June 22, 2015

The Honorable Orrin Hatch                          The Honorable Ron Wyden
Chairman                                         Ranking Member
Committee on Finance                              Committee on Finance
United States Senate                              United States Senate

The Honorable Johnny Isakson                          The Honorable Mark Warner
Senator                                          Senator
Committee on Finance                              Committee on Finance
United States Senate                              United States Senate

Submitted electronically to: chronic_care@finance.senate.gov

RE: Finance Committee Working Group Request for Input on Chronic Care Solutions

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

Prescriptions for a Healthy America (P4HA) appreciates the opportunity to provide input to the Senate Finance Chronic Care Working Group on concepts that will help improve outcomes for Medicare patients requiring chronic care. P4HA strongly supports the Committee’s formation of the bipartisan Working Group and we look forward to working with you to craft legislation to tailor programs that more effectively address this issue than current Medicare and Medicaid programs.

P4HA (www.adhereforhealth.org) is a multi-stakeholder alliance representing patients, providers, pharmacies, and life science companies. We joined together to raise awareness on the growing challenges posed by medication nonadherence, as well as to advance public policy solutions that will help reduce health care costs and improve the lives of patients across the nation through medication adherence interventions.

Medication adherence occurs when a patient takes their medications according to the prescribed dosage, time, frequency, and direction. A breakdown in any one of these elements has the potential to result in unanticipated side effects and complications. Studies show that:

- Two-thirds of all patients do not take their medications as prescribed;
- More than 1 in 5 new prescriptions go unfilled;
- Adherence is lowest among patients with chronic illnesses.

Poor medication adherence, or non-adherence, limits effective management and control of chronic illnesses. Non-adherence increases the likelihood of preventable disease progression, increased hospitalizations, avoidable doctor and emergency room visits, and other problems arising from poor health, which can significantly increase costs. At least 125,000 Americans die annually due to poor medication adherence. We know that as adherence declines, emergency
room visits and hospital stays increase. Poor medication adherence results in 33 to 69 percent of medication-related hospital admissions in the United States, at a cost of roughly $100 billion per year.

Because treatments do not work in patients who do not take them, effective patient engagement at the point of care is essential, particularly for those Medicare patients suffering with chronic conditions. Doing so will save money. In November 2012 CBO has changed its methodology related to adherence by recognizing health services savings resulting from increased utilization of prescription medications\(^1\). Policies and models that aim to improve proper medication adherence, defined as when a patient takes their medications as directed, have considerable potential to reduce health spending and improve health outcomes. We encourage the Working Group to include incentives and structures that support medication adherence strategies within any proposal you develop.

Our comments on your specific questions are outlined below:

**1. Reforms to Medicare’s current fee-for-service program that incentivize providers to coordinate care for patients living with chronic conditions**

Ninety percent of chronic diseases require medications as first-line therapy. Because of this, it is imperative to pair chronic care with proper medication management. One avenue for reforming the current FFS program is to integrate pharmacy and medication management services within primary care and Medicare Part B.

Comprehensive Medication Management (CMM) is the standard of care that ensures each patient’s medications are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended\(^2\). CMM includes an individualized care plan that achieves the intended goals of therapy with appropriate follow-up to determine actual patient outcomes and has the potential to seriously involve patients in engaging with their healthcare.

CMS awarded the University of Southern California a $12 million grant in 2012 to study pharmacy services in safety-net clinics on improving medication adherence and safe and appropriate use of prescription drugs with the intended result of optimizing patient health while reducing avoidable hospitalizations and ER visits\(^3\). Patients were targeted based on four criteria. CMM was the primary intervention. Initial results illustrated a significant decline in hospitalizations, an improvement in healthcare quality measures, an improvement in medication safety, and an improvement in provider access and satisfaction. Because of these promising

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results, we urge the Working Group to consider testing CMM, as an intervention in Medicare Part B.

2. The effective use, coordination, and cost of prescription drugs

Medicare Part D Medication Therapy Management Program

The Medicare Part D Medication Therapy Management (MTM) program was enacted as part of the Medicare Part D prescription drug benefit in the 2003 Medicare Modernization Act (MMA). The MTM program was included in Part D because it was recognized that many Medicare beneficiaries would need assistance from health professionals in assuring that they use their medications appropriately. However, experience suggests that the Part D MTM program needs to be modernized to keep pace with the rapid changes in the health care system. Specifically, we believe MTM should be reformed by:

- Reforming the eligibility criteria;
- Better defining payment for effective services;
- Enhancing incentives to provide more effective benefits that lower costs in Parts A and B; and
- Enhancing the understanding of current program effectiveness by linking Medicare Parts A and B claims data with Part D interventions.

We recommend that efforts focus on gaining a better understanding of: (1) the impact of MTM on patient-related outcomes, (2) the appropriateness of the MTM eligibility criteria, and (3) the reasons for poor take-up. A key goal in establishing the MTM program was to promote better use of medicines and ultimately better health outcomes by pharmacists engaging directly with patients. This engagement generally centers on education, a review of prescribed medication lists, provider interaction, and disease management referral, among other activities. After nearly eight years since implementation, additional evidence is needed to understand the overall effectiveness of MTM, or specific components – operational and policy – of the program.

