA-PDs tended to collect member information from medical claims and pharmacy claims data before the CMR so that the pharmacist had this information available prior to the CMR. Two organizations (Organization F and G) reported having capabilities to review member information in an EHR, and some organizations described efforts to collect additional member information prior to the CMR (either by contacting the prescriber or the member for a preliminary interview). Of note, Organization F utilized a particularly robust model that relied on a comprehensive database of disease state algorithms that flagged areas where there were deficits or gaps in care, including gaps in preventive services such as appropriate screenings, which the pharmacist then reviewed and validated (using EHR data when possible) before performing the CMR. Overall, the organizations underscored the importance of having complete and accurate member information to allow the pharmacist to conduct an efficient and effective CMR.

Most organizations conducted CMRs annually, with the exception of Organization F, which allowed members to request CMRs more frequently. The average time to complete a CMR ranged from 20 to 90 minutes, though some organizations included the time spent on preparatory work/preliminary data gathering in this estimate while others did not. Generally, organizations attempted to schedule CMRs based on their standard member identification workflow rather than scheduling ad hoc CMRs for beneficiaries who experienced specific medical events (e.g., hospital discharge). Organizations also attempted to time the scheduling of the CMR so it occurred after the member information was compiled, though exceptions were made if a member requested to have a CMR before such preparatory work was completed.

The CMRs were typically directed by web-based applications and algorithms designed to help guide the pharmacist through the CMR and address areas of particular concern. Each organization reported specific areas/interventions that were addressed as part of the CMR; this information is summarized in **Table 9-4**. Many addressed adherence and appropriate use of medications. Some organizations addressed opportunities for generic substitution as part of the CMR process, while others tended to address this issue as part of their TMRs. None of the organizations allowed pharmacists to make changes to the members' medications regimens. Pharmacists used electronic systems to document the CMR intervention.

Following the CMR, organizations reported providing members with a Personal Medication List (PML) and Medication Action Plan (MAP), usually by mail unless the CMR was conducted face-to-face. Some organizations also reported providing additional educational materials about disease states or medications, or other materials such as applications for assistance programs that were discussed during the CMR. Please note this study preceded implementation of standardized format for CMR summary (effective 1/1/2013).

Table 9-4: CMR Characteristics by Part D Organizations

CMR	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Mechanism	Telephone	Telephone	Telephone; capability of face-to-face exists, though it is infrequently utilized	Telephone; face-to-face capabilities are currently being developed, though they are not yet available	Telephone or face-to-face
Frequency	Annually	Annually with process to review beneficiary information quarterly to assess if additional CMR is needed	Annually with ability for members to request more frequently (no limit)	Annually	Annually
Average Time to Complete	30-40 minutes (not including preparatory time)	25-30 minutes; 60 minutes including preparatory time	90 minutes (including preparatory time)	20 minutes; 60 minutes including preparatory time	20 minutes
Information Given to Members after CMR	Cover letter, PML, and MAP by mail	Summary of the consultation, PML, MAP, and other education materials	Cover letter, PML, and MAP by mail	PML and MAP; other materials as discussed (e.g., applications for assistance programs or information about a specific medication issue)	PML, MAP, and education materials (mailed if CMR is telephonic and given to member if CMR is face-to-face)
Documentation	Electronic software system	Electronic software system	MTM database with interface to electronic health record	Web-based platform	Web-based application

CMR	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Particular Interventions Emphasized	• Adherence • Low-cost alternatives	• Medication reconciliation • Adherence • Preventive care needs • Side effects	• Medication reconciliation • Adherence • Drugs to avoid in the elderly • Drug interactions • Dosing issues • Cost of medications • Care gaps • Preventive care needs	• Appropriateness of medications • Safety • Cost • Adherence • Use of standard treatment medications for chronic conditions	• Appropriateness of medications • Medication reconciliation • Reasons for medication use • Disease-focused discussions • Lifestyle factors • Monitoring parameters
Notable Changes Since 2010	None	None	None	Unknown	Unknown
Other Notable Features	None	None	Strong emphasis on preventive care; instant messaging features used for communication between pharmacists and technicians; interventions for hypertension and diabetes are particularly robust	None	Organization H makes distinctions between a "consulted CMR" and a "non-consulted CMR," where a member who does not respond to outreach attempts still receives a PML and MAP in the mail.

9.1.5 Variations in Targeted Medication Reviews (TMRs)

All Part D organizations used an automated process to detect medication issues, often referred to as "flags," that signaled the possible need for a TMR. The frequency of such analyses varied, ranging from quarterly (as was most common) to continually. Some organizations were more restrictive with what flags prompted a TMR. For example, Organization A specifically looked for polypharmacy issues such as duplicative therapy and drug-drug interactions, and Organization G used flags related to opportunities for cost savings and drug interactions. In contrast Organization F used numerous flags across a variety of medication and health issues. Following this automated identification process, pharmacists then reviewed the flags and member information to confirm the need for the TMR. Additionally, Organization F noted that it attempts to prioritize TMRs for beneficiaries who were recently discharged or experienced another transition of care, or who are taking drugs that should be avoided in the elderly. The mechanism used to complete the TMR varied and included telephone, mail, or fax. None of the Part D organizations conducted face-to-face TMRs and some of the TMRs did not include the beneficiary. TMR characteristics across Part D organizations are presented in **Table 9-5**.

Table 9-5: TMR Characteristics by Part D Organization

TMR	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Mechanism	Letter or telephone for members; fax to prescriber	Telephone to member; fax to prescriber	Telephone	Letter or fax to prescriber	Fax, letter, or telephone, depending on the type of TMR
Trigger	Vendor review of member profile and medications; "polypharmacy screening"	System-generated reminder to pharmacist to review chart	Automated process to review "flags" related to gaps in care or medication issues	Vendor-initiated automated process	Vendor-initiated automated process for reviewing claims data; four different types of TMR exist: • Gaps in care • High risk medications • Compliance: new to therapy • Compliance: late to refill by 14 days
Frequency with which Triggers are Identified	Quarterly	Quarterly	Quarterly	Every 90 days	Daily
Member Involvement	Variable	Variable	Yes	None	Variable
Notable Changes Since 2010	None	None	None	Unknown	Unknown

TMR	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Other Notable Features	None	In addition to the "official" TMR, this organization offers a variety of other MTM services such as quarterly newsletters, free pillboxes, access to an online health and medication website, and access to a telephone hotline	Priority given to beneficiaries who were recently discharged or experienced another transition of care, or who are taking drugs that should be avoided in the elderly	The purpose of the TMR is to reach out to prescribers to explore opportunities for cost savings as well as drug interactions; this occurs between the MTM vendor and prescriber, and the member is not involved	None

9.1.6 Variations in Coordination with Healthcare Providers or Programs

In general, communication with prescribers occurred following a CMR and/or TMR. Communication strategies across organizations are summarized in **Table 9-6**. One organization (Organization H) reported attempts to engage or communicate with prescribers prior to the CMR/TMR. Two organizations (Organizations F and G) reported using an EHR to communicate with prescribers. The Part D organizations did not have a good sense of which mechanisms were most effective in communicating with prescribers, and some indicated that they attempted to tailor the outreach method according to prescriber preference when known.

Table 9-6: Coordination Practices by Part D Organization

Coordination Practices	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Provider Communication Mechanism	Most often by mail; also by fax and phone for more urgent issues	Most often by fax; telephone used for urgent issues	Telephone, email, fax, mail, electronic medical record messages, face-to-face	Letters sent via fax or uploaded to the EHR; by telephone in urgent situations	Usually by fax
Provider Communication Occurrence	Following CMR and as part of TMR in some cases	Following the CMR or TMR	Following the CMR or TMR	Following the CMR or TMR	Prior to and following the CMR and TMR
Coordination with Other Programs	Not widely utilized	For MA-PD, can refer to specialty programs.	Yes; pharmacists can refer members to disease case management, specialty management, and case management programs; this is done via EHR	No	No
Notable Changes Since 2010	None	None	None	Unknown	Unknown

9.1.7 Variations in Reimbursement Methods

Reimbursement methods varied across the Part D organizations and are summarized in **Table 9-7**. Some organizations used salaried pharmacists who did not bill separately for MTM services, others used a capitated arrangement, and some reimbursed pharmacists on a fee-for-service basis.

Table 9-7: MTM Reimbursement Methods

Reimbursement	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Mechanism	Per claim administrative fee; PMPM fee for CMR-related activities; mailing and postage fees for member and prescriber communication	Pharmacists are salaried and do not receive fee-based payment for MTM services. Associated vendors receive a contracted per member fee.	Pharmacists are salaried and do not receive fee-based payment for MTM services; costs of providing MTM services are factored into Part D bid	PBM vendor used for claims processing; community pharmacists submit separate bill for performing CMR	Vendor call-center pharmacists are salaried and do not bill separately for their services; community pharmacists bill for services through the online portal or via fax and are reimbursed for CMR/TMR services if they attempt to reach a member; the CMR and TMR are billed at separate rates

9.1.8 Variations in Monitored Outcomes

Generally, Part D organizations reported tracking process measures such as CMR completion rates, TMR completion rates, and opt out rates. These measures are summarized in **Table 9-8**. A few organizations tracked information on cost savings. MTM provider and/or prescriber satisfaction were not commonly measured. Organization G, which has access to EHR data, reported conducting a small, ad hoc analysis of clinical outcomes; however, the sample size was too small to reach valid conclusions.

Overall, Part D organizations did not observe or track trends in members who benefited more from MTM services, though Organization F speculated that members on more medications with more comorbidities benefited more from MTM services than members who barely met the eligibility criteria.

Table 9-8: Outcomes and Ongoing Monitoring by Part D Organization

Outcomes and Ongoing Monitoring	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Outcomes Followed	• Member engagement • Sending materials to members on time • IVR call responses • CMR completion rates (appointments scheduled and CMRs performed) • Opt-out rates • Resolution of drug therapy problems (DTPs)	• Completed medication reviews • CMR completion rate • Average time for completed medication review • Medication problems identified and communicated to prescribers • Medication problems resolved • Rate of recommendation acceptance • Hotline calls received • CMR appointments scheduled • CMR appointments missed or refused • CMRs unable to be scheduled	• CMR rates • Opt out rates • Adherence measures • PQA measures • Number of recommended changes sent to the prescriber • Changes to drug therapy	• CMR rates • Reasons why members decline MTM services • TMR trends • Resolutions of safety and formulary alerts • (Note: Organization G has done periodic tracking of other outcomes)	• CMR rate • TMR rate (overall) • Provider acceptance of "gaps in care" TMR recommendation • Provider acceptance of "high risk medication" TMR recommendation
Quality Assurance Processes	Stakeholder group structure to monitor program performance; Part D organization audits of phone calls	Internal quality assurance program to review cases periodically using standardized quality assurance protocol at biweekly meetings.	Peer-to-peer review of MTM provider's notes (to assess the quality of the MTM intervention and documentation) on a quarterly basis	None described	None described
Notable Changes Since 2010	Opt out rates have decreased over the past few years	None	None	Unknown	Unknown

9.1.9 Ongoing Operations

Most interviewed parent organizations reported that member engagement was a primary challenge. To improve CMR recruitment, Organizations A, E, and F solicited member feedback on how to improve communication about MTM. Organization F found using language such as "CMS required comprehensive medication review" and "medication therapy management" intimidated members from participation. In response Organization F revised the language their technicians used when conducting outreach for members to participate in CMRs. In the past, technicians would go into a discussion about the CMRs using stiff/formal language and abstract concepts such as "Comprehensive Medication Review" and "Medication Therapy Management Program" which are not easy or relatable concepts for members to understand. This formal language seems to scare patients off. Organization F found that using simplified language, such as, "We would like to do an annual review of your medications for safety. Are you interested in doing that?", and "Let's talk about what the goals of the program are and focus this where you want to improve safety or reduce costs" was much more approachable for members than formal language using technical program names like, "CMS requires that we offer you this Comprehensive Medication Review as part of your Medication Therapy Management Program." Members responded more positively when Organization F used language that was easier to conceptualize and understand.

Organizations G and H both plan to improve communication with providers. Organization H believes online "chatting" is one method of engaging both members and prescribers and this is being developed for future use. Organization G plans to increase the role of health information technology to build a system that can be accessed like an EHR for the health plans and build MTM within this platform to share information and to identify opportunities for education and MTM services. Organization comments about the ongoing operations of their MTM programs are summarized in **Table 9-9**.

Table 9-9: Ongoing Operations of MTM by Part D Parent Organizations

Ongoing Operations	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Current Focus, Challenges, and Future Directions	• Greatest challenge is in engaging members and raising their awareness of MTM value. • In the near future, Organization A will submit changes to CMS to explore further engagement strategies for CMRs and address barriers to completing CMRs.	• One of the greatest challenges relates to member enrollment. Over the past three years, the percent of members enrolled in the MTM program has increased, but Organization E wants to improve this further. • Organization E is working with a university to increasing enrollment rates by developing and testing different call scripts, and improving communications through the university's communication department. • Organization E recently partnered with a provider of pharmacy services to the elderly to delivery CMRs to their LTC population in 2013. Organization E has high hopes that this partnership will help reach LTC members.	• Organization F has undertaken concentrated efforts to promote and improve member participation in the medication reviews. One approach was having technicians use language that members could easily understand when attempting to engage members in outreach. Using language such as "CMS required comprehensive medication review" and "medication therapy management" intimidated members from participation. • Organization F's continued future focus for MTM is program expansion with a goal of having an increased percentage of its overall Medicare population qualify for MTM services. • Organization F reported plans to expand their MTM program; however these efforts have been placed on hold to address new CMS requirements. For example, determining effective outreach to the LTC population is a challenge. Now that CMS requires CMRs to be offered to beneficiaries in long-term care, plans have to make changes to their program to address these needs. The Organization F representative reported that their approach should account for the likelihood that this population is most likely already receiving a CMR from the nursing home pharmacists who round on LTC beneficiaries frequently.	• The greatest challenge for Organization G is prescriber participation and having these individuals act on pharmacist recommendation. • In the future, Organization G plans to increase the role of health information technology to build a system that can be accessed like an EHR for the health plans and build MTM within this platform for information sharing to identify opportunities for education and MTM services. • Organization G also hopes to build member participation. • Organization G hopes to increase healthcare provider involvement for overall healthcare efficiency.	• In the future, Organization H's MTM vendor hopes to develop options for targeting non-qualified Part D MTM members who could be considered high-risk. • Enhanced and strategic communication between pharmacists, members, and prescribers is also a topic of interest. Online "chatting" is one method of engaging both members and prescribers and is being developed for future use. • There is ongoing clinical evaluation of enhancements that could or should be made to the MTM program.

9.2 Summary of Quantitative Results for Interviewed Part D Organizations

We specifically evaluated outcomes after MTM for interviewed Part D organizations using the difference-in-difference (DiD) estimator approach. This method was better suited to analyzing smaller sample sizes than our main regression approach (though negative findings in the setting of small sample sizes must be cautiously interpreted) due to smaller confidence intervals from comparison with a much larger number of control patients. We assessed each interviewed Part D organization's results on their targeted condition areas to identify whether high performance was achieved for beneficiaries in MTM programs along dimensions of: (i) CMR penetration, (ii) adherence effects, (iii) quality of prescribing, (iv) generic use/part D costs, (v) hospital costs, and (vi) ER costs. We assessed performance on dimensions (ii) through (vi) across each Part D organization's enrollees with CHF, COPD and diabetes for each Part D organization. The summary performance assessment for each interviewed Part D organization is described in **Table 9-10**.

Three of the five organizations interviewed targeted only CHF and diabetes (A, F and G) whereas the remaining organizations targeted all three chronic conditions. Several of the organizations (A, E, F and G) showed MTM effects on adherence and quality of prescribing across disease cohorts. Two demonstrated reduced hospitalization costs (A, E) and one organization demonstrated improved part D costs (F). One organization (H) did not demonstrate strong performance across any dimension. Two organizations (F, G) showed relatively high CMR rates (**Table 9-10**).

Table 9-10: Summary of MTM Outcomes in 2010 for Interviewed Part D Organizations

FINDING	*Organization A*	*Organization E*	*Organization F*	*Organization G*	*Organization H*
Chronic Conditions Targeted in 2010 (of the 3 cohorts analyzed)	• CHF • Diabetes	• CHF • COPD • Diabetes	• CHF • Diabetes	• CHF • Diabetes	• CHF • COPD • Diabetes
Areas of high performance* supported by quantitative analysis:	• Adherence • Quality of prescribing • Hospitalization costs	• Adherence • Quality of prescribing • Hospital/ER costs	• CMR penetration • Adherence • Quality of prescribing • Drug Safety • Part D Costs	• CMR penetration • Adherence • Quality of prescribing	• None

* High performance is defined as statistically significant improved performance at 5% significance level.

9.3 MTM Best Practices Identified in Interviews of High-Performing Part D Organizations

We evaluated the quantitative outcomes for each of the interviewed Part D parent organizations and identified whether the Part D organization represented a high-performing Part D organization. These findings are summarized in **Table 9-10.** We then interviewed the Part D organization with questions targeted to identify the practices that they employed to achieve these positive results. Similarly, we also reviewed the interview findings and practices of non-high-performing Part D organizations, when available, on the performance dimensions to assess whether identified promising practices were not also employed by the non-high-performing Part D organizations. Those practices were then identified as "best practices" and organized according to each MTM performance dimension. The best practices along each performance dimension are described in **Table 9-11**. Some practices also appear to be leveraged to achieve high performance across several dimensions. A final, unique, set of best practices is presented after **Table 9-11**, based on this combined and integrated quantitative and qualitative analysis, which reflect the best practices that a hypothetical high-performing Part D organization would employ to maximize their MTM outcomes.

Table 9-11: MTM Best Practices Identified in the Part D Organization Interviews by Performance Dimension

Performance Dimension	*Practices of High-performing Part D Organizations*
High CMR Rates (Org F, G)	• Proactive, persistent and ongoing recruitment • Multi-level recruitment approach with step-up (in intensity of contact) including letters, automated phone calls, person-to-person calls • Flexibility in performing person-to-person CMRs on short notice, including "real-time" recruitment • Use of multiple data sources (including disease registries, electronic health records, medical and prescription drug claims) to identify eligible members for high-priority targeting • Leveraging trusted community providers, e.g. community pharmacists to recruit patients to CMR
High rates of adherence (Org A, E, F, G)	• Educating patients on which medications they have been prescribed and their administration • Focusing on member understanding about why medications are needed and how they help their medical conditions • Providing accurate medication lists • Investigating and addressing any cost barriers to adherence • Use of adherence tools (analyzing data from EHR or claims data) to target patients with the lowest adherence
Improved quality of prescribing (Org A, E, F)	• Targeting specific evidence-based drug classes to chronic conditions (e.g. ACEi/ARBs for CHF and statins for diabetes) • Monitoring and documenting that quality of prescribing was evaluated and addressed during MTM • Monitoring and documenting resolution of drug therapy problems, e.g. high-risk medications, drug-drug interactions, low adherence • Using electronic health records to enable communication with prescribers to suggest drug therapy changes • Quality assurance processes, e.g. peer-to-peer review of MTM provider interventions and prescriber contacts, to ensure optimal efforts to implement MTM recommendations for improved quality in prescribing • Leveraging established working relationships between pharmacists and prescribers (more common and accessible among integrated delivery health systems)
Improved hospitalization and emergency room outcomes (Org A, E, F)	• Discontinuing high-risk, contraindicated, and duplicated medications • Focusing on medical care needs and gaps in care beyond medications alone. Includes assessing patient's status on recommended preventive care and screening, e.g., HbA1c or annual eye exams for diabetes patients ○ Comprehensive approach to the "whole patient" • Referring the patient to specialty disease/case management programs, if needed, as part of the MTM intervention • Targeting individuals with a history of high-cost hospitalizations
Lower Part D Costs (F)	• Evaluating opportunities to switch to generics as part of the MTM interventions • Recommending medication changes to equivalent formulary alternatives, when possible • Documenting and monitoring cost savings identified as part of the MTM encounter

The above findings imply that a hypothetical high-performing organization would be engaged in the following set of practices aimed to maximize their MTM enrollee outcomes:

(i) Establishing proactive and persistent CMR recruitment efforts

(ii) Targeting and aggressively recruiting patients to complete a CMR based on information on medical events such as recent a hospital discharge in addition to scanning for the usual MTM eligibility criteria

(iii) Coordinating care by utilizing trusted community relationships including networks of community pharmacists to recruit MTM eligible candidates, and utilizing existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients

(iv) Employing intensive patient education efforts aimed at addressing adherence barriers including a comprehensive understanding of the importance of each medication prescribed

(v) Documenting the opportunities that were addressed with the patient for switching to generics or formulary alternatives

(vi) Improving drug adherence by providing a complete list of prescribed medicines

(vii) Addressing financial barriers to adherence such as high drug costs by potentially switching to generics or less expensive formulary alternatives

(viii) Documenting the quality and safety of prescribing as part of the MTM intervention record (e.g. ACEi/ARBs in CHF and diabetes, cardio-selective beta-blockers in CHF, drug-drug interactions, high-risk medications)

(ix) Conducting follow-up, documentation, and resolution of any identified drug safety issues

(x) Using efficient communication methods to convey medication recommendations to prescribers including the use of e-prescribing and electronic medical records

(xi) Leveraging all available data sources (EHR, registries, claims data) to determine whether gaps in medical care are present including preventive care and maintenance care related to the patient's specific medical conditions (e.g. HbA1c and screening for kidney damage in diabetes patients).

