Positive Medication Changes Resulting from Comprehensive and Noncomprehensive Medication Reviews in a Medicare Part D Population

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ABSTRACT

BACKGROUND: Health care organizations face the challenge of reducing costs while improving health outcomes. Currently, more than 39 million seniors are enrolled in a Medicare Part D prescription benefit plan, many of whom also qualify for medication therapy management (MTM) services. MTM programs provide valuable services designed to prevent or resolve medication-related problems (MRPs). Two core components of all MTM programs include comprehensive medication reviews (CMRs) with follow-up interventions and focused non-CMR interventions. Currently, there is limited research comparing the rate of MRPs resolved by CMR and non-CMR interventions.

OBJECTIVE: To determine whether CMRs versus non-CMR interventions resulted in more pharmacist-initiated intervention recommendations and positive medication changes.

METHODS: This retrospective, cross-sectional quality improvement project evaluated outcomes for individuals who received interventions following a CMR compared with those who received non-CMR interventions as part of a comprehensive MTM program. For this project, eligible individuals qualified for an MTM program. A positive medication change was defined as the addition of an appropriate medication or the removal of an inappropriate medication within 120 days of a pharmacist recommendation. Differences between the groups were calculated using the Wilcoxon rank sum test.

RESULTS: During the 2-year period (2012 and 2013), 788,756 beneficiaries were enrolled in the MTM program and evaluated for potential MRPs. In both years, pharmacists recommended more medication changes per member for those receiving a CMR (0.81 in 2012 and 0.82 in 2013) compared with the non-CMR group (0.68 in 2012 and 0.61 in 2013; P value < 0.001 for both years). However, recommendations made via non-CMR interventions (representing the vast majority of all medication reviews) were more likely to result in a positive medication change (OR = 1.24, 95% CI = 1.21-1.28 for 2012; OR = 1.26, 95% CI = 1.22-1.30 for 2013).

CONCLUSIONS: These quality improvement project results suggest that Medicare Part D beneficiaries participating in a university-based MTM program who received non-CMR interventions had a higher likelihood of having positive medication changes than those receiving CMRs. These results are enlightening and may provide initial evidence to support inclusion of a non-CMR performance metric for the Centers for Medicare & Medicaid Service's star ratings for MTM programs.

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What is already known about this subject

- The Centers for Medicare & Medicaid Services (CMS) requires medication therapy management (MTM) programs to provide targeted medication reviews and comprehensive medication reviews (CMRs) to eligible beneficiaries meeting minimum criteria.
- Targeted medication reviews assess beneficiaries' medication use to help identify medication-related problems and are subsequently addressed either by CMRs or non-CMR interventions.
- CMS includes the annual percentage of beneficiaries receiving a CMR in its star ratings for MTM programs yet lacks a metric for tracking those receiving a non-CMR intervention.

What this study adds

- This large-scale quality improvement project compared CMR and non-CMR interventions to determine which was more effective in producing positive medication changes in a Medicare Part D population enrolled in MTM.
- Findings from this project indicate that non-CMR interventions were more effective overall and may provide initial evidence to support inclusion of a non-CMR performance metric for CMS star ratings for MTM programs.

The elderly population is expanding rapidly, placing greater demands on the health care system than ever before. Seniors are the largest consumers of health care resources and fill close to one third of all prescriptions.¹ Furthermore, most seniors have at least 1 chronic medical condition, and over half take 5 or more medications regularly.^{1,2} Generally, as the number of medications taken increases, patient adherence to the prescribed regimen decreases.³ Data suggest that only about 50% of patients with chronic conditions take their medications consistently as directed.⁴

In 2006, the Centers for Medicare & Medicaid Services (CMS) launched the current Medicare Part D prescription benefit program to help beneficiaries afford necessary medications for managing their chronic conditions. As a program requirement, Medicare Part D sponsors must provide medication therapy management (MTM) services to eligible beneficiaries in an effort to reduce adverse events and ensure optimum

therapeutic outcomes.⁵ MTM eligibility standards are established by CMS on an annual basis, and Medicare Part D sponsors then select their parameters based on these criteria. This project included Medicare Part D sample populations from the 2012 and 2013 calendar years. The 2012 and 2013 MTM qualification standards included beneficiaries who (a) had at least 2 chronic conditions; (b) were taking at least 3 chronic medications; and (c) met the minimum mandatory annual drug spend (\$3,100 and \$3,144 in 2012 and 2013, respectively).⁶

MTM programs are required to perform targeted medication reviews at least quarterly and offer annual comprehensive medication reviews (CMRs) to all MTM-qualified beneficiaries. A targeted medication review is a systematic review of an individual's medication profile, designed to identify the following: (a) potential medication-related problems (MRPs; e.g., safety concerns such as inappropriate use of certain medications in the elderly, drug-drug interactions, and therapeutic duplications); (b) use of higher-cost agents when alternative medications are available (e.g., lower-cost generics); and (c) absence of guidelines-based therapeutic agents (e.g., statins in qualifying diabetic patients).

