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Hearing Examining the Medicare Part D Medication Therapy Management Program

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Chairman Pitts, Ranking Member Green, Members of the Subcommittee, thank you for holding this hearing to examine the Medicare Part D Medication Therapy Management (MTM) Program.

Prescriptions for a Healthy America (P4HA) is a non-partisan alliance of more than 50 members representing patients, providers, pharmacies, pharmacists, employers, and life science companies. We joined together to raise awareness of the growing challenges posed by medication nonadherence and to advance public policy solutions that will help reduce health care costs and improve the lives of patients across the nation through improved medication adherence. I was professional staff for the Committee on Ways and Means during the design, drafting and enactment of the Medicare Part D benefit. The comments in this testimony reflect my thoughts and those of many of our members, although our agreement on some of these issues is not uniform.

It is simple and true to state that drugs don't work in patients who don't take them. Poor medication adherence, or non-adherence, limits effective management and control of chronic illnesses. Non-adherence increases the likelihood of preventable disease progression, hospitalizations, avoidable ambulatory and emergency room visits, and other problems arising from poor health, which can significantly increase costs. In fact, according to the IMS Institute estimates misused and mismanaged use of medications result in more than 300 million annual incidences of avoidable medical services, including 10 million avoidable hospitalizations, 78 million outpatient encounters and 4 million ER visits that would not have occurred had medications been used appropriately. Poor medical outcomes, including more than 100,000 deaths, and advanced disease progression is also a result of poor medication use.

Because more than half of all Americans do not take their medications as prescribed, hundreds of billions of dollars in additional, unnecessary health costs are added to the

health spending ledger every year. In June of 2013, the IMS Institute issued a report estimating the U.S. healthcare system wasted over \$200 billion dollars in the previous year due to a lack of responsible medication use. That represented 8 percent of total healthcare expenditures in 2013.

This cannot and should not continue.

In a Medicare system that is fraught with inefficiencies, Part D continues to deliver comprehensive prescription drug coverage for a lower than expected cost. Additionally, 9 out of 10 seniors are satisfied with their coverage. But some aspects of the program, including the MTM benefit, are in need of modernization.

We support the following program improvements:

- 1. Improve eligibility criteria to better target services to those in need;
- 2. Revise required MTM services to provide better value to program enrollees; and
- 3. Realign incentives to provide services that improve outcomes and lower costs.

These changes will enhance the Part D program without undermining the current program's success in deliver a solid benefit, while holding down premiums and taxpayer costs, and still producing high satisfaction rates among enrollees.

Background

When Congress created the Part D prescription drug benefit, it required plans to offer an MTM benefit whose purpose was to ensure that covered drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Congress required the MTM program to be used in concert with drug utilization management program, quality assurance measures and systems to reduce medical errors, and programs to reduce fraud and waste. At the time Part D was created, Members of Congress envisioned these programs in concert would ultimately lower costs through more appropriate use of medications that also produce better therapeutic outcomes.

Unfortunately, ten years of evidence has produced a record that demonstrates the current MTM program has missed the mark. Low enrollment, services with questionable clinical impact and misaligned incentives lead us to believe MTM should be reformed to produce better outcomes, and more effectively target services to those in need.

1. Eligibility Criteria

The law establishes three eligibility criteria for the MTM benefit, which are minimum thresholds, and include: having more than one chronic condition, taking multiple drugs (between 2 and 8), and incurring annual costs for covered Part D drugs above a cost threshold (\$3,138 in 2015).

CMS estimates that 25 percent of Medicare Part D beneficiaries are eligible for the MTM benefit. Newly released MTM data show that, in 2012, only 11 percent (or 3.1 million enrollees) participated in an MTM program. Beneficiaries originally had to opt into the Part D MTM benefit, but CMS changed the requirement to an opt-out. This may have increased participation slightly, but did not address some of the structural problems with the MTM program design.

Sponsors may offer additional MTM services to an expanded population of beneficiaries who do not meet the statutory eligibility criteria. CMS has been tightening program rules to improve participation in, and value from, MTM programs. Despite this, the majority of Part D Plans adhere to the minimum targeting criteria. In fact, 85 percent of programs target beneficiaries with 3 or more chronic illnesses, and 52 percent of programs target beneficiaries with 8 or more drugs.

From this and in our research, we conclude that plans do not see much value in providing MTM benefits under the current structure and that the current program does not adequately identify patients who need medication management services. As CMS has indicated, plans are unable to reach many beneficiaries and many beneficiaries refuse the service because they simply do not see the value, among other issues.

We thus recommend updating the eligibility criteria to target services to those beneficiaries who need them most.

Recommendations

We recommend medication management services should be striated to target patients based on their risk for an adverse medical event. More specifically, Congress should repeal the eligibility criteria and replace them with the following structure:

- Patients should be ranked via a quantitative score based on when their medication regimen could be problematic and would therefore likely benefit from subsequent intervention.
- This score would take into account all of an individual patient's prescription medications based on the <u>dosage form</u> of each prescription (i.e. tablet, spray, gel, etc.), the <u>dosing frequency</u> (i.e. how many times a day), and <u>additional</u> <u>administrative directions</u> that could increase complexity (i.e. take prescription at specific times or with food, etc.).
- In addition to the complexity index (or score), the patient should be flagged when undergoing a transition in care or when a patient's clinical goals of care are not reached.