10 DISCUSSION

This section summarizes major research findings (**Section 10.1**), discusses important implications of this research for CMS (**Section 10.2**), comments on limitations (**Section 10.3**), and proposes next steps for further research investigations (**Section 10.4**).

10.1 Summary of Major Research Findings

This research uses a mixed methods approach to investigate whether and how MTM programs improve Medicare beneficiary health outcomes. It found that MTM programs consistently and substantially improved medication adherence and quality of prescribing for important medications treating CHF, COPD and diabetes. The effect was strongest in patients receiving CMRs. Another notable research finding is that MTM programs improved the safety of drug regimens in new enrollees, but these effects had typically dissipated by the 12-months after enrollment. This research also found that there is substantial variation in performance across Part D parent organizations, and that a group of high-performing CMR programs exist that manage to improve not only drug therapy outcomes but also hospitalizations and ER visits and cost. Moreover, there were Part D organizations that managed not only to improve quality and adherence with MTM programs but also lower total Part D costs at the same time. Interestingly, both of these organizations were MA-PD plans, which may partly reflect their unique incentives to reduce hospital and ER costs for which they are also responsible.

Through our mixed methods research approach, we further identified characteristics, strategies and operations that appear to account for these findings. The qualitative interview findings revealed that the differentiating characteristics of high-performing MTM programs address a range of factors. First, these organizations commit significant efforts in recruiting Medicare beneficiaries to CMR through a persistent, step-up approach utilizing modalities starting with form letters but quickly stepping up to higher-touch modalities such as automated phone calls and finally person-to-person phone calls, if needed. Many successful organizations target high-risk populations for enrollment and CMR recruitment through tools and assessments of electronic health records and e-prescribing systems. Organizations achieving improvements in prescribing quality explicitly focused on and recorded these items as part of their MTM documentation. The same finding was true for the organization that successfully lowered Part D costs and improved the use of generics. In addition, organizations that influenced health resource costs also reported that their organizational cultures strongly supported cost-containment efforts.

10.2 Implications for CMS

Our research findings have important implications for CMS. First, they demonstrate that MTM programs can achieve substantial and sustained improvements in adherence and quality of prescribing. MTM stakeholders who were interviewed as part of this research certainly believed in MTM program abilities to improve adherence, but the quantitative support of sustained adherence effects had not been determined. In addition to adherence, MTM programs also are able to improve quality of drug prescribing. For important high-risk conditions with effective drug therapies, this is an important finding. Again, the organizations interviewed that had quantitative evidence of improved quality of prescribing reported specifically measuring and recording in the MTM record the results of these quality assessments. An additional factor positively influencing outcomes in those with strong effects on quality of prescribing was an established working relationship between pharmacist(s) and prescribers, such as the integrated health system setting.

Second, the wide variation in Part D organization performance in hospital and ER costs along with the existence of several organizations that were able to impact resource utilization is promising. The existence of organizations that successfully influenced outcomes positively for hospital and drug costs (including preventing expected cost growth) suggests substantial Medicare benefits may be possible from further research determining how this was accomplished. The research, identification and dissemination of any identified MTM program's operational or strategic factors driving these improvements could improve health outcomes for the Medicare population and positively affect future Medicare program costs.

Third, our analysis has implications for how MTM programs target and enroll eligible Medicare beneficiaries. This includes: (i) how MTM programs target and/or prioritize medical conditions, and (ii) understanding which patients are most responsive to MTM interventions. While this analysis did not specifically set out to study targeting, we found that COPD patient outcomes varied significantly between Part D parent organizations and were significantly better for organizations reporting they targeted COPD. We interpret this to suggest that chronic disease targeting by MTM programs may especially improve outcomes associated with targeted conditions. This implies that CMS guidance on the recommended or prioritized medical conditions for MTM program eligibility can influence outcomes for effort and costs expended in MTM delivery (improve MTM cost-effectiveness). Patients with conditions most positively affected by MTM could be prioritized for eligibility and recruitment to CMR. Understanding that MTM resources are limited, and that optimizing adherence to medication therapies for different chronic conditions achieves differing health and medical cost savings, CMS could use information about the benefits of achieving improved adherence through MTM to prioritize chronic conditions.

Finally, our interviews with Part D parent organizations may have policy implications for (i) CMR elements to be included in a standardized CMR format, and (ii) the role of MTM in care redesign initiatives. High-performing Part D organizations used the CMR to improve education and understanding of recommendations for prescribed medications including their relation to chronic conditions experienced by the patient. This education and understanding of medication use through CMR was suggested to be a strong factor in achieving improved outcomes by interviewees. Interviewed Part D organizations also highlighted the utility of coordinating patient care across multiple settings including hospitals and sub-acute facilities (e.g., care transitions), physician outpatient, and pharmacy settings. This suggests that medication management interventions could be an important part of care redesign initiatives facilitating broader patient care coordination and management. Further, this extends to a consideration of medication management in novel models of care delivery focused on prevention and care coordination such as accountable care organizations (ACOs), patient-centered medical homes, or innovative community health centers.

10.3 Limitations

The results in this report are limited by several factors. First, we conducted a retrospective data analysis as our quantitative research method. This method is subject to selection bias and confounding. Our results could be affected by bias if selection into MTM programs is unable to be adequately controlled for with our methodology. Reassuringly, the comparison of MTM enrollees and their control cohort does not suggest substantive differences in their health characteristics. The selectivity of the MTM program criteria between our intervention group and comparison group also did not differ, suggesting there was enough variability in MTM program eligibility criteria to successfully exploit to "pseudo-randomize" patients to our control group. Further, the concern for selection bias could also apply to the MTM with CMR intervention group. This could introduce confounding from a "healthy user effect," which refers to individuals' health-preserving behavioral tendencies that globally affect health-promoting or risk reducing activities (including CMR participation), or if more severely ill individuals are being selected for CMRs in ways that we can't control for, could introduce bias against effects from CMR for that reason in our analysis. If the healthy user effect were involved, those who opted to receive CMRs as part of their MTM programs may have been more likely to engage in other activities to stay healthy which could confound our results. However, our analysis of factors associated with CMR showed that the Part D organization was one of the strongest factors determining whether an individual receives a CMR, which is reassuring.

Second, our analyses provided results for outcomes only in the first year after enrollment. The timeline for response to MTM for health outcomes such as reduced complications and lower health resource utilization may take longer to accrue for some patients. Improved adherence to

maintenance medications for certain diseases such as diabetes would be expected to take longer than 1 year to affect outcomes significantly given the long time course of this illness before the development of the complications that the oral anti-diabetes drugs aim to treat. Thus, the expected timeline to achieving improved health and fewer complicating events may take longer after adherence is improved than the first year. Additionally, since CMRs are only required annually, the one year outcome period prevented us from examining whether a subsequent annual CMR reinforced any outcomes of interest for this study. We also did not address whether multiple CMRs during the one-year period (a practice not required by CMS) were more effective in improving outcomes than a single CMR. The analysis of outcomes over longer periods of time would improve understanding on long-term implications of MTM interventions.

Third, our drug safety analysis only examined study-population-level trends in high-risk medication use. While we determined drug safety trends at the study population level, we did not look at specific individuals to assess whether they were re-prescribed previously discontinued medications, or whether new drugs classified under the definition of "high risk" in the elderly were added to their medication regimens. Further, it should be noted that our methods do not allow the assessment of whether any individual's use of high risk medications is appropriate or not. Rather, the decreased use of these medications across the population is suggestive of improved safety of prescribing with MTM at 6 months.

Fourth, limitations in the MTM data may have biased our estimates. In fact, our estimates might have been biased downward. As confirmed by our stakeholder and Part D organization interviews, MTM programs enroll beneficiaries not meeting Medicare's eligibility guidelines and do not always report these enrollees to CMS (e.g., one organization indicated that they offered MTM with CMR to 25-30% of all Part D patients and TMR-like interventions to another 30%, yet reported only 5-10% of their MTM enrollees to CMS). This analysis does not account for Medicare beneficiaries who were enrolled in MTM by their health plan despite the fact that they did not meet CMS requirements for eligibility. As a result, some members of the comparison group may have received MTM services despite the fact that they did not meet CMS eligibility requirements and were unidentifiable in our data.

Lastly, some of the Part D organization outcome analyses had small sample sizes with potentially inadequate power. The Part D organization results should be interpreted cautiously when no effect was found and sample sizes were small. In the setting of inadequate power, the finding of a null effect should not be misconstrued as ruling out a true effect – our samples may simply not have provided enough power to detect a true effect.

10.4 Future Research Considerations

The investigation of MTM effects and their effective components should be further investigated, specifically for other chronic condition cohorts. Additionally, improved data detailing which specific interventions were delivered by MTM programs to Medicare beneficiaries would allow for more refined quantitative analysis of MTM program effects by intervention. Research would further benefit from data on factors traditionally unobserved, such as the impact of organization structure, specific MTM delivery mechanisms, and frequency of TMR on health outcomes. Improved and accurate data on these MTM characteristics would allow more sophisticated quantitative data analysis at the level of interventions delivered. For example, more detailed data on care coordination – which may be more common in a managed care setting – could be used to explore whether coordinated care across multiple settings may explain the different outcomes observed for MA-PD versus PDP MTM programs. In addition, research on other chronic conditions or combinations of common chronic conditions would allow for additional exploration of MTM benefits across disease populations. This could facilitate CMS guidance to MTM programs that would help optimize the cost-effectiveness of MTM interventions by identifying cohorts for targeting and recruitment to MTM and CMRs.

In summary, MTM programs are an effective tool for improving the health of complex Medicare beneficiaries through sustained improvements medication adherence and quality of prescribing. Further, drug safety improvements with MTM programs were initially present but appeared fleeting without further research over a longer period of time and thus reinforcing mechanisms for achieving sustained drug safety improvements by MTM should be researched and evaluated. MTM programs also appear able to reduce health service costs, though these effects varied across organizations and more research into mechanisms accounting for these effects among high-performing organizations is needed. This research contributes to the MTM knowledge base by estimating the benefits of MTM for Medicare beneficiaries with COPD, CHF and diabetes, describing the patients who benefited the most from MTM, and outlining which MTM practices are most promising for achieving these positive outcomes.

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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.[25]

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[26] 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_AppxB 1: CHF-Specific Medications Included in Analysis

Drug Class and/or Regimens[a]	*Reason for Inclusion*

• **Tier 1 Drugs (**Evidence-Based Medications**):**
  ○ **ACE inhibitors**[27-30] **and ARB**[31,32]
  ○ **Cardioselective beta-blockers including metoprolol, bisoprolol, carvedilol**[33-36]
  ○ **Selective aldosterone receptor antagonists – spironolactone**[37] **and eplenerone**[38,39]
	• Drugs shown to improve survival in randomized controlled trials and recommended in ACC/AHA Guidelines to CHF patients based upon Level 1 evidence.[40]

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_AppxB 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.[15,16]

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.

Table_AppxB 3: Diabetes-Specific Medications Included in Analysis

Drug Class and/or Regimens[a]	*Reason for Inclusion*
Oral hypoglycemics: • **Biguanides** • **Sulfonylureas** • **Dipeptidyl peptidase-4 inhibitors (DPP-IV)** • **Thiazolidinediones**	• All FDA-approved oral anti-diabetes agents
• **HMG-CoA reductase inhibitors (i.e. statins)**	• PQA-approved measure for reducing cholesterol. [24] Included due to the high prevalence of hyperlipidemia within the diabetes cohort.
• **ACE inhibitors**[27-30] **and ARB**[31,32]	• PQA-approved measure for treating hypertension co-occurring with diabetes. [24] Drugs shown to improve survival in randomized controlled trials.[40] Included due to the high prevalence of hypertension within the diabetes cohort.

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.

Table_AppxB 4: 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 • digoxin	• propoxyphene • ***Rifamycins:*** rifampin, rifabutin, rifapentine • 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
• methotrexate	• trimethoprim/sulfamethoxazole
• ***Nitrates:*** amyl nitrite, isosorbide dinitrate, isosorbide mononitrate, nitroglycerin	• ***Phosphodiesterase inhibitors:*** sildenafil, tadalafil, vardenafil
• simvastatin (40mg & 80mg) • tamoxifen • theophylline • mercaptopurine • warfarin	• amiodarone • bupropion, duloxetine, fluoxetine, paroxetine • 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

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

Table_AppxB 5: 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
Long-acting benzodiazepines (includes combination medications)	• amitriptyline-chlordiazepoxide • chlordiazepoxide	• chlordiazepoxide-clidinium • diazepam	• flurazepam
Calcium channel blockers	• nifedipine—short-acting only		
Gastrointestinal antispasmodics	• dicyclomine	• propantheline	

Description	*Prescription*		
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	

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.

APPENDIX C: MTM OUTCOMES AT SIX MONTHS

We examined the effect of MTM on drug therapy and resource utilization outcomes after six months for patients with CHF, and COPD.[a] We found positive associations between MTM and medication adherence and uptake of evidence-based medications, and MTM was also associated with taking a reduced total number of non-CHF and non-COPD medications during the outcome period. Individuals who received MTM with CMR were additionally associated with reduced all-cause hospital and ER visits, and showed associated all-cause hospital and ER cost savings. However, we found inconsistent associations between MTM without CMR and cost and resource utilization improvements. We additionally failed to find consistent associations between MTM (with and without CMR) and improved generic substitution, or reductions in drug therapy problems such as drug-drug interaction, high-risk medication, or contra-indicated medication use.

C.1 Intervention Groups

We used the same methods to construct the MTM study population at six and twelve months, with the exception that the six-month outcome study population was created based on data from an observation period of six months rather than twelve. **Table_AppxC 1** illustrates the stepwise implementation of the exclusion criteria to build the six-month CHF and COPD intervention groups.

[a] Six-month outcomes were not examined for diabetes due to the longer timeline needed for diabetes-related interventions to impact several outcomes of interest for this study.

Table_AppxC 1: Illustration of Stepwise Implementation of Exclusion Criteria to Select Final CHF and COPD Intervention Groups

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%
Included in the MTM Intervention Groups	**242,865**			**253,288**		
Received CMR	**25,207**	**10.4%**		**29,011**	**11.5%**	
Did not receive CMR	**2217,658**	**89.6%**		**224,277**	**88.5%**	

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.

C.2 Comparison Groups

Comparison groups for each six-month MTM disease cohort were constructed in an identical manner to the comparison groups for the main analysis of twelve months. **Table_AppxC 2** and **Table_AppxC 3** 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 (based on risk scores) in 2010.

Table_AppxC 2: 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_AppxC 3: 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

C.3 Effect of MTM on Drug Therapy Outcomes at Six Months

Six months into the outcome period, we found positive associations between MTM and medication adherence and uptake of evidence-based medications. However, we found inconsistent associations between MTM and discontinuing high-risk medications, drug-drug interactions, and contraindicated medications.

C.3.1 Drug Therapy Outcomes for CHF

While MTM programs provided by PDPs and MA-PDs showed similar impacts on enrollees with CHF 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 =0.95) 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=0.64, MTM without CMR: OR=0.88). However, individuals in MA-PDs who were enrolled in MTM programs, without receiving CMRs, had higher odds (MTM without CMR: OR=1.11) 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_AppxC 4**, individuals in MTM programs had higher odds of 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=1.20; MA-PD: OR=1.38). However, those receiving CMRs as part of their MTM programs were not consistently more likely to experience these two drug therapy outcomes.

Table_AppxC 4: Risk-Adjusted Drug Therapy Outcomes for Individuals with CHF (Odds Ratio with 95% CI)

Part D Contract Type	*Intervention Group*	*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*
PDP	Comparison	208,850	---	---	---	---	---
	MTM without CMR	136,305	1.20* (1.12, 1.28)	1.04* (1.01, 1.06)	1.05 (.99, 1.12)	1.04* (1.01, 1.07)	.88* (.85, .91)
	With CMR	14,858	1.100 (.93, 1.30)	1.14* (1.07, 1.22)	0.95 (.82, 1.11)	1.04 (.97, 1.11)	0.64* (.60, .69)
MA-PD	Comparison	62,119	---	---	---	---	---
	MTM without CMR	81,353	1.38* (1.25, 1.51)	1.03 (.99, 1.08)	1.14* (1.02, 1.27)	0.95* (.91, 1.0)	1.11* (1.04, 1.18)
	With CMR	10,349	1.30* (1.06, 1.60)	1.24* (1.14, 1.35)	1.12 (.92, 1.36)	1.18* (1.08, 1.29)	1.14 (1.0, 1.30)

* Indicates significance at the p<0.05 level.

C.3.2 Drug Therapy Outcomes for COPD

As shown in **Table_AppxC 5**, beneficiaries in PDPs with COPD 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-PDs 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_AppxC 5: Risk-Adjusted Drug Therapy Outcomes for Individuals with COPD (Odds Ratio with 95% CI)

Part D Contract Type	*Intervention Group*	*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*
PDP	Comparison	250,593	---	---	---	---	---
	MTM without CMR	141,324	1.08 * (1.03 , 1.13)	1.02 (.95 , 1.10)	1.12 * (1.06 , 1.18)	1.06 (.98 , 1.13)	1.05 * (1.02 , 1.08)
	With CMR	19,149	1.17 * (1.06 , 1.28)	1.19 (.99 , 1.43)	1.30 * (1.16 , 1.45)	0.97 (.82 , 1.15)	1.05 (.98 , 1.12)
MA-PD	Comparison	86,725	---	---	---	---	---
	MTM without CMR	82,953	1.03 (.96 , 1.10)	1.02 (.92 , 1.13)	1.05 (.97 , 1.14)	1.02 (.90 , 1.16)	.95 * (.91 , 1.0)
	With CMR	9,862	1.10 (.95 , 1.26)	1.06 (.87 , 1.30)	0.97 (.81 , 1.15)	1.04 (.82 , 1.32)	1.12 * (1.02 , 1.23)

* Indicates significance at the 5% level.