In addition, we believe it is also important to examine whether or not the program is optimally targeted to impact beneficiaries who would most benefit from participation. Evidence to date suggests that eligibility criteria for MTM participation may be better targeted to reach beneficiaries at high risk for negative health events, high medical spending, or poor adherence.4

In the current Medicare environment, P4HA recognizes that Part D plans are limited in their ability to target MTM services to beneficiaries based on their clinical behavior and actions under Medicare Parts A and B. For example, PDPs cannot discern when their enrollees:

- Are admitted to an ER or institutional care provider based on a medication-related event;
- Undergo a transition in care from setting to another; or

4 Stuart B et al. Should eligibility for medication therapy management be based on drug adherence?. J Man Care Pharm. 2014;20(1):66-75
• Incur significant total medical costs as a result of high healthcare utilization.

An initial step for overcoming these barriers is to increase visibility into Medicare Parts A and B data for PDPs. These data should be provided to PDPs on a regular basis in a format that is readily accessible (i.e. flags which indicate when a beneficiary has recently experienced a hospital admission).

It is also well known that participation in comprehensive medication review— is dramatically low. Recent evidence suggests that only 11% of Medicare beneficiaries are enrolled in the MTM program and about half of those eligible are receiving benefits. In order to adequately explore these issues it is important that additional empirical research be conducted. We believe such research will require use of data that describes MTM program characteristics and outreach efforts, particularly among those who would most benefit from the MTM services, including highly impacted racial and ethnic groups. This is not currently available in releases of Medicare administrative data to external researchers. Therefore, to better understand the Part D MTM benefit, we, again, encourage linking Part D process data to reflect outcomes in Parts A and B.

Misaligned Incentives for Medication Management Services under Part D

Incentives for Part D plans to compete around MTM benefits are seriously misaligned. PDPs have few incentives to invest in medication management programs (i.e. MTM) versus their Medicare Advantage counterparts as improving medication use costs Part D plans resources, but savings (benefits) accrue to taxpayers and beneficiaries via reductions in Part A and B services and supplies. Because Medicare Advantage bundles the medical and drug benefits under one umbrella, investments in medication adherence produces returns on those investments. Furthermore, current MTM activities are considered administrative costs under the Medical Loss Ratio (MLR) rules and improvements to the program via additional beneficiary services increase plan bids and premiums, potentially impacting a plan’s ability to compete in the market. One simple modification would be to reclassify MTM activities as “quality improving” under the MLR.

Additional solutions for realigning incentives should include policies that share the savings, which accrue to Medicare Parts A and B with Medicare Part D for medication-related management interventions. Additionally, quality improvement bonuses relating to medication management services provided by PDPs could be tied to outcomes that effectively streamline services and reduce costs on the medical side of the A & B ledger.

Medication Synchronization

More than two-thirds of Medicare beneficiaries are burdened with multiple chronic conditions

that require complex medication regimens. A wealth of evidence supports the theory that greater medication complexity is associated with poor medication adherence and adverse clinical outcomes. Regimen complexity is exacerbated by the need to refill multiple prescriptions at different times over the course of a month. The burden on patients to make multiple trips to the pharmacy can have negative implications for adherence and downstream clinical outcomes.

Synchronizing medication fill dates for multiple prescriptions may reduce this burden and provide a simple mechanism for improving medication adherence. Medication synchronization is a promising intervention that is growing in use in the private market. Typically, a program will synchronize all prescription fills to one day of the month for patients to pick up or to receive via mail-order. In advance of each fill, pharmacists contact the patient to remind and receive authorization for filling the medications. This process also offers an opportunity for the pharmacist to engage with patients and conduct medication reconciliation and deliver medication management services, if needed. The combination of a pre-fill reminder phone call, a single synchronized pick-up date, and option for medication counseling has the potential to significantly impact patient care.

Thrifty White Pharmacies and the Virginia Commonwealth University completed a study on the effects of refill synchronization and counseling on medication adherence and persistence among a convenience sample of patients and found that patients enrolled in medication synchronization had a 3.4 to 6.1 times greater odds of adherence to their medications than patients not enrolled. However, limitations in the available empirical evidence of the impact of medication synchronization prohibit wide-scale adoption of this potentially simple and cost effective strategy to impact patient outcomes. Now, NCPA estimates that almost 1,500 independent pharmacies have implemented a synchronization program and major retail chains nationwide are also piloting similar programs.

P4HA suggests incorporating medication synchronization as part of traditional benefits for Part D plans. Any program should be based on current commercial best practices and should require plans to carefully measure and report on the impact medication synchronization has on medication adherence and persistence, appropriate medication use, clinical outcomes, negative health events, patient experience and level of engagement, and total healthcare costs. Plans participating in the program should offer medication synchronization as an opt-in service for beneficiaries.

Conclusion

P4HA appreciates the opportunity to comment on the Finance Committee’s request for ideas that improve outcomes for Medicare patients with chronic conditions. The Partnership believes an integral part of any solutions is the use of incentives to improve medication adherence for those Medicare patients suffering with chronic conditions. New care delivery and payment models

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should create a structural framework that rewards a broad range of healthcare providers (i.e. physicians, nurses, pharmacists) and health plans that improve outcomes and lower costs. We look forward to working with you as the workgroup develops and explores new solutions that improve care for those with chronic illnesses in Medicare.

Sincerely,

Joel C. White
President
Prescriptions for a Healthy America