The latter indication would require coordinating care and data between Medicare Parts A and B and Medicare Part D. CMS should make beneficiary-level information on MTM, comprehensive medication reviews, and other plan activities available on a timely basis

and linkable to Parts A, B and D claims data in the chronic condition warehouse. Part D Plans should also have timely access to Parts A and B data for their enrollees. This access to data could provide critical information about enrollees' use and spending on medical services, risk for adverse health events and transitions in care. These data should be provided to PDPs on a regular basis in a format that is readily accessible to assist plan efforts in identifying and supporting at-risk beneficiaries.

2. Revise required MTM services

Currently, sponsors must offer a minimum level of MTM services to all eligible beneficiaries including: an annual comprehensive medication review (CMR), which is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider for the beneficiary with an individualized, written summary in CMS' standardized format; and quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary. The vast majority of plans - 95.8 percent of programs - offer the interactive CMR consultation via the phone, while 58.2 percent of programs also offer face-to-face CMRs, and 15.9 percent of programs offer CMRs through telehealth technologies.

Beyond the required services, some sponsors provide additional value-added services, including referrals for case, specialty or disease management, beneficiary education and refill reminder programs, indicating some plans see value in competing on additional services. Sponsors are also required to offer interventions to the beneficiaries' prescribers, including resolving drug therapy problems or optimizing therapy.

According to MedPAC, because neither the legislation nor subsequent CMS regulations provided specific guidance on how MTM programs should be designed or implemented, MTM programs differ in the kinds of interventions provided to enrollees and prescribers. Furthermore, the value of plan to provider intervention is questionable at best, partly because physicians are often reluctant to accept medical advice or direction from a plan with whom they have limited or no relationship.

Recommendations

Changes to services provided to Part D enrollees should enhance outcomes and reflect the movement away from paying for discrete services to paying for added value. Services should range from basic medication reconciliation to additional services that may improve adherence (i.e. medication synchronization) to more intensive and comprehensive medication management completed by a qualified clinical professional.

Plans should have the flexibility to contract for and apply the level of intensity of medication management based on the individual patient need/score.

3. Realign incentives to provide services that improve outcomes and lower costs

Plans that invest in MTM strategies are doubly disincentivized. First, their investments count against their medical loss ratio (MLR) score. Under Medicare's program rules, if an MA plan or Part D prescription drug plan fails to have an MLR of at least 85 percent, the plan must remit to the Secretary the product of: (1) the plan's total revenue, and (2) the difference between 85 percent and the plan's MLR. If a plan fails to have an MLR of at least 85 percent for three consecutive contract years, it will be subject to enrollment sanctions. If the plan fails to have an MLR of at least 85 percent for five consecutive contract years, CMS will terminate the plan contract. That is a serious disincentive for plans to spend dollars that ultimately may disadvantage them financially or that could ultimately disqualify the plan from participation in the program.

Second, any positive outcomes or savings accrue to others. Five star rating programs include adherence measures, but for beneficiaries, incentives to invest in their health are often an afterthought and rarely involve financial incentives. For providers of care, incentives in new care and payment models are rarely tied directly to medication adherence or persistence. For plans, investing in, say, cardiovascular MTM may mean a beneficiary doesn't incur a \$50,000 heart attack, but none of these savings make it back to the plan. In fact, from the plan perspective, the MTM investment is mostly pure cost.

This one-two punch means plans have little incentive to invest in robust MTM or adherence programs.

Recommendations

Congress should address each issue to ensure all actors are incentivized to improve outcomes and lower costs. At the very least, Congress should ensure that all MTM (and related medication management) activities are "quality improving" for the purpose of calculating the Medical Loss Ratio (MLR). CMS, in releasing their recent MTM demonstration program, is allowing this change, but only for plans geographically located in the test areas.

One model might be to allow plans to earn a share of savings achieved in lowering spending and/or improving health, similar to other shared savings models Congress and the Administration have authorized or tested over the past several years.

Because higher out-of-pocket costs are often the biggest barrier to medication adherence, Congress should explicitly allow plans to waive cost sharing associated with revised MTM programs. For beneficiaries, additional incentives like premium or cost sharing reduction programs should be available and should be tied to measures of adherence and persistence. Financial incentives could be tiered based on persistence (the longer someone is adherent, the more they can earn). For enrollees in an ACO or other APM, the law should allow the enrollee to share in any savings produced in the

program (the beneficiary would take the share as part of the 75 percent savings to taxpayers).

Moreover, even though a significant number of Medicare beneficiaries remain in the fee for service program, the health care system is evolving into integrated, risk-based and coordinated care models of payment and delivery. These programs create powerful incentives for payers and providers to improve outcomes, manage costs and meet quality measures. In other words, providers are being held more accountable for what they do, and new payment and delivery models attempt to break down the "silos" of healthcare spending in favor of incentives for patient care and spending that is better managed. Assuring appropriate medication use should be an integral part of all these models.

Conclusion

Mr. Chairman and members of the Committee, we believe Congress should reform the MTM program as quickly as possible as CMS conducts its research into what may work better in the future. While we see great value in and support the CMMI MTM demo, we note the current MTM structure will persist for years in those areas not covered by the research project. For reasons outlined above, this is not good for taxpayers or beneficiaries. We need Congress to act swiftly to improve the program and target services to those beneficiaries most in need.

We look forward to continuing our work with you to develop legislation to improving medication management and adherence and to lower the cost of health coverage for all Americans.