C.4 Effect of MTM on Hospital and ER Visits at Six Months

Our six-month outcomes analysis showed some positive associations between receiving a CMR and experiencing reducing all-cause hospitalizations and ER visits in the outcome period. However, these outcomes were inconsistent for non-CMR recipients. Furthermore, other risk-adjusted disease-specific hospital and ER visit outcomes were mixed for both MTM enrollees who did and did not receive CMR.

C.4.1 Hospital and ER Visit Outcomes for CHF

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_AppxC 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=1.04) compared to the comparison group, while those who received CMRs had lower odds of experiencing such a hospitalization (OR=0.93). Individuals enrolled in MA-PDs who did not receive a CMR had higher odds of all-cause and CHF-related hospitalization (OR=1.03 and 1.13, respectively); those who received a CMR had slightly lower odds of these

events, although this effect was still significant for CHF-related hospitalization (OR=1.08). However, most intervention groups experienced lower odds of having an ER visit.

Table_AppxC 6: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Hospital and ER Visits (Odds Ratio with 95% CI)

Part D Contract Type	*Intervention Group*	*N*	*Any (All-Cause) Hospitalization*	*Any CHF-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any CHF-Related ER Visit*
PDP	Comparison	208,850	---	---	---	---
	MTM without CMR	136,305	0.99 (.97, 1.01)	1.04* (1.02, 1.06)	.96* (.94, .98)	1.03* (1.00, 1.06)
	With CMR	14,858	.88* (.84, .92)	.93* (.88, .98	.91* (.87, .95)	.93* (.87, 1.00)
MA-PD	Comparison	62,119	---	---	---	---
	MTM without CMR	81,353	1.03* (1.00, 1.06)	1.13* (1.09, 1.17)	---	---
	With CMR	10,349	0.99 (.94, 1.05)	1.08* (1.01, 1.15)	---	---

* Indicates significance at the 5% level.

C.4.2 Hospital and ER Visit Outcomes for COPD

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_AppxC 7**). 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=1.05), 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=.90). Among individuals enrolled in MA-PDs, those who received CMRs had lower odds of all-cause hospitalization and ER visits (OR=0.86 and 0.88, respectively). Those who were enrolled in MTM but did not receive a CMR also had lower odds of all-cause ER visits (OR=0.97).

Table_AppxC 7: Risk-Adjusted Resource Utilization for Individuals with COPD: Hospital and ER Visits (OR with 95% CI)

Part D Contract Type	*Comparison or Intervention Group Assignment*	*N*	*Any (All-Cause) Hospitalization*	*Any COPD-Related Hospitalization*	*Any (All-Cause) ER Visit*	*Any COPD-Related ER Visit*
PDP	Comparison	250,593	---	---	---	---
	MTM without CMR	141,324	.98 * (.96 , .99)	1.01 (.99 , 1.03)	.97 * (.95 , .98)	1.02 (.99 , 1.04)
	With CMR	19,149	.86 * (.82 , .89)	0.96 (.92 , 1.01)	.88 * (.85 , .92)	1.03 (.98 , 1.09)
MA-PD	Comparison	86,725	---	---	---	---
	MTM without CMR	82,953	1.05 * (1.02 , 1.08)	1.03 (1.00 , 1.07)	---	---
	With CMR	9,862	0.96 (.91 , 1.02)	.90 * (.84 , .97)	---	---

* Indicates significance at the 5% level.

C.5 Effect of MTM on Medicare Use and Healthcare Costs at Six Months

After six months, MTM was associated with reductions in all-cause hospital and ER costs for individuals who received CMR and who were diagnosed with either CHF or COPD. All-cause hospitalization savings were approximately $61 to $81 per month and ER costs lowered by $2-3 per month. In some cases, MTM enrollees also experienced lower Part D costs of approximately $3-7 per month for their non-CHF or non-COPD medications. MTM was additionally associated with a reduction in the total number of non-CHF and non-COPD medications filled during the outcome period.

C.5.1 Medication Use and Healthcare Cost Outcomes for CHF

After adjusting for covariates, individuals in PDP MTM programs – regardless of receipt of CMRs – tended to show slight differences in their medication and costs outcomes compared to the PDP comparison group. Their results are shown in **Table_AppxC 8** 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_AppxC 8**, 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.
- **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_AppxC 8: Risk-Adjusted Resource Utilization Outcomes for Individuals with CHF: Medications and Costs (OLS Estimate with 95% CI)

Part D Contract Type	*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*
PDP	Comparison	208,850	---	---	---	---	---	---	---
	MTM without CMR	136,305	-.14 * (-.15 , -.12)	.000 (-.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	-.05 * (-.091 , -.007)	.000 (-.002 , .002)	-$30.22 (-67.889 , 7.455)	-$490.15* (-764.66 , -215.64)	-$211.87 (-429.23 , 5.50)	-$15.60* (-28.60 , -2.60)	-$6.47 (-13.66 , .72)
MA-PD	Comparison	62,119	---	---	---	---	---	---	---
	MTM without CMR	81,353	-.29 * (-.308 , -.262)	-.002 * (-.003 , -.000)	-$30.75 * (-52.553 , -8.951)	---	---	---	---
	With CMR	10,349	-.27 * (-.319 , -.229)	-.006 * (-.009 , -.004)	-$31.33 (-74.072 , 11.420)	---	---	---	---

* Indicates significance at the 5% level.

C.5.2 Medication Use and Healthcare Cost Outcomes for COPD

Similar to the CHF cohort, individuals in PDP MTM programs tended to show slight differences in their medication and cost outcomes compared to the PDP comparison group. Their results are shown in **Table_AppxC 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.
- 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_AppxC 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.
- **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_AppxC 9: Risk-Adjusted Resource Utilization Outcomes for Individuals with COPD: Medications and Costs (OLS Estimate with 95% CI)

Part D Contract Type	*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*
PDP	Comparison	250,593	---	---	---	---	---	---	---
	MTM without CMR	141,324	-.13 * (-.14 , -.11)	.002 * (.001 , .004)	-42.18 * (-56.19 , -28.16)	$61.90 (-45.17 , 168.97)	$35.15 (-38.09 , 108.40)	-$5.60* (-10.89 , -.30)	-$1.23 (-4.96 , 2.49)
	With CMR	19,149	-.08 * (-.12 , -.04)	.004 * (.001 , .006)	-34.61 * (-67.50 , -1.73)	-$369.55* (-592.31 , -146.78)	-$50.55 (-218.72 , 117.62)	-$20.30* (-31.8 , -8.80)	$2.13 (-5.90 , 10.17)
MA-PD	Comparison	86,725	---	---	---	---	---	---	---
	MTM without CMR	82,953	-.14 * (-.16 , -.12)	.006 * (.004 , .007)	-$17.39 (-36.52 , 1.728)	---	---	---	---
	With CMR	9,862	-.05 * (-.10 , -.01)	.006 * (.002 , .009)	-$10.62 (-50.29 , 29.05)	---	---	---	---

* Indicates significance at the 5% level.

APPENDIX D: ALTERNATIVE ESTIMATION APPROACH: THE DIFFERENCE-IN-DIFFERENCES METHOD

We conducted alternative analyses using a difference-in-differences (DiD) estimation approach to evaluate outcomes among Medicare beneficiaries enrolled in MTM programs in 2010 compared with a different set of beneficiaries selected using a cell matching method. This DiD analysis compared changes in outcomes between MTM enrollees and matched control beneficiaries from the baseline period to the one-year period following MTM enrollment. We assessed MTM effects for each drug therapy outcome for each chronic condition cohort and presented drug therapy and resource utilization outcomes for each Part D organization. The DiD analysis provided results for all Part D parent organizations even when the main linear regression often could not (due to model non-convergence with small intervention groups). **Section D.1** describes the empirical approach for the DiD analysis. **Subsections D.2, D.3,** and **D.4** present the results from the DiD analyses for drug therapy outcomes after MTM in the overall congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes cohorts and the Part D organization results for drug therapy and resource utilization outcomes.

D.1 Empirical Approach

We used a DiD estimator to calculate the differences in outcome changes between MTM enrollees and matched controls from the baseline period preceding MTM enrollment to the one-year outcome period following enrollment. We constructed the comparison groups for the DiD analysis using an exact cell matching method; Medicare beneficiaries in the comparison groups were exactly matched with MTM enrollees on each of the selected demographic and health characteristics, and the assessed outcome in the baseline period. In the main linear regression analysis, however, the comparison groups consisted of beneficiaries who were not matched individually to MTM enrollees along these dimensions but selected more loosely based MTM eligibility factors, and risk-adjusted for remaining differences in baseline demographic and health characteristics. The main regression method also includes hospital referral region (HRR) fixed effects and Part D organization fixed effects whereas the DiD estimator method does not. This was due to the inability to match a large percent of the intervention group (> 10%) when these factors were added to the matching algorithm for controls. The intervention group selection and stratification process, and the outcomes assessed remained the same in the DiD analysis as in the main linear regression analysis. As in the main analysis, we also conducted DiD analysis for sub-populations of MTM enrollees receiving MTM services from different Part D organizations. **Subsections D.1.1** and **D.1.2** describe the selection of the intervention groups and comparison groups for the DiD analysis. **Subsection D.1.3** then details the empirical specification used to calculate the DiD estimator.

D.1.1 Intervention Groups

The intervention group selection and stratification process in the DiD analysis was the same as in the main linear regression analysis. Beneficiaries in the intervention group were restricted to those:

- Continuously enrolled in Part D during study period
- Enrolled in the same Part D contract during outcome period
- Enrolled in a Part D contract that passed data validation for MTM section
- With Part D 2009 risk data, and not identified as new in their Medicare Risk-Adjustment System file
- With congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), or diabetes[a]
- With at least one Prescription Drug Event (PDE) claim in 2010
- Without end-stage renal disease in 2009[b]
- Not receiving long-term institutional (LTI) care in 2010
- Enrolled in at least one MTM program for at least one day in 2010
- New to MTM in 2010
- With the same contract reported in MTM beneficiary-level and Part D enrollment files.

The intervention groups went through several stratifications. First, MTM enrollees were divided into disease cohorts based on the presence of CHF, COPD, or diabetes mellitus, and further stratified based on whether they were enrolled in a Medicare Advantage Prescription Drug (MA-PD) plan or a Prescription Drug Plan (PDP). Finally, the MA-PD and PDP beneficiaries in each disease cohort were divided into those receiving a comprehensive medication review (CMR) and those not receiving a CMR as a part of the MTM intervention. The individually constructed intervention groups in the Part D organization-level analysis also went through the same stratification.

[a] Some beneficiaries met criteria for more than one of the studied chronic conditions (CHF, COPD, and/or diabetes) and are thus included in multiple cohorts

[b] Patients with a diagnosis of ESRD were excluded from the analysis due to their systematically different Medicare eligibility criteria and resource utilization profile.

D.1.2 Cell Matched Comparison Groups

We employed an exact cell matching method to construct the comparison groups for the DiD analysis. The comparison groups were constructed from the universe of Medicare beneficiaries restricted by all the factors listed above for the intervention group but not enrolled in any MTM program in 2010 according to their Part D plan data. In the DiD analysis, MTM enrollees were matched with controls from this restricted pool of Medicare beneficiaries regardless of their MTM eligibility unlike in the main linear regression analysis. These beneficiaries were then grouped with MTM enrollees into cells defined by the unique combination of each of the demographic and drug use characteristics listed in **Table_Appx D.1** and **Table_Appx D.20**. For example, beneficiaries between the ages of 66-75, who were female, white, and with 9-10 maintenance drug prescriptions in the baseline period were grouped into the same cell with an MTM enrollee who shared each of these characteristics. For the analysis of changes in an outcome, beneficiaries in the comparison group had to also match with MTM enrollees on that outcome in the baseline period. For example, for the analysis of changes in adherence to a diabetes regimen, an MTM enrollee was exactly matched to his/her control beneficiary on adherence to that regimen in the baseline period (either '1' for a PDC ≥ 80%, or '0' for a PDC < 80%) in addition to each of the specific brackets for age, gender, race, socioeconomic and disability status, and drug use listed in **Table_Appx D.1**. MTM enrollees without any matched controls in their cell had to be excluded from the study. This cell matching approach is equivalent to matching on propensity scores when the propensity score equation contains the same set of fully interacted categorical variables and the matching is performed on exact probabilities.

Table_Appx D.1: Variables Used to Match MTM Enrollees with Controls for the Difference-in-differences Analysis of Drug Therapy and Health Service Utilization Outcomes

Matching Variables	*Description*
Age	4 Age brackets: ≤ 65, 66 to 75, 76 to 85, and 86+
Gender	Takes on the value of '1' for male, or '2' for female.
Race or Ethnicity	Takes on the value of '1' for white, '2' for black, '3'for Hispanic and'4' for others.
Number of Maintenance Drugs (in the baseline period)	4 brackets for number of maintenance drugs : ≤ 8, 9 to 10, 11 to 12, 13+
Socioeconomic Status (SES)	Takes on the value of '1' if LIS eligible, or '2'.
Disability Status	Takes on the value of '1' if eligible for disability benefits, or '2'.
Drug Cost Score	Obtained by running an OLS regression of normalized drug costs in the baseline period on all health condition indicators for available RxHCCs, and are evenly divided into 4 brackets.
Number of Prescribers (in the baseline period)	4 brackets for number of prescribes: ≤ 2, 3 to 4, 5 to 6, and 7+
Hospital Referral Region (HRR) Hospital Costs	A category of missing HRR hospital costs, and 5 evenly divided categories of non-missing HRR hospital costs.
Outcome Assessed (in the baseline period)	Takes on the value of '1' or '0' for drug therapy outcomes, hospitalizations, and ER visits; 5 evenly divided brackets for other outcomes.

D.1.3 Difference-in-Differences Estimator Method

The difference-in-differences (DiD) matching estimator used in this study compared changes in outcomes between MTM enrollees and their matched controls during the 12-month period following MTM enrollment date or index date, relative to a baseline period of 12 months preceding enrollment. This DiD estimation was performed in several steps. **Subsection D.1.2** describes the first step of grouping MTM enrollees and non-enrollees into cells defined by unique combinations of demographic, drug use, and outcome characteristics listed in **Table_Appx D.1**. Non-enrollees who fell into the same cell as an MTM enrollee were considered matched controls for that MTM enrollee. Once these cell groupings were determined, we calculated the average change in outcomes among matched controls in each cell, weighted by the share of MTM enrollees in each cell to account for differences. We then summed these average changes among matched controls across cells to obtain the average change in outcomes for the entire comparison group. We next averaged changes in outcomes among all MTM enrollees in the intervention group. The DiD estimators then calculated the differences between the average changes in outcomes in the comparison groups and the average changes in outcomes in the intervention groups. The computation of the DiD estimator is illustrated below for each outcome "*Y*":

$$DiD_Y = \left[\frac{1}{N}\sum_i \left(Y_i^{t'} - Y_i^t\right)\right] - \left[\sum_k \sum_{j \in k} \frac{N_k}{N}\left(\frac{Y_j^{t'} - Y_j^t}{M_{jk}}\right)\right]$$, where:

Y_i^t is the assessed outcome for MTM enrollee *i* in time *t,*

Y_j^t is the assessed outcome for matched control *j* in time *t,*

t and *t'* are the time periods before and after MTM enrollment,

k represents cells containing MTM enrollees and matched controls,

N is the number of MTM enrollees,

N_k is the number of MTM enrollees allocated to cell *k,* and

M_{jk} is the number of matched controls allocated to cell *k.*

This estimation strategy assumes that beneficiaries in the same cell *k* have the same expected change in outcomes in the absence of participation, and controls for observed differences in time-invariant characteristics between MTM enrollees and controls that could affect outcomes before the MTM enrollment date. The DiD method applied to well matched

cells thus has potential to reduce the bias introduced by time invariant factors such as health-seeking behavior among MTM enrollees.

We finally calculated the standard errors to determine the statistical significance of the resulting DiD estimators for assessed outcomes at the 95% confidence level using the following formulation:

$$\text{standard error} = \left[\frac{\hat{\sigma}_a^2}{N}\right] + \left[\sum_k \rho_k{}^2 \left(\frac{\hat{\sigma}_{b_k}^2}{m_k}\right)\right], \text{ where}$$

$\hat{\sigma}_a^2$ is the variance of changes in outcome from baseline period to outcome period among MTM enrollees,

N is the total number of MTM enrollees across cells, n_k is the number of MTM enrollees in cell k, $\rho_k = \frac{n_k}{N}$,

$\hat{\sigma}_{b_k}^2$ is the variance of changes in outcome from baseline period to outcome period among controls, and

m_k is the number of controls in cell k.

D.2 Results: Impact on MTM Beneficiaries with CHF

Medicare beneficiaries with congestive heart failure (CHF) who were enrolled in an MTM program in 2010 experienced improvements in their adherence to and take-up of evidence-based CHF medications, did not experience improvements in quality of prescribing measures, increased their number of medications and total drug costs, and experienced mixed effects on hospitalizations, ER visits and associated costs. The DiD results for individual Part D organizations varied widely across drug therapy and resource utilization outcomes. **Section D.2.1** describes the demographic characteristics, medical costs, and health service utilization in the baseline period of MTM enrollees and their matched controls enrolled in Part D prescription drug plans (PDP) or Medicare advantage drug plans (MA-PD). **Section D.2.2** presents the difference-in-differences (DiD) analysis results for all drug therapy outcomes for the entire CHF cohort, while **Section D.2.3** presents the same by Part D organization. **Section D.2.4** then presents the DiD analysis results on all resource utilization outcomes for the entire CHF cohort, and **Section D.2.5** presents the same by Part D organization.

D.2.1 Characteristics of the Study Population

MTM beneficiaries and controls in the CHF cohort were exactly matched on gender, age, black and white race, low incomes subsidy (LIS) status, and disability status, and fairly well matched on other races; regions of residence; mortality rate (in the outcome period); and the incidence of chronic conditions, number of maintenance drug prescriptions, drug and medical costs in the one-year baseline period preceding MTM enrollment. **Table_Appx D.2** compares these demographic and health characteristics between MTM enrollees and their matched controls included in the analysis of all-cause hospitalizations. The comparisons of demographic and health characteristics were similar for the intervention and comparison groups constructed for the other outcomes assessed for the CHF cohort. Additionally, **Table_Appx D.2** shows that the PDP cohort consisted for larger shares of beneficiaries who were 65 years of age or younger, disabled, and eligible for low income subsidy compared with the MA-PD cohorts. The average number of chronic maintenance drugs in the baseline period was larger among MTM beneficiaries receiving CMR compared with MTM beneficiaries not receiving CMR within the PDP or MA-PD cohorts.