For the university-based MTM program evaluated for this study, the MRPs identified during a targeted medication review were subsequently addressed via a CMR or non-CMR interventions. CMRs are person-to-person consultations that include a review of the beneficiary's allergies and medical history, a complete medication reconciliation, and an assessment and review of therapeutic goals. The qualified MTM provider performing the CMR (a pharmacist or pharmacy intern acting under the supervision of a pharmacist) creates a medication action plan and personal medication list that is given to the beneficiary following the CMR. Additionally, the pharmacist contacts the beneficiary's prescriber with recommendations to modify treatment to address any identified medication-related problems. In contrast, non-CMRs involve shorter and more focused discussions, written beneficiary outreach, and/or direct provider outreach to address problems. Non-CMR interventions are performed for beneficiaries unable or unwilling to complete a CMR or in cases where the intervention is time sensitive and prescriber outreach must occur quickly.

Research shows that MTM services are effective in decreasing adverse medication events and hospital readmission rates and that pharmacist-delivered MTM medication education decreases health care use and overall expenditures.⁷⁻¹⁶ However, the published literature comparing CMRs and non-CMR interventions is limited. To date, most studies have focused solely on CMRs. Perlroth et al. (2013) found that annual CMRs were effective in producing positive outcomes (e.g., improved prescribing quality in MTM populations).¹⁷ In addition, Isetts et al. (2008) reported that face-to-face MTM services were effective in resolving medication-related problems without prescriber involvement.¹⁶ Roane et al. (2014) found that an electronic

record review in tandem with a telephonic MTM program resulted in a more thorough assessment of patient therapy.¹⁸ Finally, Chinthammit et al. (2015) showed that non-CMR interventions were less costly and more effective than CMRs.¹⁹

CMRs can be highly beneficial, yet they typically incorporate an extensive amount of information that may overwhelm some beneficiaries. Educational research suggests that simplified and repeated messaging may facilitate more effective learning of complex information.²⁰ Non-CMR interventions are designed to address specific prioritized problems, so beneficiaries may find this type of intervention less intimidating, since it allows for more concise and focused education. However, the only CMS star metric for MTM programs is the percentage of qualified beneficiaries receiving a CMR in a given calendar year.³ Presently, no performance measure exists for non-CMR interventions.

Currently, more than 39 million seniors are enrolled in the Medicare Part D program,²¹ and approximately 11% of those seniors are enrolled in an MTM program.²² In 2015, CMS released the first star cut points for the CMR completion rate measure, thereby placing additional emphasis on this metric. While CMS uses star measures pertaining to use of guidelines-based therapy and adherence, it is important to note that there are no current measures for resolution of MRPs for CMRs or non-CMR interventions. As health care organizations strive to reduce medication costs while simultaneously improving patient health outcomes, it is apparent that more research is needed to determine the optimal approach for accomplishing this task.

The purpose of this quality improvement project was to compare CMR versus non-CMR interventions for patients receiving services via a university-based MTM program to determine which approach achieved more pharmacist-initiated intervention recommendations and more positive medication changes.

Methods

Project Design

This retrospective, cross-sectional, observational project compared the number of interventions and positive medication changes resulting from CMR versus non-CMR interventions in a Medicare Part D population receiving MTM services from a university-based program. The university's institutional review board deemed this a quality improvement project.