Table_Appx D.2: Baseline Characteristics of MTM Beneficiaries with CHF and their Matched Controls in the Analysis of Hospitalizations by Part D Plan Type

Demographic and Health Characteristics	*Beneficiaries Enrolled in:*							
	PDPs				*MA-PDs*			
	MTM with CMR	*Controls*	*MTM without CMR*	*Controls*	*MTM with CMR*	*Controls*	*MTM without CMR*	*Controls*
N	12,412	356,820	101,286	627,784	10,732	230,201	59,764	339,358
Gender								
Male	31.6%	31.6%	40.0%	40.0%	47.2%	47.2%	44.5%	44.5%
Age								
≤ 65	25.3%	25.3%	13.7%	13.7%	7.5%	7.5%	11.4%	11.4%
66-75	33.2%	33.2%	31.6%	31.6%	35.5%	35.5%	34.9%	34.9%
76-85	30.9%	30.9%	37.1%	37.1%	42.8%	42.8%	39.3%	39.3%
≥ 85	10.6%	10.6%	17.6%	17.6%	14.2%	14.2%	14.4%	14.4%
Race								
White	75.8%	75.8%	83.5%	83.5%	82.6%	82.6%	81.4%	81.4%
Black	18.6%	18.6%	11.0%	11.0%	10.6%	10.6%	12.3%	12.3%
Hispanic	3.2%	2.8%	2.4%	2.5%	2.8%	3.1%	3.3%	3.3%
Other or Unknown	2.4%	2.7%	3.2%	3.0%	4.0%	3.7%	2.9%	2.9%
Region of Residence								
New England	2.0%	3.6%	3.1%	3.7%	3.0%	2.9%	6.6%	3.6%
Mid-Atlantic	5.8%	9.9%	17.0%	13.6%	7.6%	16.2%	21.0%	18.3%
East North Central	20.2%	17.1%	13.9%	16.5%	3.5%	9.1%	10.6%	10.3%
West North Central	8.4%	7.3%	6.4%	7.3%	0.7%	3.8%	3.8%	4.4%
South Atlantic	21.0%	20.9%	21.1%	20.3%	12.9%	16.7%	18.1%	18.0%
East South Central	11.3%	11.4%	9.0%	9.5%	1.7%	4.4%	6.5%	5.9%
West South Central	24.7%	17.8%	13.8%	14.2%	3.1%	8.8%	10.3%	9.6%
Mountain	2.5%	3.4%	4.0%	4.4%	9.7%	9.6%	6.3%	8.2%
Pacific	4.0%	8.4%	11.5%	10.3%	57.6%	28.3%	16.5%	21.4%
Socioeconomic Status								
Eligible for Low Income Subsidy	71.1%	71.1%	44.0%	44.0%	21.5%	21.5%	35.2%	35.2%
Disability Status & Mortality Rate								
Disabled	27.5%	27.5%	15.2%	15.2%	8.8%	8.8%	12.7%	12.7%
Mortality Rate in the Outcome Period	0.7%	0.5%	0.7%	0.6%	0.8%	0.5%	0.7%	0.5%
Drug Use in the Baseline Period								
Average Number of Maintenance Drugs	13.3	12.7	11.9	11.4	11.7	11.2	11.3	10.8
Specific Health Conditions								
Diabetes	69.6%	55.2%	63.0%	48.3%	65.4%	50.1%	65.9%	50.4%
Dyslipidemia	77.2%	74.4%	78.8%	74.1%	84.9%	77.6%	83.1%	76.8%
Rheumatoid Arthritis	6.4%	5.9%	4.4%	4.9%	3.9%	4.5%	4.1%	4.9%
AMI & Unstable Angina	67.7%	67.5%	70.4%	68.2%	68.0%	66.7%	71.4%	66.5%
Stroke & Cerebral Hemorrhage	23.1%	25.4%	25.6%	25.6%	20.9%	23.1%	24.3%	23.1%
Vascular Disease	32.5%	32.6%	32.6%	33.1%	36.7%	34.8%	35.9%	34.3%
Asthma & COPD	58.7%	51.7%	46.1%	44.3%	45.4%	45.1%	44.9%	45.5%

Demographic and Health Characteristics	Beneficiaries Enrolled in:							
	PDPs				MA-PDs			
	MTM with CMR	*Controls*	*MTM without CMR*	*Controls*	*MTM with CMR*	*Controls*	*MTM without CMR*	*Controls*
Costs in the Baseline Period[a]								
Part D Costs (All Drugs)	$7,788	$6,144	$5,955	$4,895	$4,741	$3,586	$4,832	$3,632
Hospitalization Costs	$9,858	$11,345	$10,514	$10,800	N/A	N/A	N/A	N/A
Emergency Room Costs	$522	$590	$409	$454	N/A	N/A	N/A	N/A

a. Medical cost outcomes were not available for beneficiaries enrolled in Medicare advantage prescription drug (MA-PD) plans.

D.2.2 Drug Therapy Outcomes

MTM enrollees with CHF increased their adherence to evidence-based CHF medications in both the PDP and MA-PD cohorts, and those receiving MTM without CMR also increased their take-up of evidence-based CHF medications. However, we did not find positive effects on quality of prescribing measures such as removal of drug-drug-interactions, and discontinuation of high-risk and contraindicated medications for CHF among MTM beneficiaries compared with controls. The number of PDP enrollees with an adherence of 80% or more to evidence-based CHF medications ("adherent beneficiaries") increased by 4.0% in the MTM with CMR sub-cohort, and by 2.7% in the MTM without CMR sub-cohort. The number of adherent MA-PD beneficiaries increased by 5.8% in the MTM with CMR sub-cohort, and by 2.5% in the MTM without CMR sub-cohort. The number of PDP and MA-PD beneficiaries taking up evidence-based CHF medications increased by 1.4% and 2.9% in the MTM without CMR sub-cohorts. The number of MTM beneficiaries with removed drug-drug interactions, and discontinued use of high-risk and contraindicated medications for CHF, however, were 2.2-14.7% smaller than matched controls in the PDP cohort, and 2.4-4.2% smaller than matched controls in the MA-PD cohort. **Table_Appx D.3** and **Table_Appx D.4** present the detailed difference-in-differences (DiD) estimation results for the MTM beneficiaries with CHF in the PDP and MA-PD cohorts.

Table_Appx D.3: Drug Therapy Outcomes among MTM Beneficiaries with CHF and Matched Controls Enrolled in PDPs

Part D Contract Type	*MTM Type*	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
			MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
PDP	*With CMR*	**Quality of Prescribing**										
		% Take-Up of Evidence-Based CHF Meds	838	15,554	0.0%	0.0%	23.5%	22.4%	1.1%	1.5%	-1.8%	4.0%
		Adherence										
		% Adherent to Evidence-Based CHF Meds	9,485	226,812	88.1%	88.1%	83.5%	79.4%	4.0%*	0.4%	3.3%	4.8%
		Drug Safety										
		% With Removed Drug-Drug Interaction	1,215	8,295	0.0%	0.0%	37.2%	44.3%	-7.1%*	1.4%	-9.8%	-4.4%
		% With Discontinued Use of High Risk Medications	5,119	107,612	0.0%	0.0%	23.7%	28.4%	-4.7%*	0.6%	-5.8%	-3.5%
		% With Discontinued Use of Contraindicated Medications	4,336	43,538	0.0%	0.0%	37.0%	51.7%	-14.7%*	0.7%	-16.2%	-13.3%
	Without CMR	**Quality of Prescribing**										
		% Take-Up of Evidence-Based CHF Medications	7,869	87,718	0.0%	0.0%	24.0%	22.6%	1.4%*	0.5%	0.5%	2.4%
		Adherence										
		% Adherent to Evidence-Based CHF Medications	74,550	386,227	86.5%	86.5%	82.2%	79.5%	2.7%*	0.1%	2.4%	3.0%
		Drug Safety										
		% With Removed Drug-Drug Interaction	9,309	25,196	0.0%	0.0%	42.8%	45.0%	-2.2%*	0.5%	-3.2%	-1.2%
		% With Discontinued Use of High-Risk Medications	44,363	200,982	0.0%	0.0%	24.7%	28.3%	-3.5%*	0.2%	-3.9%	-3.1%
		% With Discontinued Use of Contraindicated Medications	24,488	93,882	0.0%	0.0%	45.4%	52.6%	-7.2%*	0.3%	-7.8%	-6.6%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.4: Drug Therapy Outcomes among MTM Beneficiaries with CHF and Matched Controls Enrolled in MA-PDs

Part D Contract Type	*MTM Type*	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
			MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
MA-PD	*With CMR*	**Quality of Prescribing**										
		% Take-Up of Evidence-Based CHF Medications	462	12,600	0.0%	0.0%	26.4%	23.1%	3.3%	2.1%	-0.7%	7.3%
		Adherence										
		% Adherent to Evidence-Based CHF Medications	8,634	138,579	91.4%	91.4%	88.8%	83.0%	5.8%*	0.4%	5.1%	6.5%
		Drug Safety										
		% With Removed Drug-Drug Interaction	746	3,427	0.0%	0.0%	46.8%	47.6%	-0.9%	1.8%	-4.4%	2.7%
		% With Discontinued Use of High-Risk Medications	3,974	54,851	0.0%	0.0%	28.1%	30.5%	-2.4%*	0.7%	-3.8%	-1.0%
		% With Discontinued Use of Contraindicated Medications	1,799	16,120	0.0%	0.0%	55.9%	54.9%	1.0%	1.2%	-1.3%	3.3%
	Without CMR	**Quality of Prescribing**										
		% Take-Up of Evidence-Based CHF Medications	3546	41,072	0.0%	0.0%	24.2%	21.4%	2.9%*	0.7%	1.5%	4.3%
		Adherence										
		% Adherent to Evidence-Based CHF Medications	44,293	205,900	87.3%	87.3%	83.3%	80.8%	2.5%*	0.2%	2.1%	2.8%
		Drug Safety										
		% With Removed Drug-Drug Interaction	4,132	9,212	0.0%	0.0%	45.6%	48.0%	-2.4%*	0.8%	-3.9%	-0.9%
		% With Discontinued Use of High Risk Medications	23,572	91,931	0.0%	0.0%	25.5%	29.7%	-4.2%*	0.3%	-4.8%	-3.7%
		% With Discontinued Use of Contraindicated Medications	10,962	40,962	0.0%	0.0%	54.7%	54.1%	0.6%	0.5%	-0.3%	1.5%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.2.3 Drug Therapy Outcomes by Part D Organization

Most Part D organizations were associated with increases in CHF medication adherence, while only a few were associated with improvements in quality of prescribing measures. PDP or MA-PD beneficiaries receiving MTM from Part D organizations A-F improved their adherence to CHF medications, with Organization A and F having the largest estimated increases in the percentage of adherent beneficiaries. Those receiving MTM from Organization A, C, D, and F also improved their take-up of evidence-based CHF drugs. However, only those receiving MTM from Organization A, C, or F were associated with discontinued use of contraindicated medications or removal of drug-drug interactions. The results for Organization G and H were limited due to small sample sizes. **Table_Appx D.5** and **Table_Appx D.6** provide the detailed drug therapy outcome results by Part D organization for the PDP and MA-PD cohorts.

In the PDP cohorts, all organizations except for Organization C were associated with improvements in adherence outcomes; however, only Organization C was associated with removal of drug-drug interactions. The number of adherent PDP beneficiaries increased by 3.7-12.2% for Organization A, B, D, and E in the MTM with CMR sub-cohort, and by 1.8-3.8% for Organization A, B, C, and E in the MTM without CMR sub-cohort. We observed a 3.0% and 20.9% increase in the number of PDP enrollees taking up evidence-based CHF drugs for Organization C and D in the MTM without CMR sub-cohort. While most organizations were not associated with improvements in quality of prescribing measures, 4.7% more PDP beneficiaries receiving MTM without CMR from Organization C removed their drug-drug interactions compared with matched controls.

In the MA-PD cohort, Organization A and F were associated with both increases in adherence to and take-up of evidence-based CHF drugs, and discontinued use of contraindicated medications, while Organization C, D and E were also only associated with improved adherence to and/or take-up of CHF medications. The number of adherent MA-PD beneficiaries increased by 4.0-10.3% for Organizations A, D, E, and F in the MTM with CMR sub-cohort, and by 1.7-7.8% for Organizations A, C, E and F in the MTM without CMR sub-cohort. We also observed a 14.5% increase in MA-PD beneficiaries taking up evidence-based CHF drugs for Organization F in the MTM with CMR sub-cohort, and by 5.9-15.1% for Organization A, C, and F in the MTM without CMR sub-cohort. The number of MA-PD enrollees who discontinued their use of medications contraindicated for CHF was 8.2-9.1% more than controls for Organization F, and 2.8% more than controls for Organization F in the MTM without CMR sub-cohort. For most of the other Part D organizations, however, there were smaller percentages of MTM enrollees who had removed drug-drug interactions, and discontinued use of high-risk and contraindicated medications compared with controls in both the PDP and MA-PD cohorts.

Table_Appx D.5: Drug Therapy Outcomes among MTM Beneficiaries with CHF Compared with Matched Controls by Part D Organization for Individuals Enrolled in PDPs

MTM Type	*Outcome*	*Part D Organization*									
		A		*B*		*C*		*D*		*E*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Quality of Prescribing**										
	% Take-Up of Evidence-Based CHF Medications	-	N/A	307	0.7%	38	13.1%	391	0.8%	-	N/A
	Adherence										
	% Adherent to Evidence-Based CHF Medications	139	12.2%*	2927	4.2%*	224	-1.1%	5196	3.7%*	79	8.2%*
	Drug Safety										
	% With Removed Drug-Drug Interaction	26	-13.6%	417	-8.7%*	18	-2.4%	648	-4.1%*	-	N/A
	% With Discontinued Use of High Risk Medications	79	-9.0%*	1,792	-6.6%*	115	-3.8%	2,568	-3.9%*	43	5.2%
	% With Discontinued Use of Contraindicated Medications	28	4.7%	2,162	-22.2%*	59	-12.5%	1,821	-7.6%*	21	-28.1%*
Without CMR	**Quality of Prescribing**										
	% Take Up of Evidence-Based CHF Medications	458	2.3%	1,354	0.9%	1,335	3.0%*	19	29.0%*	277	0.0%
	Adherence										
	% Adherent to Evidence-Based CHF Medications	13,677	3.8%*	11,424	2.6%*	10,020	1.8%*	249	4.9%	4,033	4.7%*
	Drug Safety										
	% With Removed Drug-Drug Interaction	1,916	-5.9%*	1,490	-3.1%*	912	4.7%*	45	-2.7%	496	1.0%
	% With Discontinued Use of High Risk Medications	8,386	-3.5%*	6,734	-5.2%*	5,460	-1.7%*	159	-5.7%	2,146	-2.5%*
	% With Discontinued Use of Contraindicated Medications	2,722	-0.4%	7,493	-16.9%*	2,573	0.4%	76	-0.3%	1,212	-7.3%*

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.6: Drug Therapy Outcomes among MTM Beneficiaries with CHF Compared with Matched Controls by Part D Organization for Individuals Enrolled in MA-PDs

MTM Type	*Outcome*	*Part D Organization*															
		A		*B*		*C*		*D*		*E*		*F*		*G*		*H*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Quality of Prescribing**																
	% Take-Up of Evidence-Based CHF Medications	-	N/A	-	N/A	29	13.4%	38	-9.5%	-	N/A	127	14.5%*	-	N/A	-	N/A
	Adherence																
	% Adherent to Evidence-Based CHF Medications	128	10.3%*	99	-1.1%	356	3.7%	479	4.0%*	12	9.5%*	4784	7.3%*	115	4.0%	-	N/A
	Drug Safety																
	% With Removed Drug-Drug Interaction	17	-10.4%	14	-4.3%	36	-3.7%	46	-18.4%*	-	N/A	330	5.0%	20	2.7%	N/A	N/A
	% With Discontinued Use of High Risk Medications	73	-0.2%	57	-6.9%	198	-2.9%	243	-6.4%*	-	N/A	1804	1.3%	69	-1.2%	-	N/A
	% With Discontinued Use of Contra-indicated Medications	34	-3.3%	63	-20.1%*	96	2.1%	138	-0.8%	-	N/A	677	9.1%*	13	15.7%	-	N/A
With-out CMR	**Quality of Prescribing**																
	% Take Up of Evidence-Based CHF Medications	335	6.8%*	17	23.3%	960	5.9%*	-	N/A	11	-10.1%	82	15.1%*	-	N/A	N/A	N/A
	Adherence																
	% Adherent to Evidence-Based CHF Medications	9,431	1.7%*	233	-1.7%	7,757	2.1%*	22	2.7%	414	7.8%*	3,235	4.9%*	110	-0.3%	108	-1.4%
	Drug Safety																
	% With Removed Drug-Drug Interaction	975	-3.6%*	22	3.2%	632	0.9%	-	N/A	32	-2.2%	226	-0.4%	13	8.9%	N/A	N/A
	% With Discontinued Use of High Risk Medications	5,369	-5.9%*	152	-1.9%	4,220	-2.2%*	14	2.8%	187	-8.9%*	1,176	0.7%	59	1.6%	65	-3.0%
	% With Discontinued Use of Contra-indicated Medications	2,151	2.8%*	99	-9.9%*	2,369	0.1%	-	N/A	117	-0.9%	428	8.2%*	16	-1.3%	20	-19.6%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.2.4 Resource Utilization Outcomes

MTM beneficiaries with CHF experienced increased rates of hospitalizations, and increased number of medications. In the PDP cohort, MTM beneficiaries experienced increase in hospitalizations and number of medications, mixed effects on ER visits and costs, and no change in the generic substitution ratio for CHF or non-CHF drugs compared with controls. PDP beneficiaries receiving MTM with CMR experienced a 1.4-1.8% increase in all-cause and CHF-related hospitalizations, 1.1% increase in CHF-related ER visits, and 1.3% increase in number of medications, but a 0.0% increase in the generic substitution ratio for CHF medications. PDP beneficiaries receiving MTM without CMR experienced a 1.0-1.5% increase in all-cause and CHF-related hospitalizations but a 0.8% decrease in all-cause ER visits. PDP beneficiaries receiving MTM without CMR cohort also experienced 0.0% increase in generic substitution ratio for both CHF and non-CHF drugs and a slightly smaller increase of 0.8% in the number of medications than the MTM with CMR cohort. MTM beneficiaries in the MA-PD cohorts had similar results for number of medications and generic substitution ratio but slightly larger estimates of the increases in all-cause and CHF-related hospitalizations at 2.2-4.0% for the MTM with CMR sub-cohort, and 2.8-3.3% in the MTM without CMR sub-cohort. Complete information on ER visits and costs were not available for the MA-PD enrollees and have thus not been reported for the MA-PD cohort. **Table_Appx D.7** and **Table_Appx D.8** provide detailed resource utilization results for MTM beneficiaries with CHF in the PDP and MA-PD cohorts.

Table_Appx D.7: Resource Utilization Outcomes for MTM Beneficiaries and Controls with CHF Enrolled in PDPs

MTM Type	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Hospital and Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	12,412	356,820	50.8%	50.8%	46.8%	45.4%	1.4%*	0.6%	0.4%	2.5%
	Any CHF-Related Hospitalization (%)	12,433	381,165	31.6%	31.6%	29.2%	27.4%	1.8%*	0.5%	0.9%	2.8%
	Any (All-cause) ER Visits (%)	12,399	356,098	48.1%	48.1%	48.2%	47.7%	0.4%	0.5%	-0.6%	1.5%
	Any CHF-Related ER Visit (%)	12,428	415,439	15.5%	15.5%	16.3%	15.2%	1.1%*	0.4%	0.3%	1.9%
	Average Medication Use										
	Number of Medications	12,052	370,766	20.0	19.7	19.9	18.2	1.3*	0.1	1.2	1.4
	Generic Substitution Ratio (CHF)	12,401	420,967	1.0	1.0	1.0	1.0	0.0*	0.0	0.0	0.0
	Generic Substitution Ratio (Non-CHF)	12,155	313,687	0.9	0.9	0.9	0.9	0.0	0.0	0.0	0.0
Without CMR	**Hospital and Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	101,286	627,784	50.8%	50.8%	43.3%	42.2%	1.0%*	0.2%	0.6%	1.4%
	Any CHF-Related Hospitalization (%)	101,371	631,534	31.9%	31.9%	27.0%	25.6%	1.5%*	0.2%	1.1%	1.8%
	Any (All-cause) ER Visits (%)	101,311	627,540	41.2%	41.2%	40.2%	40.9%	-0.8%*	0.2%	-1.2%	-0.4%
	Any CHF-Related ER visits (%)	101,430	634,958	12.2%	12.2%	12.4%	12.2%	0.2%	0.1%	0.0%	0.5%
	Average Medication Use										
	Number of Medications	99,213	610,593	17.5	17.1	17.1	15.9	0.8*	0.0	0.8	0.8
	Generic Substitution Ratio (CHF)	100,524	597,697	1.0	1.0	1.0	1.0	0.0*	0.0	0.0	0.0
	Generic Substitution Ratio (Non-CHF)	97,861	527,693	0.9	0.9	0.9	0.9	0.0*	0.0	0.0	0.0

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.8: Resource Utilization Outcomes for MTM Beneficiaries and Controls with CHF Enrolled in MA-PDs

MTM Type	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Hospital and Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	10,732	230,201	42.6%	42.6%	35.2%	32.9%	2.2%*	0.6%	1.1%	3.4%
	Any CHF-Related Hospitalization (%)	10,742	240,851	28.3%	28.3%	24.6%	20.6%	4.0%*	0.5%	2.9%	5.0%
	Average Medication Use										
	Number of Medications	10,294	227,221	16.6	16.3	16.1	14.6	1.2*	0.1	1.1	1.3
	Generic Substitution Ratio (CHF)	10,878	246,340	0.9	1.0	1.0	1.0	0.0*	0.0	0.0	0.0
	Generic Substitution Ratio (Non-CHF)	10,294	187,227	0.9	0.9	0.9	0.9	0.0*	0.0	0.0	0.0
Without CMR	**Hospital and Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	59,764	339,358	45.1%	45.1%	36.4%	33.6%	2.8%*	0.2%	2.3%	3.3%
	Any CHF-Related Hospitalization (%)	59,785	342,239	27.5%	27.5%	22.7%	20.4%	2.3%*	0.2%	1.9%	2.7%
	Average Medication Use										
	Number of Medications	57,216	327,095	16.0	15.7	15.6	14.4	0.8*	0.0	0.8	0.9
	Generic Substitution Ratio (CHF)	60,520	324,554	1.0	1.0	1.0	1.0	0.0*	0.0	0.0	0.0
	Generic Substitution Ratio (Non-CHF)	57,374	276,086	0.9	0.9	0.9	0.9	0.0*	0.0	0.0	0.0

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.2.5 Resource Utilization Outcomes by Part D Organization

MTM beneficiaries with CHF experienced increases in total number of medications, total drug costs, and hospitalizations for most Part D organizations; mixed effects on ER visits and costs across Part D organizations; and no effect on generic substitution ratio for CHF or non-CHF medications for all organizations. Organization A was associated with reductions in ER and hospitalization costs for the PDP cohort. **Table_Appx D.9** and **Table_Appx D.10** present the detailed drug therapy results by Part D organization for the PDP and MA-PD cohorts.

In the PDP cohort, Organizations A-E were associated with $320-$810 increase total drug costs, and mixed cost and utilization results for hospitalizations and ER. Organization A was associated with a $4,991 decrease in all-cause hospitalization costs among beneficiaries receiving MTM with CMR but an increase of $552 in hospitalization costs and 1.1% increase in all-cause hospitalizations among beneficiaries receiving MTM without a CMR. However, we also observed increases in hospitalizations and hospitalization costs for Organizations B and C in the MTM without CMR sub-cohort and for Organization D in the MTM with CMR sub-cohort. The results for ER visits and costs were mixed in the MTM without CMR sub-cohorts: Organizations A and B were associated with decreases in all-cause ER visits or ER costs, while Organizations A, B, and C were associated with increases in CHF-related ER visits or costs. There was a 0.0% or no change in the generic substitution ratio for CHF or non-CHF medications for most Part D organizations.

In the MA-PD cohort, Organizations A-F were associated with increases in total drug costs and hospitalizations. Organizations A-F were associated with a wide range of increase in total drug costs. Organizations A, C, D, E, F and H were also associated with a 2.1-13.2% increase in all-cause hospitalizations. As in the PDP cohort, MA-PD enrollees did not experience changes in their generic substitution ratio for CHF or non-CHF medications.

Table_Appx D.9: Resource Utilization Outcomes of MTM Beneficiaries with CHF Enrolled in PDPs by Part D Organization

MTM Type	*Outcome*	*Part D Organization*									
		A		*B*		*C*		*D*		*E*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
	Hospital and Emergency Room Visits:										
	Any (All-cause) Hospitalization (%)	165	-3.9%	3,977	0.7%	336	2.0%	6,646	2.9%*	96	0.1%
	Any CHF-Related Hospitalization (%)	164	1.1%	3,982	0.3%	338	1.0%	6,658	3.6%*	94	0.4%
	Any (All-cause) ER Visits (%)	164	3.0%	3,971	1.9%*	338	1.3%	6,639	-0.1%	94	-4.2%
	Any CHF-Related ER visits (%)	163	-0.5%	3,986	0.5%	338	0.3%	6,648	1.6%*	94	1.4%
	Average Medication Use and Costs:										
With CMR	Generic Substitution Ratio (CHF)	164	0.0	3,898	0.0*	336	-0.0	6,589	0.0*	95	0.0
	Generic Substitution Ratio (Non-CHF)	160	0.0	3,813	0.0	325	0.0	6,430	0.0	94	0.0
	Part D costs for CHF Drugs	160	$136	3,858	$93*	332	$72*	6,420	$71*	93	$43
	Part D costs for Non-CHF Drugs	162	-$45	3,835	$393*	335	$303*	6,398	$271*	95	$292
	All-Cause Hospitalization Costs	161	-$4,991*	3,863	$421	334	$1,553	6,455	$1,306*	89	-$3,504
	CHF-Related Hospitalization Costs	159	-$1,427	3,884	$403	336	-$179	6,479	$889*	91	-$2,969
	All-Cause ER Costs	160	-$111	3,873	$32	336	$21	6,439	$23	93	$140
	CHF-Related ER costs	157	-$24	3,897	-$8	336	-$15	6,483	$16	93	-$34
	Hospital and Emergency Room Visits:										
	Any (All-cause) Hospitalization (%)	17,269	1.1%*	15,575	1.7%*	14,581	2.6%*	330	4.1%	5,071	-0.7%
	Any CHF-Related Hospitalization (%)	17,279	3.1%*	15,602	1.8%*	14,586	1.8%*	331	6.4%*	5,081	1.1%
	Any (All-cause) ER Visits (%)	17,277	-1.3%*	15,593	-1.0%*	14,583	1.4%*	327	-0.6%	5,073	-1.0%
	Any CHF-Related Hospitalization (%)	17,303	0.7%*	15,600	0.0%	14,593	1.0%*	329	-1.2%	5,081	0.5%
	Average Medication Use and Costs:										
With-out CMR	Generic Substitution Ratio (CHF)	17,368	0.0	15,144	0.0*	14,399	0.0*	319	0.0	5,127	0.0*
	Generic Substitution Ratio (Non-CHF)	16,781	0.0*	14,882	0.0*	13,864	0.0	316	0.0	4,888	0.0*
	Part D costs for CHF Drugs	16,769	$49*	15,202	$99*	14,424	$73*	319	$54	4,882	$49*
	Part D costs for Non-CHF Drugs	16,835	$266*	15,021	$438*	14,369	$301*	309	$875*	4,849	$303*
	All-Cause Hospitalization Costs	16,861	$552*	15,164	$722*	14,342	$521*	318	$368	4,873	$299
	CHF-Related Hospitalization Costs	16,866	$746*	15,216	$619*	14,368	$441*	317	$1,027	4,899	$262
	All-Cause ER Costs	16,901	-$25*	15,153	$17	14,384	$15*	315	$101	4,896	$1
	CHF-Related ER costs	17,462	-$8	15,737	$13*	14,665	-$8	332	$2	5,158	-$3

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.10: Resource Utilization Outcomes of MTM Beneficiaries with CHF Enrolled in MA-PDs by Part D Organization

MTM Type	*Outcome*	*Part D Organization*															
		A		***B***		***C***		***D***		***E***		***F***		***G***		***H***	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Hospital Visits:**																
	Any (All-cause) Hospitalization (%)	170	-1.6%	136	-5.3%	497	3.0%	625	0.8%	17	-22.1%	5,572	3.6%*	141	2.2%	-	N/A
	Any CHF-Related Hospitalization (%)	176	-2.7%	137	-4.3%	494	0.3%	625	1.4%	17	-15.1%	5,571	7.6%*	141	3.3%	-	N/A
	Average Medication Use and Costs:															-	
	Generic Substitution Ratio (CHF)	175	0.0	137	0.0	508	0.0	628	0.0	17	0.0*	5,030	0.0	143	0.0	-	N/A
	Generic Substitution Ratio (Non-CHF)	160	0.0	132	0.0	473	0.0	590	0.0	15	0.0*	5,058	0.0*	139	0.0	-	N/A
	Part D costs for CHF Drugs	153	$137*	119	$177*	465	$46	586	$86*	15	$148	5,201	-$19*	131	$103	-	N/A
	Part D costs for Non-CHF Drugs	159	-$165	125	$274	463	$100	584	$235	17	$126	5,188	$177*	132	$102	-	N/A
With-out CMR	**Hospital Visits:**																
	Any (All-cause) Hospitalization (%)	12,231	2.1%*	312	3.0%	11,503	2.2%*	34	18.2%*	503	7.8%*	3,770	2.4%*	131	7.0%	136	-1.3%
	Any Diabetes-Related Hospitalization (%)	12,238	2.8%*	314	1.3%	11,508	0.1%	34	0.2%	510	-3.1%	3,749	5.1%*	129	0.2%	133	3.5%
	Average Medication Use and Costs:																
	Generic Substitution Ratio (CHF)	12,639	0.0*	318	0.0	11,589	0.0	34	0.0	522	0.0*	3,430	0.0*	129	0.0	134	0.0
	Generic Substitution Ratio (Non-CHF)	11,425	0.0*	308	0.0	10,735	0.0	32	0.0	506	0.0	3,412	0.0*	121	0.0	133	0.0
	Part D costs for CHF Drugs	11,087	$114*	292	$82*	11,081	$54*	32	$178*	457	$46	3,513	-$10	120	$218*	127	$49
	Part D costs for Non-CHF Drugs	11,149	$237*	291	$221	11,063	$173*	30	$948*	462	-$239	3,512	-$71	115	$398*	123	$225*

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.3 Results: Impact on MTM Beneficiaries with COPD

Medicare beneficiaries with COPD who were enrolled in an MTM program in 2010 experienced improvements in adherence to COPD medication regimens, mixed effects on drug safety measures, increases in the number of medications, total drug costs and hospitalizations, and mixed effects on ER visits compared with matched controls. The DiD results for individual Part D organizations however varied widely across both drug therapy and resource utilization outcomes. **Section D.3.1** describes the demographic and health characteristics in the baseline period of MTM beneficiaries with COPD and their matched controls enrolled in Part D prescription drug plans (PDP) or Medicare advantage drug plans (MA-PD). **Section D.3.2** presents the difference-in-differences (DiD) analysis results for all drug therapy outcomes for the entire COPD cohort, while **Section D.3.3** presents the same by Part D organization. **Section D.3.4** then presents the DiD analysis results on all resource utilization outcomes for the entire COPD cohort, and **Section D.3.5** presents the same by Part D organization.

D.3.1 Characteristics of the Study Population

MTM beneficiaries and controls in the COPD cohort were exactly matched on gender, age, black and white race, low incomes subsidy (LIS) status, and disability status, and fairly well matched on other races; regions of residence; mortality rate (in the outcome period); and the incidence of chronic conditions, number of maintenance drug prescriptions, drug and medical costs in the one-year baseline period preceding MTM enrollment. **Table_Appx D.11** compares these demographic and health characteristics between MTM enrollees and their matched controls included in the analysis of all-cause hospitalizations. The comparisons of demographic and health characteristics were similar for the intervention and comparison groups constructed for the other outcomes assessed for the COPD cohort. Additionally, **Table_Appx D.11** shows that the PDP cohort consisted for larger shares of beneficiaries who were 65 years of age or younger, disabled, and eligible for low-income subsidy compared with the MA-PD cohorts. The average number of chronic maintenance drugs in the baseline period was larger among MTM beneficiaries receiving CMR compared with MTM beneficiaries not receiving CMR within the PDP or MA-PD cohorts.

Table_Appx D.11: Baseline Demographic and Health Characteristics of MTM Beneficiaries with COPD and their Matched Controls for Hospitalization Outcomes by Part D Plan Type

Demographic and Health Characteristics	*Beneficiaries Enrolled in:*							
	PDPs				*MA-PDs*			
	MTM with CMR	*Controls*	*MTM without CMR*	*Controls*	*MTM with CMR*	*Controls*	*MTM without CMR*	*Controls*
N	16,078	508,935	108,138	776,071	10,132	335,971	61,957	483,192
Gender								
Male	30.5%	30.5%	37.9%	37.9%	45.0%	45.0%	42.8%	42.8%
Age								
≤ 65	34.5%	34.5%	23.2%	23.2%	10.0%	10.0%	15.5%	15.5%
66-75	34.6%	34.6%	35.7%	35.7%	38.9%	38.9%	40.9%	40.9%
76-85	24.7%	24.7%	30.9%	30.9%	40.7%	40.7%	34.8%	34.8%
≥ 85	6.2%	6.2%	10.2%	10.2%	10.4%	10.4%	8.8%	8.8%
Race								
White	82.5%	82.5%	86.7%	86.7%	86.4%	86.4%	86.6%	86.6%
Black	13.3%	13.3%	8.6%	8.6%	8.2%	8.2%	8.7%	8.7%
Hispanic	2.2%	2.2%	1.9%	2.0%	2.2%	2.5%	2.4%	2.5%
Other or Unknown	2.0%	2.0%	2.7%	2.6%	3.1%	2.9%	2.3%	2.3%
Region of Residence								
New England	2.4%	4.4%	3.5%	4.4%	4.0%	3.7%	7.7%	3.6%
Mid-Atlantic	5.0%	8.6%	14.8%	11.7%	7.7%	16.0%	17.9%	16.1%
East North Central	21.8%	18.3%	14.4%	17.0%	4.5%	8.4%	11.7%	9.2%
West North Central	10.1%	7.8%	7.5%	7.4%	0.9%	3.5%	3.7%	4.1%
South Atlantic	22.0%	21.8%	22.3%	21.7%	13.8%	18.1%	19.7%	20.2%
East South Central	12.1%	12.9%	10.4%	11.1%	2.2%	5.4%	8.8%	6.8%
West South Central	20.3%	14.8%	12.9%	12.9%	3.8%	8.7%	9.5%	9.1%
Mountain	2.4%	3.4%	3.8%	4.3%	11.9%	9.2%	6.8%	8.9%
Pacific	3.9%	7.9%	10.2%	9.5%	51.0%	26.9%	14.0%	21.6%
Socioeconomic Status								
Eligible for Low Income Subsidy	77.0%	77.0%	54.1%	54.1%	24.2%	24.2%	38.0%	38.0%
Disability Status & Mortality Rate								
Disabled	37.0%	37.0%	25.2%	25.2%	11.4%	11.4%	17.2%	17.2%
Mortality Rate in the Outcome Period	0.5%	0.4%	0.5%	0.5%	0.7%	0.4%	0.6%	0.4%
Drug Use in the Baseline Period								
Average Number of Maintenance Drugs	12.8	12.1	11.5	10.8	11.1	10.5	10.6	9.8
Specific Health Conditions								
Diabetes	56.4%	43.1%	52.4%	38.2%	55.5%	37.9%	56.0%	37.0%
Congestive Heart Failure	40.1%	37.9%	37.8%	36.7%	40.5%	36.4%	37.7%	33.4%
Hypertension	53.0%	51.6%	53.9%	51.7%	53.2%	52.8%	54.7%	53.7%
Dyslipidemia	72.0%	68.8%	73.7%	68.2%	80.3%	72.0%	78.9%	69.9%
Rheumatoid Arthritis	6.6%	5.4%	4.8%	4.9%	4.2%	4.8%	4.3%	5.0%

Demographic and Health Characteristics	*Beneficiaries Enrolled in:*							
	PDPs				*MA-PDs*			
	MTM with CMR	*Controls*	*MTM without CMR*	*Controls*	*MTM with CMR*	*Controls*	*MTM without CMR*	*Controls*
Specific Health Conditions								
AMI & Unstable Angina	50.1%	50.7%	51.6%	50.3%	50.4%	48.9%	51.7%	45.9%
Stroke & Cerebral Hemorrhage	18.8%	20.9%	20.6%	21.1%	18.1%	19.4%	20.2%	18.9%
Vascular Disease	27.2%	28.3%	28.3%	28.4%	33.4%	31.6%	32.2%	29.8%
Costs in the Baseline Period[a]								
Part D Costs (All Drugs)	$8,441	$6,752	$6,610	$5,536	$4,902	$3,904	$4,968	$3,989
Hospitalization Costs	$7,885	$9,141	$8,543	$8,779	N/A	N/A	N/A	N/A
Emergency Room Costs	$498	$575	$421	$467	N/A	N/A	N/A	N/A

a. Medical cost outcomes were not available for beneficiaries enrolled in Medicare advantage prescription drug (MA-PD) plans.

D.3.2 Drug Therapy Outcomes

MTM beneficiaries across all PDP and MA-PD cohorts were associated with increases in adherence to all assessed COPD medication regimens; however, only the MA-PD, MTM with CMR cohort was associated with a positive effect on a quality of prescribing measure. Beneficiaries who were adherent to the long-acting beta-adrenergics (LABA) regimens increased by 2.1-4.3%; beneficiaries adherent to the long-acting anticholinergics (LAAC) regimens increased by 2.4-5.5%; and those adherent to LABA-LAAC combination regimens increased by 0.9-3.3%. The larger increases in adherent beneficiaries to all three regimens were seen among those receiving MTM with CMR. Most cohorts had smaller percentages of MTM beneficiaries with removed drug-drug interactions, or discontinued use of high-risk medication compared with matched controls. Only the MA-PD, MTM with CMR sub-cohort had 6.7% more beneficiaries with removed drug-drug interactions compared with matched controls suggesting an improvement in quality of prescribing for this sub-cohort. **Table_Appx D.12** and **Table_Appx D.13** report drug therapy results for MTM beneficiaries with COPD in greater detail for the PDP and MA-PD cohorts.

Table_Appx D.12: Drug Therapy Outcomes among MTM Beneficiaries with COPD and Matched Controls Enrolled in PDPs

MTM Type	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Adherence**										
	% Adherent to LABA Medications[c]	4,743	62,448	17.5%	17.5%	20.4%	16.1%	4.3%*	0.5%	3.3%	5.3%
	% Adherent to LAAC Medications[d]	1,185	11,905	18.3%	18.3%	23.2%	19.6%	3.6%*	1.2%	1.3%	5.9%
	% Adherent to LABA + LAAC Combinations[e]	4,577	45,000	10.3%	10.3%	14.4%	11.2%	3.3%*	0.5%	2.3%	4.2%
	Drug Safety										
	% With Removed Drug-Drug Interaction	1,108	4,909	0.0%	0.0%	37.5%	43.7%	-6.1%*	1.5%	-9.0%	-3.3%
	% With Discontinued Use of High-Risk Medication	5,745	115,919	0.0%	0.0%	24.3%	27.8%	-3.5%*	0.6%	-4.6%	-2.4%
Without CMR	**Adherence**										
	% Adherent to LABA Medications	28,249	136,188	13.7%	13.7%	17.3%	13.9%	3.4%*	0.2%	3.0%	3.8%
	% Adherent to LAAC Medications	9,165	52,346	17.1%	17.1%	21.9%	18.4%	3.5%*	0.4%	2.7%	4.3%
	% Adherent to LABA + LAAC Combinations	26,049	93,708	7.9%	7.9%	11.7%	9.4%	2.3%*	0.2%	2.0%	2.7%
	Drug Safety										
	% With Removed Drug-Drug Interaction	6,365	13,859	0.0%	0.0%	43.1%	44.5%	-1.4%*	0.6%	-2.7%	-0.2%
	% With Discontinued Use of High-Risk Medication	39,474	192,354	0.0%	0.0%	25.8%	29.2%	-3.4%*	0.2%	-3.8%	-2.9%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

c. LABA stands for long-acting beta-adrenergics.

d. LAAC stands for long-acting anticholinergics.

e. LABA-LAAC combination regimens include long-acting beta-adrenergics and long-acting anticholinergics.