Target Population

The target population was beneficiaries who received MTM services from the University of Arizona Medication Management Center (UAMMC), which serves beneficiaries nationwide who qualify for MTM services through Medicare Part D. Inclusion criteria for this project were beneficiaries who qualified for MTM services based on their Medicare Part D sponsor's criteria and filled medications during the 2012 or 2013 calendar year. A positive medication change was defined

Positive Medication Changes Resulting from Comprehensive and Noncomprehensive Medication Reviews in a Medicare Part D Population

TABLE 1 Sociodemographic and Health-Related Characteristics of Medicare Part D Beneficiaries Who Received a CMR or Non-CMR Intervention

Characteristic	2012			2013		
	CMR Group (n = 42,253)	Non-CMR (n = 384,477)	P Value ^a	CMR Group (n = 38,967)	Non-CMR (n = 342,701)	P Value ^a
	n (%)	n (%)		n (%)	n (%)	
Gender						
Female	26,740 (63)	232,222 (60)	<0.001	22,895 (59)	201,750 (59)	0.65
Male	15,513 (37)	152,255 (40)		16,072 (41)	140,936 (41)	
Chronic disease ^b						
Hypertension	38,405 (91)	357,466 (93)		35,321 (91)	316,367 (92)	
Dyslipidemia	30,854 (73)	289,591 (75)		28,605 (73)	247,457 (72)	
Diabetes	24,426 (58)	204,681 (53)		20,396 (52)	153,895 (45)	
Depression	13,676 (32)	135,709 (35)		10,560 (27)	105,131 (31)	
Heart failure	9,237 (22)	93,929 (24)		8,318 (21)	78,692 (23)	
Respiratory	10,880 (26)	90,017 (23)		8,941 (23)	79,135 (23)	
Osteoporosis	6,025 (14)	53,362 (14)		3,950 (10)	37,075 (11)	
Dollars spent on prescription medications (U.S. dollars)						
Mean (SD)	1,912 (2,511)	1,871 (2,423)	0.001	2,192 (4,011)	2,071 (3,250)	<0.001
Median (IQR)	1,315 (1,101)	1,291 (1,075)		1,391 (1,277)	1,350 (1,214)	
Number of chronic medications						
Mean (SD)	10.7 (3.5)	10.8 (3.6)	<0.001	11.3 (4.7)	11.2 (4.8)	0.05
Median (IQR)	10 (4)	10 (5)		10 (5)	10 (5)	

^aAnalysis of the baseline characteristic compared the CMR group with the non-CMR group for each year.

^bThese are not mutually exclusive disease categories. Patients with multiple chronic diseases may be represented in 2 or more of these chronic disease categories. CMR = comprehensive medication review; IQR = interquartile range; non-CMR = noncomprehensive medication review; SD = standard deviation.

as the addition of an appropriate medication or the removal of an inappropriate medication within 120 days of a pharmacist recommendation, as determined by electronic review of claims data. Retrospective group assignment was based on the type of intervention received (CMR or non-CMR).

Data Collection

Each beneficiary who qualified for MTM services received a targeted medication review to assess for potential MRPs every time a prescription claim was processed and every time a prescription claim refill was expected for a chronic medication. Targeted medication reviews were conducted via electronic evaluation of claims data. When a medication-related problem was identified, a UAMMC staff member (i.e., pharmacist, pharmacy intern, or pharmacy technician) contacted the patient by telephone to initiate a CMR. If the beneficiary was unreachable, unwilling, or unable to complete a CMR, a staff member completed a non-CMR intervention such as a brief phone discussion focused solely on the potential MRPs, a letter sent to the beneficiary, and/or a phone call or facsimile sent to the prescriber.

The intervention method was selected systematically based on the type and severity of the problem, according to a preset algorithmic ranking system. Implementation of a non-CMR intervention could also occur if the problem identified was

time sensitive or severe (e.g., a potentially serious drug-drug interaction between warfarin and azithromycin) and required immediate outreach to the beneficiary's prescriber. The UAMMC staff documented the type of review performed (CMR or non-CMR), the number of each type of intervention recommended to providers, and the number of intervention recommendations accepted by providers (i.e., positive medication changes). Beneficiaries who had multiple intervention recommendations sent to their providers or multiple positive medication changes were only included in the dataset once. Intervention recommendation data were collected to demonstrate the number of MRPs identified through the present algorithms and the number addressed by pharmacists.

The data collected also show the effect of pharmacist-provided medication reviews on ensuring that patients receive the correct medication therapy and reduce medication-related problems. In addition, the UAMMC software system collected beneficiary information including demographics, medical claims data, prescriptions processed through Medicare Part D, and self-reported information (e.g., medications, allergies, and conditions). For inclusion in the final datasets, beneficiaries also had to meet CMS 2012 and 2013 eligibility criteria to receive MTM services (e.g., having at least 2 chronic conditions; taking at least 3 chronic medications; and meeting mandated annual drug cost (\$3,100 in 2012 and \$3,144 in 2013).