Table_Appx D.13: Drug Therapy Outcomes among MTM Beneficiaries with COPD and Matched Controls Enrolled in MA-PDs

MTM Type	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Adherence**										
	% Adherent to LABA Medications[c]	2,065	32,013	10.9%	10.9%	16.5%	12.7%	3.7%*	0.8%	2.2%	5.2%
	% Adherent to LAAC Medications[d]	850	8,510	15.6%	15.6%	23.4%	18.0%	5.5%*	1.4%	2.8%	8.1%
	% Adherent to LABA + LAAC Combinations[e]	1,838	21,301	5.2%	5.2%	9.8%	7.3%	2.5%*	0.7%	1.2%	3.8%
	Drug Safety										
	% With Removed Drug-Drug Interaction	483	1,547	0.0%	0.0%	51.8%	45.1%	6.7%*	2.3%	2.2%	11.2%
	% With Discontinued Use of High-Risk Medication	3,228	56,517	0.0%	0.0%	29.9%	32.0%	-2.1%*	0.8%	-3.6%	-0.5%
Without CMR	**Adherence**										
	% Adherent to LABA Medications	13,568	69,528	9.9%	9.9%	13.8%	11.7%	2.1%*	0.3%	1.6%	2.6%
	% Adherent to LAAC Medications	5,204	28,982	13.7%	13.7%	18.9%	16.5%	2.4%*	0.5%	1.4%	3.4%
	% Adherent to LABA + LAAC Combinations	11,766	45,584	5.0%	5.0%	8.4%	7.5%	0.9*	0.2%	0.4%	1.4%
	Drug Safety										
	% With Removed Drug-Drug Interaction	2,581	4,863	0.0%	0.0%	45.6%	45.6%	0.0%	1.0%	-1.9%	1.9%
	% With Discontinued Use of High-Risk Medication	20,913	97,757	0.0%	0.0%	27.3%	31.2%	-03.9%*	0.3%	-4.5%	-3.3%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

c. LABA stands for long-acting beta-adrenergics.

d. LAAC stands for long-acting anticholinergics.

e. LABA-LAAC combination regimens include long-acting beta-adrenergics and long-acting anticholinergics.

D.3.3 Drug Therapy Outcomes by Part D Organization

PDP beneficiaries with chronic obstructive pulmonary disease (COPD) receiving MTM from Organization B, D, and E experienced improvements in adherence to COPD medication regimens but did not improve their quality of prescribing measures, whereas MA-PD beneficiaries with COPD receiving MTM from Organization F experienced improvements in both. In the PDP cohort, Organizations B, D and E were associated with improvements in adherence to COPD medications, while Organizations A and C were not. For Organizations B, D and E, the number of beneficiaries adherent to COPD LABA, LAAC, and LABA-LAAC combination regimens increased by 1.9-9.9%. For Organizations A, B, D, and E, the percentage of PDP beneficiaries with removed drug-drug interactions, and discontinued use of high-risk medications were smaller than those for matched controls, suggesting no improvement in quality of prescribing measures. The PDP beneficiary results for MTM with CMR sub-cohorts for Organization A, C and E were limited due to small sample sizes. Results for most Part D Organizations in the MA-PD cohort were also limited by small sample sizes except for Organization F which was associated with improvements in both adherence and quality of prescribing measures, and for the MTM without CMR sub-cohorts for Organization A, B, and C which were not associated with improvements in either. For Organization F, adherent MA-PD beneficiaries increased by 2.8-10.5%, and the number of beneficiaries with removed drug-drug interactions and discontinued use of high-risk medications was 3.1-14.4% higher than matched controls suggesting an improvement in quality of prescribing measures for Organization F. **Table_Appx D.14** and **Table_Appx D.15** provide detailed drug therapy results by Part D organization for MTM beneficiaries with COPD.

Table_Appx D.14: Drug Therapy Outcomes for MTM Beneficiaries with COPD Enrolled in PDPs by Part D Organization

MTM Type	*Outcome*	*Parent Organization*									
		A		*B*		*C*		*D*		*E*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Adherence**										
	% Adherent to LABA Medications[c]	18	3.4%	2,172	3.7%*	66	-0.5%	2,187	4.6%*	21	12.9%
	% Adherent to LAAC Medications[d]	13	11.4%	264	3.3%	27	-8.5%	738	4.1%*	-	N/A
	% Adherent to LABA + LAAC Combinations[e]	12	4.7%	1,990	4.6%*	52	-4.6%*	2,183	1.9%*	30	13.9%
	Drug Safety										
	% With Removed Drug-Drug Interaction	-	N/A	428	-6.5%*	14	7.8%	582	-5.2%*	-	N/A
	% With Discontinued Use of High-Risk Medication	53	6.7%	2,474	-5.7%*	106	-6.4%	2,603	-1.8%*	39	-10.3%
Without CMR	**Adherence**										
	% Adherent to LABA Medications	2,158	1.0%	8,080	5.1%*	3,023	-0.4%	103	5.0%	1,146	7.6%*
	% Adherent to LAAC Medications	1,011	0.0%	1,236	3.5%*	1,474	0.1%	34	4.3%	340	9.9%*
	% Adherent to LABA + LAAC Combinations	1,887	0.2%	7,326	2.7%*	2,222	-1.2%*	99	1.4%	973	7.3%*
	Drug Safety										
	% With Removed Drug-Drug Interaction	995	-4.5%*	1,399	-3.3%*	502	0.0%	37	0.7%	329	2.4%
	% With Discontinued Use of High-Risk Medication	5,094	-2.2%*	8,273	-5.2%*	4,521	0.0%	153	-9.1%*	1,741	-4.1%*

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

c. LABA stands for long-acting beta-adrenergics.

d. LAAC stands for long-acting anticholinergics.

e. LABA-LAAC combination regimens include long-acting beta-adrenergics and long-acting anticholinergics.

Table_Appx D.15: Drug Therapy Outcomes for MTM Beneficiaries with COPD Enrolled in MA-PDs by Part D Organization

MTM Type	*Outcome*	*Part D Organization*															
		A		*B*		*C*		*D*		*E*		*F*		*G*		*H*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Adherence**																
	% Adherent to LABA Medications[c]	21	-1.2%	88	2.3%	137	-3.5%	146	0.4%	-	N/A	779	6.2%*	13	11.4%	N/A	N/A
	% Adherent to LAAC Medications[d]	12	10.4%	-	N/A	42	0.1%	60	7.3%	-	N/A	427	7.9%*	-	N/A	N/A	N/A
	% Adherent to LABA + LAAC Combinations[e]	20	24.0%*	57	-0.5%	79	1.5%	197	2.3%	-	N/A	674	2.8%*	-	N/A	N/A	N/A
	Drug Safety										N/A						
	% With Removed Drug-Drug Interaction	-	N/A	17	-11.9%	25	17.4%	37	-9.0%	-	N/A	184	14.4%*	-	N/A	N/A	N/A
	% With Discontinued Use of High-Risk Medication	55	5.7%	100	-10.1%*	201	0.1%	239	-7.0%*	-	N/A	1,223	3.1%*	30	-0.2%	-	N/A
Without CMR	**Adherence**																
	% Adherent to LABA Medications	1,839	0.5%	159	-1.3%	2,904	-0.4%	-	N/A	123	3.7%	577	5.8%*	26	9.9%	27	9.5%
	% Adherent to LAAC Medications	736	0.6%	16	-9.2%*	1,154	-2.0%*	-	N/A	23	-9.9%*	248	10.5%*	-	N/A	N/A	N/A
	% Adherent to LABA + LAAC Combinations	1,634	-0.1%	141	-0.3%	2,231	-0.7%	11	-2.3%*	61	10.1%*	468	3.9%*	13	-2.0%*	N/A	N/A
	Drug Safety																
	% With Removed Drug-Drug Interaction	576	0.3%	30	-5.6%	409	3.1%	-	N/A	24	-7.5%	112	8.8%	-	N/A	N/A	N/A
	% With Discontinued Use of High-Risk Medication	3,816	-6.0%*	215	-4.6%	4,523	-3.0%*	12	-13.7%	162	-7.1%*	869	0.9%	39	-2.6%	41	11.5%

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.
c. LABA stands for long-acting beta-adrenergics.
d. LAAC stands for long-acting anticholinergics.
e. LABA-LAAC combination regimens include long-acting beta-adrenergics and long-acting anticholinergics.

D.3.4 Resource Utilization Outcomes

MTM beneficiaries with COPD experienced increases in the number of medications, no effect on generic substitution ratios for COPD or non-COPD medications, increases in hospitalizations, and mixed effects on ER visits. In the PDP cohort, MTM beneficiaries increased their rates of all-cause and COPD-related hospitalizations, increased their COPD-related ER visits, decreased all-cause ER visits, and increased their number of medications. All-cause and COPD-related hospitalizations increased by 1.3 to 3.9%, COPD-related ER visits increased by 1.0-2.6% for PDP beneficiaries in all cohorts, while all-cause ER visits decreased by 0.6% only for PDP beneficiaries in the MTM without CMR sub-cohort. The MA-PD cohort experienced similar increases in hospitalizations and number of medications. Complete information on ER visits was not available for the MA-PD cohort and thus not been reported. **Table_Appx D.16** and **Table_Appx D.17** provide detailed resource utilization results for the MTM beneficiaries with COPD in the PDP and MA-PD cohorts.

Table_Appx D.16: Resource Utilization Outcomes for MTM Beneficiaries and Controls with COPD Enrolled in PDPs

MTM	Outcome	N[a]		Baseline Period		Outcome Period		DiD [b]	Standard Error	Confidence Interval	
		MTM Enrollees	Controls	MTM Enrollees	Controls	MTM Enrollees	Controls				
With CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	16,078	508,935	45.9%	45.9%	43.8%	42.4%	1.3%*	0.5%	0.4%	2.3%
	Any COPD-Related Hospitalization (%)	16,086	529,120	33.2%	33.2%	32.8%	28.9%	3.9%*	0.4%	3.0%	4.8%
	Any (All-cause) ER Visits (%)	16,067	501,077	47.7%	47.7%	47.9%	48.3%	-0.4%	0.5%	-1.3%	0.5%
	Any COPD-Related ER Visits (%)	16,092	550,593	22.0%	22.0%	23.5%	20.9%	2.6%*	0.4%	1.8%	3.3%
	Average Medication Use and Costs										
	Number of Medications	15,702	514,937	20.3	19.9	20.3	18.5	1.4*	0.0	1.3	1.5
	Generic Substitution Ratio (COPD)	9,821	152,010	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Generic Substitution Ratio (Non-COPD)	9,150	70,710	0.7	0.7	0.7	0.7	0.0	0.0	0.0	0.0
Without CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	108,138	776,071	46.0%	46.0%	41.2%	39.7%	1.4%*	0.2%	1.1%	1.8%
	Any COPD-Related Hospitalization (%)	108,117	779,280	31.6%	31.6%	29.1%	26.8%	2.3%*	0.2%	2.0%	2.6%
	Any (All-cause) ER Visits (%)	108,163	774,364	42.2%	42.2%	41.6%	42.2%	-0.6%*	0.2%	-1.0%	-0.3%
	Any COPD-Related ER Visits (%)	108,318	781,068	17.9%	17.9%	18.2%	17.2%	1.0%	0.1%	0.7%	1.3%
	Average Medication Use and Costs										
	Number of Medications	106,007	756,997	17.8	17.4	17.5	16.3	0.8*	0.02	0.77	0.83
	Generic Substitution Ratio (COPD)	55,435	221,025	0.0	0.0	0.0	0.0	0.0	0.00	0.00	0.00
	Generic Substitution Ratio (Non-COPD)	51,714	193,782	0.7	0.7	0.7	0.7	0.0*	0.00	-0.01	0.00

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.17: Resource Utilization Outcomes for MTM Beneficiaries and Controls with COPD Enrolled in MA-PDs

MTM	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Hospital Visits**										
	Any (All-cause) Hospitalization (%)	10,132	335,971	35.5%	35.5%	32.0%	29.7%	2.2%*	0.6%	1.1%	3.4%
	Any COPD-Related Hospitalization (%)	10,163	345,495	23.0%	23.0%	21.8%	19.8%	2.0%*	0.5%	0.9%	3.0%
	Average Medication Use and Costs										
	Number of Medications	9,710	321,371	16.35	15.96	16.1	14.5	1.2*	0.1	1.1	1.3
	Generic Substitution Ratio (COPD)	5,038	80,472	0.02	0.02	0.0	0.0	0.0*	0.0	0.0	0.0
	Generic Substitution Ratio (Non-COPD)	4,418	40,701	0.75	0.75	0.8	0.8	0.0	0.0	0.0	0.0
Without CMR	**Hospital Visits**										
	Any (All-cause) Hospitalization (%)	61,957	483,192	38.5%	38.5%	33.0%	29.7%	3.3%*	0.2%	2.8%	3.7%
	Any COPD-Related Hospitalization (%)	61,918	486,705	24.2%	24.2%	22.0%	19.6%	2.4%*	0.2%	2.0%	2.8%
	Average Medication Use and Costs										
	Number of Medications	59,614	467,246	15.8	15.4	15.5	14.3	0.8*	0.0	0.7	0.8
	Generic Substitution Ratio (COPD)	27,184	124,445	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Generic Substitution Ratio (Non-COPD)	23,856	100,708	0.7	0.7	0.8	0.8	0.0	0.0	0.0	0.0

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.3.5 Resource Utilization Outcomes by Part D Organization

Beneficiaries receiving MTM services from Organization A-F were associated with increases in number of medications, and total Part D drugs, with higher total drugs cost increases for the PDP cohort. Only Organization A was associated with decreases in hospitalizations or hospitalization costs, while most other Part D organizations were associated with increases in the same. None of the Part D organizations were associated with changes in the generic substitution ratio for COPD or non-COPD drugs. **Table_Appx D.18** and **Table_Appx D.19** present the detailed drug therapy results by Part D organizations for the PDP and MA-PD cohorts.

In the PDP cohort, Part D organizations A-E were associated with increases in number of medications and total Part D drugs; Organization A was also associated with decreases in hospitalization and ER costs; while Organizations B-D were associated with increase in hospitalization and ER costs. The increase in total drug costs ranged from $274 for Organization A to $628 for Organization D. Organization A was associated with a $6,669 decrease in all-cause hospitalization costs and $203 decrease in all-cause ER costs, whereas Organizations B-D were associated with a $284-$1,589 increase in hospitalization costs and $16-$31 increase in ER costs. The generic substitution ratio for COPD and non-COPD did not change for any Part D organizations.

In the MA-PD cohort, Organizations A-F where associated with increases in number of medications, Organizations A, C, D, E and H were associated with increases in total drug costs, and the effects on hospitalizations were mixed across organizations. The increases in total drug costs ranged from $137 for Organization F to $973 for Organization E. In the MA-PD cohort, all-cause and COPD-related hospitalizations increased by 1.2-5.8% for Organizations A- G. None of the Part D organizations were associated with changes in the generic substitution ratio for COPD or non-COPD drugs. The drug therapy results for the MTM with CMR sub-cohorts for Organization E and H, and for the MTM without CMR sub-cohorts for Organization D and G were limited due to small sample sizes for outcome measures.

Table_Appx D.18: Resource Utilization Outcomes of MTM Beneficiaries with COPD in PDPs by Part D Organization

MTM Type	*Outcome*	*Part D Organization*									
		A		*B*		*C*		*D*		*E*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	115	-10.9%	6,350	0.8%	287	-1.8%	8,024	3.1%*	101	-0.7%
	Any (All-cause) ER Visits (%)	113	-1.8%	6,352	-0.8%	288	-0.9%	8,014	-0.1%	98	1.6%
	Average Medication Use and Costs										
	Generic Substitution Ratio (COPD)	41	-0.0	4,342	0.0	118	-0.0	4,625	0.0	48	0.0
	Generic Substitution Ratio (Non-COPD)	39	-0.0	4,039	0.0*	114	0.0*	4,288	0.0	46	-0.0
	Part D costs for COPD Drugs	113	$60	6,036	$100*	281	$19	7,794	$64*	96	$159*
	Part D costs for Non-COPD Drugs	110	$218	6,215	$326*	283	$110	7,778	$218*	97	$550*
	All-Cause Hospitalization Costs	109	-$6,669*	6,192	$564*	287	-$241	7,808	$1,589*	99	-$2,513
	All-Cause ER Costs	110	-$203*	6,202	$14	287	$4	7,800	$41*	97	$194
Without CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	11,186	0.5%	24,110	1.9%*	14,032	3.5%*	400	4.3%	4,744	-0.1%
	Any (All-cause) ER Visits (%)	11,205	-1.3%*	24,126	-0.3%	14,025	1.7%*	401	6.7%*	4,752	-0.8%
	Average Medication Use and Costs										
	Generic Substitution Ratio (COPD)	3,783	0.00	15,736	0.00	5,196	0.00	238	0.0	2,289	0.0
	Generic Substitution Ratio (Non-COPD)	3,482	-0.01*	14,458	-0.01*	5,029	0.02*	213	0.0*	1,957	0.0*
	Part D costs for COPD Drugs	11,101	$37*	23,157	$101*	13,971	$37*	386	$153*	4,588	$123*
	Part D costs for Non-COPD Drugs	10,892	$284*	23,518	$419*	13,826	$247*	382	$511*	4,541	$309*
	All-Cause Hospitalization Costs	10,908	$411	23,547	$929*	13,832	$360*	384	$2,726	4,588	$571
	All-Cause ER Costs	10,947	-$20	23,502	$11	13,890	$18*	383	$46	4,587	$27

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.19: Resource Utilization Outcomes of MTM Beneficiaries with COPD in MA-PDs by Part D Organization

MTM Type	*Outcome*	*Part D Organization*															
		A		***B***		***C***		***D***		***E***		***F***		***G***		***H***	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
	Hospital & Emergency Room Visits																
	Any (All-cause) Hospitalization (%)	126	-0.1%	221	3.2%	613	1.7%	674	4.5%	19	-9.7%	4,508	1.2%	84	1.8%	-	N/A
	Average Medication Use and Costs																
	Generic Substitution Ratio (COPD)	48	0.0	147	0.0	209	0.0	362	0.0	-	N/A	2,454	0.0*	23	0.0*	N/A	N/A
With CMR	Generic Substitution Ratio (Non-COPD)	40	0.0	127	0.0	182	0.0	320	0.0	-	N/A	2,110	0.0	19	0.0	N/A	N/A
	Part D costs for COPD Drugs	122	$75	205	-$7	609	$14	639	$9	16	$92	4,260	$98*	80	-$69	-	$319*
	Part D costs for Non-COPD Drugs	114	$238	205	$281	596	$183	630	$279*	16	$366	4,157	$58	76	$298	-	N/A
	Hospital & Emergency Room Visits																
	Any (All-cause) Hospitalization	9,541	2.4%*	501	2.0%	14,348	2.7%*	30	16.0%	458	5.9%*	3,084	1.3%	89	6.9%	109	1.2%
	Average Medication Use and Costs																
	Generic Substitution Ratio (COPD)	3,517	0.0	284	0.0	4,961	0.0	18	0.0*	175	0.0	1,577	0.0*	39	0.0	N/A	N/A
Without CMR	Generic Substitution Ratio (Non-COPD)	2,897	0.0*	237	0.0	4,471	0.0*	14	-0.0	128	0.0	1,354	0.0*	30	0.0	N/A	N/A
	Part D costs for COPD Drugs	9,211	$23*	469	-$12	14,119	$15*	26	$202	433	$35	2,903	$70*	89	-$1	102	$50
	Part D costs for Non-COPD Drugs	8,790	$325*	472	$41	13,874	$193*	28	$382	420	$427*	2,880	-$78	87	$177	103	$139

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.4 Results: Impact on MTM Beneficiaries with Diabetes

Medicare beneficiaries with diabetes who were enrolled in an MTM program in 2010 experienced improvements in a number of drug therapy outcomes, increases in the number of medications and total drug costs, and mixed effects on resource utilization outcomes including hospitalizations, hospitalization costs, ER costs, and ER visits compared with matched controls. The DiD results for individual Part D organizations however varied widely across drug therapy and resource utilization outcomes. **Section D.4.1** describes the demographic and health characteristics in the baseline period of MTM beneficiaries and their matched controls enrolled in Part D prescription drug plans (PDP) or Medicare advantage drug plans (MA-PD). **Section D.4.2** presents the difference-in-differences (DiD) analysis results for all drug therapy outcomes for the entire diabetes cohort, while **Section D.4.3** presents the same by Part D organization. **Section D.4.4** then presents the DiD analysis results on all resource utilization outcomes for the entire diabetes cohort, and **Section D.4.5** presents the same by Part D organization.