Positive Medication Changes Resulting from Comprehensive and Noncomprehensive Medication Reviews in a Medicare Part D Population

TABLE 2 Beneficiaries Who Received an Intervention Recommendation and Positive Medication Change by Group and Project Year

	2012			2013		
	CMR Group (n = 43,490)	Non-CMR Group (n = 375,159)	P Value	CMR Group (n = 38,101)	Non-CMR Group (n = 332,006)	P Value
Number of intervention recommendations, n (%) ^a						
None	19,259 (44)	199,143 (53)	<0.001	18,012 (47)	196,873 (59)	<0.001
1	16,141 (37)	118,620 (32)		12,505 (33)	87,973 (25)	
2	5,876 (14)	42,050 (11)		5,092 (13)	33,037 (10)	
3	1,691 (4)	11,682 (3)		1,764 (5)	10,235 (3)	
4 or more	523 (1)	3,664 (1)		728 (2)	3,888 (1)	
Number of positive medication changes, ^b n (%) ^a						
No changes	35,778 (82)	310,464 (83)	<0.001	31,067 (82)	277,035 (83)	<0.001
1	6,108 (14)	47,417 (13)		5,747 (15)	43,932 (13)	
2	1,243 (3)	12,617 (3)		1,085 (3)	9,011 (3)	
3	278 (1)	3,379 (1)		172 (1)	1,657 (1)	
4 or more	83 (0.2)	1,282 (0.3)		30 (0.1)	371 (0.1)	

^aPercentages may not equal 100% due to rounding.

^bA positive medication change was defined as the addition of an appropriate medication or the removal of an inappropriate medication within 120 days of a pharmacist recommendation.

CMR=comprehensive medication review; non-CMR=noncomprehensive medication review.

Demographic information was not part of the initial data collection, since this was a retrospective project. Thus, the baseline demographic characteristics were collected at a different time and include all beneficiaries that met the CMS eligibility criteria for that year.

Data Analysis

Data analysis was conducted using STATA SE, version 12.1 (StataCorp, College Station, TX). The number of recommendations and medication changes per member were calculated by dividing the sum total of prescriber interventions (or medication changes) by the number of beneficiaries for each group (CMR or non-CMR) for each project year (2012 or 2013). Demographic characteristics were compared using chi-square tests. Wilcoxon rank sum tests were used to determine differences in the total recommendations and total positive medication changes attained between beneficiaries receiving CMRs versus those receiving non-CMR interventions for each calendar year. Odds ratios were calculated to determine the odds of receiving a prescriber intervention or medication change for each calendar year. A two-tailed a priori alpha level of 0.05 was used.

Results

A total of 808,398 beneficiaries met the project's inclusion criteria (426,730 in 2012 and 381,668 in 2013). A total of 19,642 beneficiaries were excluded because they declined MTM services with their insurance company or were disenrolled by their insurance provider. Thus, the remaining 788,756 eligible beneficiaries were included in the CMR versus non-CMR calculations during the 2-year project period: 418,649 beneficiaries in 2012 and 370,107 in 2013.

In the 2012 calendar year, the majority (61%) of beneficiaries were female. Beneficiaries filled 10 chronic medication prescriptions on average, totaling \$1,874.00 (standard deviation [SD] \$2,431.59) per quarter. The most frequently reported chronic conditions were hypertension (93%), dyslipidemia (75%), and diabetes (54%; Table 1). Out-of-pocket medication costs were higher for CMR recipients (mean \$1,911.88 [SD \$2,510.67]) compared with non-CMR recipients (mean \$1,870.90 [SD \$2,422.71]; $P=0.001$). However, CMR beneficiaries filled fewer medications (mean 10.7 [SD 3.49]) than non-CMR beneficiaries (mean 10.8 [SD 3.58]; $P<0.001$).

In the 2013 calendar year, there were more (59%) female beneficiaries than male. On average, beneficiaries filled 11 chronic medication prescriptions, totaling \$2,083.05 (SD \$3,336.21) per quarter. The top comorbid conditions were hypertension (92%), dyslipidemia (72%), and diabetes (46%). CMR recipients had a higher out-of-pocket medication cost (mean \$2,191.75 [SD \$4,011.42]) compared with non-CMR recipients (mean \$2,070.69 [SD \$3,250.34]; $P<0.001$). However, there were no differences in number of medications taken between groups.