D.4.1 Characteristics of the Study Population

MTM beneficiaries and controls were exactly matched on gender, age, black and white race, low income subsidy (LIS) status, and disability status, and fairly well matched on other races; regions of residence; mortality rate (in the outcome period); and the incidence of chronic conditions, number of maintenance drug prescriptions, drug and medical costs in the one-year baseline period preceding MTM enrollment. **Table_Appx D.20** compares these demographic and health characteristics between MTM enrollees and their matched controls included in the analysis of all-cause hospitalizations. The comparisons of demographic and health characteristics were similar for the intervention and comparison groups constructed for the other outcomes assessed for the diabetes cohort. Additionally, **Table_Appx D.20** shows that the PDP cohort consisted of larger shares of beneficiaries who were 65 years of age or younger, disabled, and eligible for low income subsidy compared with the MA-PD cohorts. The average number of chronic maintenance drugs in the baseline period was larger among MTM beneficiaries receiving CMR compared with MTM beneficiaries not receiving CMR within the PDP or MA-PD cohorts. MTM enrollees and controls in the diabetes cohort did not have a 100% incidence of claims-identified diagnosis of diabetes in the baseline period because this disease cohort was selected based on Part D claims for diabetes drug use.

Table_Appx D.20: Baseline Characteristics of MTM Beneficiaries with Diabetes and their Matched Controls in the Analysis of Hospitalizations by Part D Plan Type

Demographic and Health Characteristics	*Beneficiaries Enrolled in:*							
	PDPs				*MA-PDs*			
	MTM with CMR	*Controls*	*MTM without CMR*	*Controls*	*MTM with CMR*	*Controls*	*MTM without CMR*	*Controls*
N	16,010	537,766	144,392	757,893	12,081	384,823	85,317	514,994
Gender								
Male	30.7%	30.7%	40.2%	40.2%	46.3%	46.3%	42.8%	42.8%
Age								
≤ 65	28.8%	28.8%	16.5%	16.5%	8.2%	8.2%	12.2%	12.2%
66-75	35.9%	35.9%	40.2%	40.2%	46.6%	46.6%	47.0%	47.0%
76-85	28.2%	28.2%	33.8%	33.8%	38.5%	38.5%	34.3%	34.3%
≥ 85	7.1%	7.1%	9.5%	9.5%	6.6%	6.6%	6.5%	6.5%
Race								
White	77.8%	77.8%	82.7%	82.7%	80.0%	80.0%	80.5%	80.5%
Black	15.5%	15.5%	9.6%	9.6%	10.6%	10.6%	11.2%	11.2%
Hispanic	3.4%	3.3%	2.7%	3.1%	3.0%	3.5%	3.8%	3.6%
Other or Unknown	3.2%	3.3%	5.0%	4.6%	6.4%	5.9%	4.5%	4.7%
Region of Residence								
New England	2.5%	4.3%	3.5%	3.8%	3.1%	4.0%	5.4%	3.9%
Mid-Atlantic	5.8%	11.6%	16.7%	14.3%	11.0%	24.2%	23.1%	24.5%
East North Central	19.8%	15.6%	13.1%	15.0%	3.3%	9.1%	11.0%	9.1%
West North Central	8.9%	7.4%	6.3%	7.0%	1.0%	4.1%	3.4%	3.8%
South Atlantic	21.5%	21.4%	21.9%	21.6%	15.0%	14.4%	18.1%	16.4%
East South Central	12.8%	11.2%	9.2%	9.8%	4.4%	4.5%	7.1%	5.5%
West South Central	21.9%	15.2%	12.5%	13.7%	4.1%	9.7%	10.3%	10.1%
Mountain	2.3%	3.5%	4.2%	4.2%	6.2%	8.0%	6.1%	7.8%
Pacific	4.4%	9.4%	12.3%	10.4%	51.9%	22.0%	15.4%	18.6%
Socioeconomic Status								
Eligible for Low Income Subsidy	68.2%	68.2%	42.8%	42.8%	20.7%	20.7%	33.8%	33.8%
Disability Status & Mortality Rate								
Disabled	30.5%	30.5%	17.7%	17.7%	9.1%	9.1%	13.3%	13.3%
Mortality Rate in the Outcome Period	0.3%	0.2%	0.3%	0.2%	0.3%	0.2%	0.3%	0.2%
Drug Use in the Baseline Period								
Average Number of Maintenance Drugs	11.5	11.3	10.4	10.3	10.2	10.1	9.7	9.7
Specific Health Conditions								
Diabetes	94.5%	95.7%	94.2%	96.2%	97.3%	97.2%	96.2%	96.8%
Congestive Heart Failure	22.8%	22.3%	20.1%	20.5%	20.4%	19.3%	18.3%	17.7%
Hypertension	68.7%	68.6%	70.6%	70.5%	73.5%	72.5%	73.6%	73.5%
Dyslipidemia	76.2%	76.5%	79.2%	77.7%	85.4%	80.8%	82.7%	80.3%
Rheumatoid Arthritis	5.2%	4.1%	3.2%	3.3%	2.8%	3.2%	2.9%	3.0%
AMI & Unstable Angina	39.2%	39.9%	40.5%	41.2%	40.1%	39.6%	39.0%	36.9%

Demographic and Health Characteristics	*Beneficiaries Enrolled in:*							
	PDPs				*MA-PDs*			
	MTM with CMR	*Controls*	*MTM without CMR*	*Controls*	*MTM with CMR*	*Controls*	*MTM without CMR*	*Controls*
Specific Health Conditions								
Stroke & Cerebral Hemorrhage	15.4%	16.4%	16.6%	16.8%	14.6%	16.0%	15.0%	15.2%
Vascular Disease	20.3%	21.1%	20.1%	20.7%	22.7%	23.3%	21.5%	22.1%
Asthma & COPD	33.9%	30.2%	25.9%	25.2%	27.7%	27.8%	25.7%	26.6%
Costs in the Baseline Period[a]								
Part D Costs (All Drugs)	$6,720	$6,178	$5,299	$5,196	$4,198	$4,350	$4,314	$4,323
Hospitalization Costs	$4,070	$4,516	$4,177	$4,105	N/A	N/A	N/A	N/A
Emergency Room Costs	$297	$340	$231	$257	N/A	N/A	N/A	N/A

a. Medical costs were not available for individuals in MA-PD plans.

D.4.2 Drug Therapy Outcomes

MTM beneficiaries with diabetes in both the PDP and MA-PD cohorts experienced significant improvements in all drug therapy outcomes compared with matched controls. The improvements were generally greater for MTM beneficiaries receiving a comprehensive medication review (CMR) as a part of the MTM intervention than for those not receiving a CMR as a part of their MTM program. **Table_Appx D.21** reports the difference-in-differences (DiD) estimation results for MTM beneficiaries enrolled in PDP, while **Table_Appx D.22** reports the same for MTM beneficiaries enrolled in MA-PD. The number of PDP enrollees receiving MTM with CMR who were adherent (i.e. PDC $\geq$ 0.80) to their diabetes regimen ("adherent beneficiaries") increased by 2.1- 4.9% in the outcome period for all assessed diabetes regimens. Among PDP enrollees receiving MTM without a CMR, adherent beneficiaries increased by 1.5-3.1% for all assessed diabetes regimens. The results were similar for MTM beneficiaries enrolled in MA-PD; adherent beneficiaries increased by 3.8- 7.0% for the MTM with CMR sub-cohort and by 1.2-2.3% for the MTM without CMR cohort for all diabetes regimens. The greatest improvements were seen in adherence to DPP-IV inhibitors and thiazolidinediones regimens. Among beneficiaries receiving MTM with CMR, MA-PD enrollees had a larger estimated increase in adherence compared with controls. MTM beneficiaries enrolled in PDP and MA-PD also increased their take up of ACEi/ARB drugs and statins compared with matched controls. **Table_Appx D.21** and **Table_Appx D.22** report the drug therapy results in greater detail for the PDP and MA-PD cohorts.

Table_Appx D.21: Drug Therapy Outcomes among MTM Beneficiaries with Diabetes and Matched Controls Enrolled in PDPs

MTM Type	*Outcome*	*N*[a]		*Percentage of Beneficiaries*				*DiD*[b]	*Standard Error*	*Confidence Interval*	
				Baseline Period		*Outcome Period*					
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Adherence**										
	% Adherent to Any Diabetes Medications	12,521	384,823	88.4%	88.4%	81.7%	78.3%	3.4%*	0.4%	2.7%	4.1%
	Biguanides	7,913	222,318	79.9%	79.9%	70.4%	66.8%	3.6%*	0.5%	2.6%	4.6%
	% Adherent to DPP-IV Inhibitors	888	4,389	83.9%	83.9%	70.7%	65.8%	4.9%*	1.5%	1.9%	7.9%
	% Adherent to Sulfonylureas	5,933	149,610	83.3%	83.3%	71.8%	69.7%	2.1%*	0.6%	0.9%	3.2%
	Thiazolidinediones	2,728	35,533	81.4%	81.4%	63.2%	58.9%	4.3%*	0.9%	2.4%	6.1%
	Quality of Prescribing										
	% Take-up of ACEi/ARB Drugs	15,975	513,537	69.2%	69.2%	69.2%	66.0%	3.2%*	0.3%	2.7%	3.7%
	% Take-up of Statins	15,979	493,308	77.3%	77.3%	77.8%	74.6%	3.2%*	0.2%	2.8%	3.6%
Without CMR	**Adherence**										
	% Adherent to Any Diabetes Medications	110,292	570,741	86.4%	86.4%	79.8%	77.6%	2.2%*	0.1%	2.0%	2.5%
	Biguanides	69,146	372,357	77.7%	77.7%	68.2%	66.0%	2.1%*	0.2%	1.8%	2.5%
	% Adherent to DPP-IV Inhibitors	7,446	19,413	79.5%	79.5%	67.3%	64.2%	3.1%*	0.5%	2.0%	4.1%
	% Adherent to Sulfonylureas	54,078	268,430	80.7%	80.7%	70.6%	69.1%	1.5%*	0.2%	1.1%	1.9%
	Thiazolidinediones	23,164	79,304	76.4%	76.4%	57.8%	55.6%	2.3%*	0.3%	1.6%	2.9%
	Quality of Prescribing										
	% Take-up of ACEi/ARB Drugs	144,358	762,032	67.9%	67.9%	67.5%	65.3%	2.2%*	0.1%	2.0%	2.3%
	% Take-up of Statins	144,817	750,306	82.4%	82.4%	81.1%	78.7%	2.4%*	0.1%	2.3%	2.6%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period

Table_Appx D.22: Drug Therapy Outcomes among MTM Beneficiaries with Diabetes and Matched Controls Enrolled in MA-PDs

MTM Type	*Outcome*	*N*[a]		*Percentage of Beneficiaries*				*DiD*[b]	*Standard Error*	*Confidence Interval*	
				Baseline Period		*Outcome Period*					
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Adherence**										
	% Adherent to Any Diabetes Medications	9,746	266,265	90.8%	90.8%	85.3%	80.6%	4.7%*	0.4%	4.0%	5.5%
	Biguanides	5,750	164,524	81.9%	81.9%	72.1%	68.3%	3.8%*	0.6%	2.5%	5.0%
	% Adherent to DPP-IV Inhibitors	270	2,210	74.1%	74.1%	62.2%	56.2%	6.0%*	2.8%	0.6%	11.5%
	% Adherent to Sulfonylureas	5,375	115,642	85.2%	85.2%	77.2%	72.1%	5.1%*	0.6%	3.9%	6.3%
	Thiazolidinediones	1,720	20,888	78.4%	78.4%	60.2%	53.2%	7.0%*	1.2%	4.6%	9.4%
	Quality of Prescribing										
	% Take-up of ACEi/ARB Drugs	12,136	360,693	79.2%	79.2%	78.8%	74.2%	4.6%*	0.3%	4.1%	5.2%
	% Take-up of Statins	12,239	350,085	88.7%	88.7%	88.1%	84.2%	3.9%*	0.2%	3.5%	4.4%
Without CMR	**Adherence**										
	% Adherent to Any Diabetes Medications	65,299	378,712	87.5%	87.5%	81.0%	78.8%	2.2%*	0.2%	1.9%	2.5%
	Biguanides	40,181	250,905	77.9%	77.9%	68.0%	66.3%	1.8%*	0.2%	1.3%	2.2%
	% Adherent to DPP-IV Inhibitors	2,550	7,823	70.4%	70.4%	58.2%	56.0%	2.3%*	1.0%	0.3%	4.3%
	% Adherent to Sulfonylureas	32,585	186,488	82.0%	82.0%	71.7%	70.5%	1.2%*	0.3%	0.7%	1.7%
	Thiazolidinediones	11,485	39,929	72.9%	72.9%	53.7%	52.2%	1.5%*	0.5%	0.6%	2.5%
	Quality of Prescribing										
	% Take-up of ACEi/ARB Drugs	85,636	513,980	71.9%	71.9%	71.1%	69.0%	2.2%*	0.1%	1.9%	2.4%
	% Take-up of Statins	86,479	506,179	86.3%	86.3%	84.7%	82.6%	2.1%*	0.1%	1.9%	2.3%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.4.3 Drug Therapy Outcomes by Part D Organization

We observed mixed results for drug therapy outcomes across sub-cohorts and regimens for sub-populations receiving MTM services from separate Part D organizations. PDP enrollees receiving MTM with CMR from Organization A, B, C, D, and E generally experienced positive changes in adherence to most oral diabetes medications, and take-up of ACEi/ARB drugs and statins. MA-PD enrollees receiving MTM with CMR, however, had smaller numbers of MTM enrollees available for outcome measures and generally experienced smaller improvements in fewer drug therapy outcomes for Organization A, B, C, D, and E. Among MTM beneficiaries not receiving CMR, the results were mixed across regimens and organizations. In contrast with the MA-PD cohorts for all other organizations, Organization F had large and positive changes in almost all drug therapy outcomes except for adherence to DPP-IV inhibitors, and much larger numbers of MA-PD, MTM enrollees available for each outcome measure. None of the beneficiaries in Organization F, G, or H were enrolled in PDPs. **Table_Appx D.23** presents the difference-in-differences (DiD) analysis results for all assessed drug therapy outcomes for MTM beneficiaries in the PDP cohort, while **Table_Appx D.24** presents the same for MTM beneficiaries in the MA-PD cohort. The DiD estimator measured the difference in outcome changes between MTM enrollees and their matched controls. The results were limited for Organization G, and H due to their small sample sizes for the MA-PD, MTM with CMR cohorts.

While PDP enrollees in all Part D organizations were associated with improvements in drug therapy outcomes, Organization C was also associated with decreased adherence to DPP-IV ihhibitors and thiazolidinediones. Organization E was associated with the largest improvements, and the MTM without CMR cohorts for Organization B and E showed improvements in all outcomes. Part D Organization A was associated with improvements in adherence to any diabetes medications, sulfonylureas, and increase in take-up of ACEi/ARB drugs and statins, and these improvements were smaller for MTM beneficiaries not receiving CMR. MTM beneficiaries receiving CMR from Part D organization B experienced improvements in all drug therapy outcomes except for adherence to DPP-IV inhibitors, while MTM beneficiaries not receiving CMR from Organization B experienced improvements in all outcomes with larger effect sizes in most cases. Organization C was associated with improvements in adherence to any diabetes medications among MTM beneficiaries receiving CMR but also with large decreases in adherence to thiazolidinediones and DPP-IV inhibitors among those not receiving CMR. The MTM with CMR cohorts for Organization D and E were associated with improvements in all drug therapy outcomes except for adherence to DPP-IV inhibitors, sulfonylureas, and thiazolidinediones. The MTM without CMR sub-cohort for Organization E was associated with improvements in all drug therapy outcomes.

MA-PD enrollees receiving MTM services from Organization A, B, D, and E experienced improvements in fewer drug therapy outcomes than their PDP counterparts; while Organization F which only had MA-PD enrollees was associated with large improvements in most outcomes. Organization C, however, was associated with improvements in more drug therapy outcomes but also with larger decreases in adherence to DPP-IV ihhibitors and thiazolidinediones compared with their PDP counterparts. Organization F was associated with improvements in all drug therapy outcomes except for adherence to DPP-IV inhibitors. Organization G was associated with improved adherence to any diabetes regimens and thiazolidinediones, and take-up of ACEi/ARBs and statins.