In 2012 and 2013, the majority of beneficiaries in both groups received either zero or 1 recommendation; less than 2% in either group received 4 or more recommendations. Overall, nearly 20% of beneficiaries had a positive medication change as a result of receiving either type of intervention (Table 2).

In 2012, those beneficiaries in the CMR group received significantly more intervention recommendations per member than those in the non-CMR group (0.809 vs. 0.677; $P<0.001$). There were no significant differences in the number of medication changes per member (0.236 for the CMR group vs. 0.225 for the non-CMR group; $P=0.16$) between the groups.

Positive Medication Changes Resulting from Comprehensive and Noncomprehensive Medication Reviews in a Medicare Part D Population

TABLE 3 Total Number of Intervention Recommendations and Medication Changes per Member by Group and Project Year

	2012				2013			
	CMR Group	Non-CMR Group	Total	P Value ^a	CMR Group	Non-CMR Group	Total	P Value ^a
	n	n	n		n	n	n	
Members	43,490	375,159	418,649		38,101	332,006	370,107	
Intervention recommendations ^b	35,207	253,494	288,701		31,181	201,670	232,851	
Intervention recommendations per member ^c	0.809	0.678	0.687	<0.001	0.818	0.608	0.632	<0.001
Medication changes ^b	9,796	88,467	98,263		8,559	68,477	77,036	
Medication changes per member ^c	0.225	0.236	0.230	0.160	0.225	0.207	0.210	<0.001

^aP values indicate the comparison between CMR group and non-CMR group for number of interventions per member and the number of medication changes per member by project year.

^bPrescriber interventions and medication changes reflect total sum.

^cAnalyzed using Wilcoxon rank sum test.

CMR = comprehensive medication review; non-CMR = noncomprehensive medication review.

In 2013, similar to 2012, the CMR group received significantly more recommendations per member than those in the non-CMR intervention group (0.818 vs. 0.608; $P < 0.001$). Additionally, there was a significant difference in the number of medication changes per member between the CMR and non-CMR groups (0.225 vs. 0.207; $P < 0.001$; Table 3).

CMR recipients were more likely to receive an intervention recommendation than non-CMR recipients (2012: OR=0.70, 95% CI=0.69-0.72; 2013: OR=0.62, 95% CI=0.60-0.63). However, in both years, the odds of having a positive medication change was higher in the non-CMR group compared with the CMR group (2012: OR=1.24, 95% CI=1.21-1.28; 2013: OR=1.26, 95% CI=1.22-1.30; Table 4).

Discussion

In the 2012 and 2013 samples, the CMR group was significantly more likely than the non-CMR group to have an intervention recommendation sent to their providers. While CMRs allow pharmacists to probe in depth regarding beneficiaries' medication use, non-CMR interventions are more focused and typically only address any MRPs identified by the targeted medication review using nonpatient-reported information. Consequently, CMRs may result in identification of additional MRPs that may not be noted during non-CMRs. However, both interventions are clearly effective in resolving MRPs that lead to unnecessary health expenditures.

This quality improvement project found that beneficiaries in the non-CMR group received fewer intervention recommendations per person; yet, the recommendations made were more likely to result in positive medication changes. This parallels the literature, which shows that a focused approach to medication changes may be more effective.²⁴ In the 2012 non-CMR sample, the vast majority of recommendations accepted by prescribers involved guideline-based recommendations (e.g., addition of an angiotensin-converting enzyme inhibitor

for a hypertensive diabetic) or safety recommendations (e.g., discontinuation of duplicative therapy).²³ Conversely, CMRs generated other interventions (e.g., potential adverse reactions to medications) based on the pharmacist's individual analysis of the beneficiary's medication use. This intrinsic difference in recommendation type may account for the higher incidence of provider acceptance of recommendations made via non-CMR interventions.

A statistically significant difference in the number of medication changes per member was observed between the 2 groups in 2013, perhaps because of the large sample; however, it may not represent an appreciable difference between the types of interventions. While non-CMR recipients comprised the majority of the sample, they also received the majority of medication changes.

In today's MTM landscape, providers focus much more heavily on completing CMRs because they are the only type of intervention recognized by CMS in its star ratings metric for MTM programs. However, recent research suggests that non-CMR interventions are more cost effective than CMRs.²⁴ The results presented here parallel those of another study,²⁵ and they provide initial evidence that non-CMR interventions offer a viable avenue to address medication-related problems, reduce adverse drug events, and minimize medication costs for patients and insurance payers (notably CMS). While still preliminary, these results represent important information for MTM pharmacists, providers, and regulatory officials as they strive to improve patient safety and outcomes while reducing health care costs.

Limitations

It is important to acknowledge several limitations of this quality improvement project. First, the UAMMC aims to maximize CMR rates in accordance with the CMS performance metric. Beneficiaries who receive CMRs may inherently differ from

Positive Medication Changes Resulting from Comprehensive and Noncomprehensive Medication Reviews in a Medicare Part D Population

TABLE 4 Odds Ratio Analysis Comparing Odds of Receiving a Prescriber Intervention or Medication Change for CMR Recipients by Project Year

	2012			2013		
	CMR Group	Non-CMR Group	OR (95% CI)	CMR Group	Non-CMR Group	OR (95% CI)
	n	n		n	n	
Intervention recommendation	24,231	176,016	0.70 (0.69-0.72)	20,089	135,133	0.62 (0.60-0.63)
No intervention recommendation	192,259	199,259		18,012	196,873	
Medication change ^a	7,369	61,969	1.24 (1.21-1.28)	7,034	54,971	1.26 (1.22-1.30)
No medication change	16,862	114,047		13,055	80,182	

^aOnly beneficiaries that received a positive intervention recommendations were included in the medication change calculation.

CI=confidence interval; CMR=comprehensive medication review; non-CMR=noncomprehensive medication review.

those receiving non-CMR interventions, and beneficiaries receiving non-CMRs may be unable or unwilling to complete the in-depth review.

Second, in the 2012 and 2013 samples, there were significant differences in the sociodemographic characteristics of the groups at baseline (gender, dollars spent on prescription medications, and number of concomitant medications). It is reasonable to assume that the difference in the female-male ratio of these Medicare Part D beneficiaries mirrors the national statistics for this more senior group.²⁶ The reason for the observed differences in the other baseline characteristics is unclear. Further investigation is warranted to gain a better understanding of these differences.

Third, in the 2012 and 2013 samples, it is possible that the observed differences in average dollars spent and concomitant medications is related to individuals for whom MTM was designed (e.g., beneficiaries taking more than 3 chronic medications and incurring higher annual medication costs); the large sample sizes may also help account for some of these sociodemographic differences. Despite these observed differences, the results indicate that higher-risk beneficiaries are indeed receiving the additional support needed for their greater medication use and associated costs.

Fourth, the data used for this quality improvement project were initially included as part of a mandatory annual report required by CMS for all MTM programs. These reports included beneficiaries who qualified for MTM services and met additional requirements. However, some beneficiaries were excluded from these reports based on criteria established by CMS: excluded individuals were not enrolled or participating within the previous 60 days or opted out of receiving MTM services with their insurance company. Therefore, the demographic data used for this study included all beneficiaries who qualified for MTM services regardless of inclusion in the CMS annual reports. Consequently, the demographic sample was slightly larger (e.g., for 2012, 426,730 vs. 418,649 included in the CMS annual report) and may have differed slightly from the dataset analyzed when comparing the CMR and non-CMR groups.

Finally, the recommendations resulting from CMRs may differ inherently from those made for non-CMR recipients. The primary difference is potentially attributable to additional information obtained during CMRs compared with the information available through non-CMR interventions. These intrinsic differences may have had an effect on the number of medication-related problems addressed in each of the groups.

Conclusions

This quality improvement project found that non-CMR interventions resulted in fewer overall intervention recommendations but more positive medication changes for a Medicare Part D population participating in a university-based MTM program. While these findings are promising, further research is warranted to determine their replicability in more diverse populations and in other MTM settings (e.g., face to face or clinic based). These results provide initial evidence to support inclusion of non-CMR interventions as a performance metric for the CMS MTM star rating program.

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Positive Medication Changes Resulting from Comprehensive and Noncomprehensive Medication Reviews in a Medicare Part D Population

Buhl and Augustine contributed study concept and design, collected the data, and wrote the manuscript. Data interpretation was performed by all the authors. Taylor, Warholak, Augustine, and Martin revised the manuscript.

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