Table_Appx D.23: Drug Therapy Outcomes among MTM Beneficiaries with Diabetes Compared with Matched Controls by Part D Organization for Individuals Enrolled in PDPs

MTM Type	*Outcome*	*Part D Organization*									
		A		*B*		*C*		*D*		*E*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Adherence**										
	% Adherent to Any Diabetes Medications	262	8.3%*	3,752	3.3%*	352	5.1%*	6,708	2.4%*	96	9.7%*
	% Adherent to Biguanides	175	5.9%	2,332	2.7%*	217	5.5%	4,292	2.8%*	63	14.7%*
	% Adherent to DPP-IV Inhibitors	17	3.4%	248	1.4%	-	N/A	481	3.9%	-	N/A
	% Adherent to Sulfonylureas	139	8.0%*	1,706	2.7%*	186	3.4%	3,261	1.2%	45	9.1%
	% Adherent to Thiazolidinediones	35	11.1%	720	7.5%*	52	2.5%	1,639	1.2%	17	7.0%
	Quality of Prescribing										
	% Take-up of ACEi/ARB Drugs	329	4.6%*	4,860	2.4%*	440	3.9%*	8,479	3.6%*	119	8.9%*
	% Take-up of Statins	332	5.4%*	4,855	1.6%*	436	2.6%	8,492	4.0%*	115	4.9%*
Without CMR	**Adherence**										
	% Adherent to Any Diabetes Medications	23,631	2.2%*	15,024	3.0%*	14,062	0.3%	323	4.8%*	5,235	5.1%*
	% Adherent to Biguanides	14,937	1.6%*	9,524	2.9%*	8,973	-0.1%	205	11.0%*	3,419	4.7%*
	% Adherent to DPP-IV Inhibitors	1,380	-1.1%	1,295	2.9%*	231	-11.7%*	12	-1.7%	318	7.1%*
	% Adherent to Sulfonylureas	12,870	1.5%*	6,793	3.8%*	7,385	-1.0%	156	3.7%	2,829	2.0%*
	% Adherent to Thiazolidinediones	3,779	-0.5%	3,184	3.9%*	2,807	-6.1%*	72	-4.3%	1,178	4.3%*
	Quality of Prescribing										
	% Take-up of ACEi/ARB Drugs	30,617	2.9%*	19,810	2.0%*	18,612	1.5%*	385	1.4%	6,376	4.0%*
	% Take-up of Statins	30,743	3.5%*	19,808	2.1%*	18,609	0.7%*	384	4.9%*	6,377	4.1%*

*Indicates statistical significance at the 5% level.
a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.
b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.24: Drug Therapy Outcomes among MTM Beneficiaries with Diabetes Compared with Matched Controls by Part D Organization for Individuals Enrolled in MA-PDs

MTM Type	*Outcome*	*Part D Organization*															
		A		*B*		*C*		*D*		*E*		*F*		*G*		*H*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Adherence**																
	% Adherent to Any Diabetes Medications	198	4.70%	156	0.7%	470	1.9%	815	0.5%	20	-0.3%	4,351	7.1%*	193	5.2%*	-	N/A
	% Adherent to Biguanides	129	8.6%*	98	-3.6%	298	-0.1%	516	5.4%*	12	-4.0%	2,339	6.0%*	123	1.9%	N/A	N/A
	% Adherent to DPP-IV Inhibitors	-	N/A	-	N/A	-	N/A	50	8.1%	-	N/A	29	0.2%	N/A	N/A	N/A	N/A
	% Adherent to Sulfonylureas	89	-0.10%	75	1.9%	241	5.2%	442	-0.2%	13	19.3%	2,647	7.3%*	126	5.6%	N/A	N/A
	% Adherent to Thiazolidinediones	27	-0.80%	21	8.7%	78	10.4%	175	4.1%	-	N/A	762	14.1%*	42	11.5%	N/A	N/A
	Quality of Prescribing																
	% Take-up of ACEi/ARB Drugs	251	5.8%*	203	2.1%	630	5.9%*	1,016	1.8%	25	7.4%	5,213	7.0%*	207	5.7%*	-	N/A
	% Take-up of Statins	259	3.5%*	199	5.8%*	634	3.9%*	1,019	2.4%*	25	0.2%*	5,273	5.5%*	214	3.6%	-	N/A
With-out CMR	**Adherence**																
	% Adherent to Any Diabetes Medications	13,054	1.4%*	323	-2.0%	11,761	1.6%*	25	10.0%	527	3.7%*	3,183	5.7%*	182	2.0%	158	-2.2%
	% Adherent to Biguanides	8,021	0.10%	213	-0.4%	7,605	1.2%*	15	5.4%	319	6.0%*	1,753	5.7%*	113	-4.9%	102	-3.5%
	% Adherent to DPP-IV Inhibitors	431	-0.30%	-	15.4%	205	-13.4%*	-	N/A	-	- 13.5%	-	9.4%	N/A	N/A	N/A	N/A
	% Adherent to Sulfonylureas	6,612	0.50%	142	-0.8%	5,973	1.9%*	-	N/A	298	0.2%	1,956	4.9%*	111	-3.8%	88	-2.2%
	% Adherent to Thiazolidinediones	1,975	-1.10%	47	5.3%	2,107	-5.1%*	-	N/A	-	0.1%	579	11.5%*	28	22.3%*	N/A	N/A
	Quality of Prescribing																
	% Take-up of ACEi/ARB Drugs	17,154	3.0%*	432	1.6%	15,963	1.9%*	37	8.3%	644	4.8%*	3,873	5.1%*	208	5.5%*	200	2.8%
	% Take-up of Statins	17,389	2.6%*	448	1.4%	15,986	1.3%*	38	1.5%	650	2.2%*	3,930	3.5%*	214	7.3%*	201	4.0%

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.4.4 Resource Utilization Outcomes

MTM enrollment was associated with increase in total drug use and costs for diabetes patients in all cohorts but the utilization and cost results for hospitalizations and ER were mixed. MTM beneficiaries in both the PDP and MA-PD cohort experienced increases in non-Diabetes drug costs of approximately $150 and $60, respectively. We observed higher rates of increase in the number of non-diabetes drugs (0.4-0.9%) compared with rates of increase in diabetes drugs (0.1%) for all cohorts. In the PDP cohort, MTM enrollment was associated with 0.9% increase in diabetes-related hospitalizations and a 1.1% increase in diabetes-related ER visits among beneficiaries receiving CMR but this did not lead to statistically significant increases in hospitalization or ER costs. PDP enrollees receiving MTM without CMR, in contrast, experienced decreases in all-cause and diabetes-related ER visits, a corresponding average decrease of $25 and $19 in all-cause and diabetes-related ER costs, and also an average decrease of $165 and $213 in all-cause and diabetes-related hospitalization costs. In the MA-PD cohort, beneficiaries receiving MTM without CMR experienced a 0.5-0.6% increase in all-cause and diabetes-related hospitalizations. Complete data on hospitalization costs, and ER visits and costs were not available for MTM beneficiaries enrolled in MA-PDs and these outcomes have thus not been reported for the MA-PD cohort. **Table_Appx D.25** and **Table_Appx D.26** provide more details on the resource utilization results for the PDP and MA-PD cohorts.

Table_Appx D.25: Resource Utilization Outcomes for MTM Beneficiaries and Controls with Diabetes Enrolled in PDPs

MTM Type	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	16,010	537,766	28.3%	28.3%	30.1%	29.2%	0.9%	0.4%	0.0%	1.7%
	Any Diabetes-Related Hospitalization (%)	16,012	542,864	24.0%	24.0%	27.5%	26.6%	0.9%*	0.4%	0.1%	1.8%
	Any (All-cause) ER Visits (%)	15,971	518,064	35.4%	35.4%	38.1%	37.7%	0.4%	0.5%	-0.5%	1.3%
	Any Diabetes-Related ER Visits (%)	15,993	537,243	23.5%	23.5%	27.6%	26.5%	1.1%*	0.4%	0.2%	1.9%
	Average Medication Use and Costs										
	Number of Medications	15,276	512,169	16.8	16.7	17.2	16.1	1.0*	0.0	0.9	1.0
	Generic Substitution Ratio (Diabetes)	16,222	530,966	86.1%	99.5%	86.2%	99.6%	-0.1%*	0.0%	-0.1%	0.0%
	Generic Substitution Ratio (Non-Diabetes)	15,686	488,287	93.4%	93.1%	96.9%	96.3%	0.2%*	0.1%	0.0%	0.3%
	Part D costs for Diabetes Drugs	11,611	373,729	$694	$718	$645	$668	$1	$5	-$9	$11
	Part D costs for Non-Diabetes Drugs	15,801	587,128	$5,852	$5,842	$5,938	$5,777	$151*	$25	$103	$200
	All-Cause Hospitalization Costs	15,732	597,010	$3,802	$3,920	$4,727	$4,947	-$103	$126	-$349	$144
	Diabetes-Related Hospitalization Costs	15,752	603,100	$2,624	$2,735	$3,762	$3,999	-$126	$94	-$310	$58
	All-Cause ER Costs	15,726	574,627	$281	$286	$329	$344	-$11	$7	-$25	$4
	Diabetes-Related ER costs	15,747	603,294	$173	$177	$220	$228	-$3	$6	-$15	$8
Without CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	144,392	757,893	27.0%	27.0%	26.9%	26.8%	0.1%	0.1%	-0.2%	0.4%
	Any Diabetes-Related Hospitalization (%)	144,417	758,193	23.1%	23.1%	24.4%	24.5%	-0.1%	0.1%	-0.4%	0.2%
	Any (All-cause) ER Visits (%)	144,405	755,831	29.1%	29.1%	30.3%	31.4%	-1.1%*	0.1%	-1.4%	-0.8%
	Any Diabetes-Related ER Visits (%)	144,457	755,391	18.6%	18.6%	20.9%	21.7%	-0.7%*	0.1%	-1.0%	-0.5%
	Average Medication Use and Costs										
	Number of Medications	139,746	731,421	14.7	14.6	14.9	14.3	0.5*	0.0	0.4	0.5
	Generic Substitution Ratio (Diabetes)	146,467	680,675	84.7%	99.4%	84.8%	99.6%	-0.1%*	0.0%	-0.1%	-0.1%
	Generic Substitution Ratio (Non-Diabetes)	141,759	734,458	92.2%	92.3%	95.8%	96.1%	-0.2%*	0.0%	-0.2%	-0.1%
	Part D costs for Diabetes Drugs	82,803	477,743	$788	$787	$777	$740	$37*	$2	$33	$41
	Part D costs for Non-Diabetes Drugs	141,986	721,870	$4,496	$4,551	$4,595	$4,452	$198*	$8	$182	$215
	All-Cause Hospitalization Costs	142,088	717,881	$3,877	$3,918	$4,339	$4,545	-$165*	$43	-$250	-$80
	Diabetes-Related Hospitalization Costs	142,168	717,674	$2,686	$2,691	$3,429	$3,647	-$213*	$32	-$277	-$149
	All-Cause ER Costs	141,811	714,807	$218	$221	$237	$265	-$25*	$2	-$29	-$21
	Diabetes-Related ER costs	142,276	713,582	$129	$129	$158	$177	-$19*	$2	-$22	-$15

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.26: Resource Utilization Outcomes for MTM Beneficiaries and Controls with Diabetes Enrolled in MA-PDs

MTM Type	*Outcome*	*N*[a]		*Baseline Period*		*Outcome Period*		*DiD*[b]	*Standard Error*	*Confidence Interval*	
		MTM Enrollees	*Controls*	*MTM Enrollees*	*Controls*	*MTM Enrollees*	*Controls*				
With CMR	**Hospital Visits**										
	Any (All-cause) Hospitalization (%)	12,081	384,823	20.0%	20.0%	20.9%	21.0%	-0.1%	0.5%	-1.0%	0.8%
	Any Diabetes-Related Hospitalization (%)	12,090	387,665	16.9%	16.9%	19.2%	19.4%	-0.2%	0.5%	-1.1%	0.7%
	Average Medication Use and Costs										
	Number of Medications	11,181	348,634	13.9	13.9	14.1	13.4	0.8*	0.0	0.7	0.8
	Generic Substitution Ratio for Diabetes Drugs	12,547	380,311	91.2%	99.6%	91.2%	99.7%	0.0%	0.0%	-0.1%	0.0%
	Generic Substitution Ratio for Non-Diabetes Drugs	11,374	349,140	92.4%	92.5%	95.9%	96.5%	-0.5%*	0.1%	-0.7%	-0.3%
	Part D costs for Non-Diabetes Drugs	11,637	394,133	$3,591	$3,739	$3,511	$3,600	$60*	$25	$12	$108
Without CMR	**Hospital Visits**										
	Any (All-cause) Hospitalization (%)	12,709	514,994	19.9%	19.9%	21.0%	20.4%	0.6%*	0.2%	0.3%	1.0%
	Any Diabetes-Related Hospitalization (%)	12,709	515,539	17.0%	17.0%	19.1%	18.7%	0.5%*	0.2%	0.1%	0.8%
	Average Medication Use and Costs										
	Number of Medications	89,797	485,496	13.4	13.4	13.6	13.1	0.5*	0.0	0.4	0.5
	Generic Substitution Ratio for Diabetes Drugs	81,081	480,969	88.0%	99.7%	88.1%	99.7%	0.0%	0.0%	0.0%	0.0%
	Generic Substitution Ratio for Non-Diabetes Drugs	78,429	489,482	93.8%	94.0%	96.5%	97.0%	-0.2%*	0.0%	-0.3%	-0.2%
	Part D costs for Non-Diabetes Drugs	82,433	477,852	$3,626	$3,675	$3,639	$3,560	$128*	$9	$110	$146

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

D.4.5 Resource Utilization Outcomes by Part D Organization

MTM beneficiaries experienced increases in total Part D drug use and costs for most Part D organizations, and increases in hospitalizations and hospitalization costs for a few Part D organizations but experienced mixed effects on ER visits and costs across organizations and sub-cohorts. We observed an $823 increase in all-cause hospitalization costs for Organization D in the PDP, MTM with CMR cohort; and a $442 increase in hospitalization costs for Organization B in the PDP, MTM without CMR cohort. We also observed increases in ER visits and costs for Organization D in the PDP, MTM with CMR cohort and similar results for Organization C in the PDP, MTM without CMR cohort. However, we observed a decrease in ER visits and costs for Organization A and B in the PDP, MTM without CMR cohort. **Table_Appx D.27** and **Table_Appx D.28** present detailed results by Part D organization for the PDP and MA-PD cohorts.

In the PDP cohort, MTM beneficiaries experienced increases in hospitalizations, and hospitalization costs for Organizations B and D, and increase in total drug use and costs for Organizations A-D but mixed effects on ER visits, and ER costs across organizations. Receipt of MTM with CMR from Organization D was associated with 2.7-2.8% increases in all-cause and diabetes-related hospitalizations, and an increase of $823 in all-cause hospitalization costs and an increase of $24 in all-cause ER costs. Among PDP enrollees receiving MTM without CMR, we observed a $442 increase in all-cause hospitalization costs for Organization B. However, while ER visits and ER costs increased for Organization C, ER visits and costs decreased for Organization A and B. In the drug use and costs analysis, we observed increases in the number of medications among PDP enrollees for Organizations A-D in both the MTM with CMR and MTM without CMR sub-cohorts. We also observed $142-$305 increases in total drug costs for Organizations B and D in the MTM with CMR sub-cohort, and $160- $459 increases in total drugs costs for Organization A, B, and C in the MTM without CMR sub-cohort. **Table_Appx D.27** presents detailed results by Part D organization for the PDP cohort.

In the MA-PD cohort, none of the Part D organizations were associated with changes in all-cause and diabetes-related hospitalizations, while Organizations A-G were associated with increases in total drug use or costs among MTM beneficiaries. Complete data on hospitalization costs, and ER visits and costs were not available for MTM beneficiaries enrolled in MA-PDs and these outcomes have thus not been reported for the MA-PD cohort. **Table_Appx D.28** presents detailed results by Part D organization for the MA-PD cohort.

Table_Appx D.27: Resource Utilization Outcomes of MTM Beneficiaries with Diabetes Enrolled in PDPs by Part D Organization

MTM Type	*Outcome*	*Part D Organization*									
		A		***B***		***C***		***D***		***E***	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	332	-5.6%	4,892	0.0%	441	-4.0%	8,482	2.7%*	118	-1.1%
	Any (All-cause) ER Visit (%)	328	0.9%	4,869	0.2%	438	2.8%	8,487	0.5%	120	-3.5%
	Average Medication Use and Costs										
	Generic Substitution Ratio (Diabetes)	334	0.0%	4,943	-0.1%*	444	-0.3%*	8,616	0.0%	121	-0.2%
	Generic Substitution Ratio (Non-Diabetes)	327	0.1%	4,797	-0.3%*	437	0.3%	8,265	0.7%*	114	0.3%
	Part D costs for Diabetes Drugs	320	-$2	4,671	$56*	421	$97*	8,066	$30*	110	$58
	Part D costs for Non-Diabetes Drugs	311	-$48	4,658	$242*	394	$181	8,057	$114*	107	$400
	All-Cause Hospitalization Costs	312	-$1,077	4,669	-$105	427	$56	8,045	$823*	112	$397
	All-Cause ER Costs	316	$36	4,644	$2	422	$34	8,005	$24*	105	-$30
With-out CMR	**Hospital & Emergency Room Visits**										
	Any (All-cause) Hospitalization (%)	30,564	-0.2%	19,833	0.2%	18,595	1.3%*	389	0.6%	6,360	-1.4%
	Any (All-cause) ER Visits (%)	30,575	-1.4%*	19,820	-1.7%*	18,581	1.1%*	385	-0.2%	6,370	-1.6%
	Average Medication Use and Costs										
	Generic Substitution Ratio (Diabetes)	30,990	0.0%	20,151	-0.2%*	18,816	0.0%	392	0.0%	6,498	-0.1%
	Generic Substitution Ratio (Non-Diabetes)	30,091	-0.1%*	19,379	-0.2%*	18,628	0.3%*	371	0.8%*	6,371	-0.4%
	Part D costs for Diabetes Drugs	29,452	$19*	18,835	$80*	17,962	$11*	367	-$58	5,942	$91
	Part D costs for Non-Diabetes Drugs	29,276	$149*	18,794	$378*	17,139	$108*	355	$316	5,841	$171
	All-Cause Hospitalization Costs	29,200	$161	18,901	$442*	17,860	$167	366	-$257	6,032	-$144
	All-Cause ER Costs	29,206	-$16*	18,768	-$22*	17,881	$13*	364	-$16	6,012	-$17

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.

Table_Appx D.28: Resource Utilization Outcomes of MTM Beneficiaries with Diabetes Enrolled in MA-PD Plans by Part D Organization

MTM Type	*Outcome*	*Part D Organization*															
		A		*B*		*C*		*D*		*E*		*F*		*G*		*H*	
		N[a]	*DiD*[b]	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*	*N*	*DiD*
With CMR	**Hospital Visits**																
	Any (All-cause) Hospitalization (%)	256	-2.7%	203	-2.7%	622	-0.6%	1,011	0.7%	23	-10.0%	5,153	-0.3%	206	3.0%	-	N/A
	Average Medication Use and Costs																
	Generic Substitution Ratio (Diabetes)	261	-0.1%*	208	-0.1%*	656	0.0%*	1,043	0.0%	25	0.0%	5,389	0.0%	215	0.0%*	-	N/A
	Generic Substitution Ratio (Non-Diabetes)	254	0.9%	200	-0.7%	635	0.6%	963	0.8%*	23	0.5%	4,409	-1.2%*	197	0.6%	-	N/A
	Part D costs for Diabetes Drugs	162	$6	568	$4	894	$45*	20	-$45	4,488	-$91*	190	$231*	N/A	N/A	224	$124*
	Part D costs for Non-Diabetes Drugs	221	$271	176	$130	541	$55	895	$211*	17	-$72	4,437	$65	188	$145	-	N/A
Without CMR	**Hospital Visits**																
	Any (All-cause) Hospitalization (%)	16,977	-0.3%	435	-2.1%	15,943	0.4%	35	-0.3%	640	2.9%	3,809	-1.1%	209	1.4%	193	-4.6%
	Average Medication Use and Costs																
	Generic Substitution Ratio (Diabetes)	17,872	-0.1%*	463	0.1%	16,569	0.0%*	39	-0.1%*	668	0.0%	3,967	0.1	217	-0.1%*	205	-0.1%
	Generic Substitution Ratio (Non-Diabetes)	16,032	-0.2%*	445	0.1%	16,058	0.2%*	36	-0.5%	638	-0.1%	3,292	-1.2%*	197	0.8%	202	-0.5%
	Part D costs for Diabetes Drugs	14,936	$57*	402	$90*	14,453	-$14*	29	$18	542	$76*	3,366	-$89*	185	$149*	190	-$92*
	Part D costs for Non-Diabetes Drugs	14,721	$207*	373	$280*	13,853	$55*	32	$1,042	537	-$115*	3,357	$3	191	$237*	180	$221

*Indicates statistical significance at the 5% level.

a. *N* stands for the number of MTM enrollees available for each outcome measure. *N* is censored (indicated with a hyphen, "-") when sample size is under 11.

b. The difference-in-differences (DiD) estimator measured the difference in outcome changes between MTM enrollees and their matched controls from the baseline period to the outcome period.