Prescriptions for a Healthy America

"A Partnership for Advancing Medication Adherence"

March 6, 2015

Sean Cavanaugh
Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter

VIA ELECTRONIC FILING TO: AdvanceNotice2016@cms.hhs.gov

Dear Deputy Administrator Cavanaugh:

Prescriptions for a Healthy America (P4HA) is a multi-stakeholder alliance representing patients, providers, pharmacies, pharmaceutical manufacturers, and employers. We joined together to raise awareness on the growing challenges posed by medication non-adherence, 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. To this end, P4HA is committed to the continued success of both Medicare Parts C and D and their vital impact on patient adherence to prescription medications.

Our comments on the specific aspects of the 2016 Call Letter are outlined below.

Attachment VI. 2016 Call Letter

Making the Exceptions and Appeals Processes More Accessible for Beneficiaries

We applaud CMS for its commitment to improving the Medicare Advantage (MA) and Part D appeals processes for Medicare beneficiaries, family caregivers and health care providers. It is essential to ensure that accurate decisions are made at the earliest possible stage to eliminate unnecessary delays in access to needed medications to help avoid primary nonadherence.

Beneficiaries struggle to navigate an overly onerous Part D appeals process—resulting in delays in access to needed prescription drugs, abandonment of prescribed medications, reduced adherence to treatment

protocols and higher than appropriate out-of-pocket health care costs for older adults, people with disabilities and their families.[1]

In keeping with CMS' stated goals in the draft 2016 call letter, P4HA recommends CMS establish a multi-stakeholder workgroup (including, but not limited to, Part D plan enrollees, Medicare beneficiary advocates, pharmacists, plan sponsors, pharmacy benefit managers and pharmaceutical manufacturers) to work on developing a streamlined Part D appeals process that is initiated when a request for coverage of a prescription drug is denied in whole (or in part) at the pharmacy counter. We also encourage CMS to engage in a similar dialogue with multiple stakeholders on potential improvements to the MA appeals process.

Enhancements to the 2016 Star Ratings and Beyond

CMS proposes to add Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) to the Star Ratings measures for Part D in 2016. The MTM program is an important service for Medicare Part D beneficiaries. It is intended to ensure patients are adequately educated on their prescription drug regimen and take the right drug at the right dosage and time. The proposed measure is a process measure and has been endorsed by the Pharmacy Quality Alliance (PQA) and we believe it provides a solid foundation for the assessment of CMRs. We encourage CMS to continue to advance the measures for MTM evaluation and effectiveness in order to ensure the quality of the programs and activities are truly improving health outcomes.

CMS also proposes to update and modify other Star Ratings measures specifically related to medication adherence. Specifically, CMS notes that NCQA is proposing to expand its Medication Reconciliation Post-Discharge measure to include more beneficiaries by applying it to all Medicare Advantage plans and adults. P4HA supports the inclusion of additional beneficiaries. Medication reconciliation is an important step to ensuring: (1) patients are receiving appropriate medication therapy; (2) patients understand how and why to take their medications; and (3) prescribed therapy is accurately reflected in the patients' records.

Medication Therapy Management (MTM)

The draft Call Letter states that the 2016 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2016 Call Letter. It also states that the CY 2016 guidance memo will be released about one month in advance of the 2016 MTM program submission deadline.

Targeting beneficiaries who would most benefit from MTM services is important for ensuring that these services achieve improved medication utilization and decreased medical expenditures, such as hospitalizations and emergency department visits. P4HA believes that the current MTM eligibility criteria do not sufficiently target those beneficiaries most in need of MTM services, and whose inclusion in the program would result in overall cost savings for Medicare.

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[1] Letter to MedPAC from 30+ consumer advocates and health care providers (October 10, 2014), available at: http://www.medicarerights.org/pdf/101014-medpac-part-d-appeals.pdf; Letter to MedPAC from the Medicare Rights Center (September 20, 2013), available at: http://www.medicarerights.org/pdf/092013-part-d-appeals-medpac.pdf

We believe that the current eligibility criteria results in the exclusion of many chronically ill beneficiaries who are at high risk for nonadherence of medicines and inclusion of many beneficiaries who likely do not benefit from MTM services. Evidence to date suggests that eligibility criteria for MTM participation is not well targeted to those who need services. P4HA believe CMS should better target beneficiaries at high risk for negative health events, high medical spending, or poor adherence.[2]

P4HA recommends that CMS consider explicitly testing alternative minimum MTM eligibility criteria that identify individuals at high risk for hospitalizations or other poor health outcomes. For example, beneficiaries might be targeted for MTM enrollment based on meeting any of the following criteria:

- Beneficiaries who incur significant total medical costs (as opposed to only Part D drug costs) or are in the top 10% of per-capita beneficiary spending, based on Parts A and B claims data; or
- Beneficiaries who have been admitted and then readmitted to an institutional care provider (hospital, SNF) or emergency department within one plan year; or
- Beneficiaries undergoing a transition of care from one setting to another (identified either by provider referral or CMS notification of Part D Plans); or
- Beneficiaries that have at least one specific medical condition, demonstrated by their medication regimen, which have been shown to respond positively to improved adherence (i.e. CHF, diabetes, hypertension).

In addition to the proposal above, P4HA suggests that in order to maximize the potential of the MTM program, P4HA recommends that the Center for Medicare and Medicaid Innovation consider strategies to work with Part D plans to structure controlled studies to determine which approaches to MTM are most successful in improving beneficiary outcomes. Identifying best practices would allow CMS to continue to develop clear and consistent service level expectations for the delivery of MTM benefits and would facilitate the development of performance evaluation standards that reinforce that the goal of MTM is to improve clinical outcomes and assure appropriate use of medicines.

Below are several recommendations about how to share these valuable data with researchers:

- *Link MTM Program Data to the Chronic Conditions Warehouse*

  CMS should add Part D MTM data to its Chronic Conditions Data Warehouse, authorized under Section 723 of the Medicare Modernization Act (MMA), in a form and manner that would allow MTM program data to be linked to encrypted beneficiary-level claims data for Medicare Parts A, B, and D. This linkage would allow researchers to independently evaluate MTM program outcomes and suggest improvements that could

[2] Stuart B et al. Should eligibility for medication therapy management be based on drug adherence?. J Man Care Pharm. 2014;20(1):66-75

lead to additional savings.

- *Expand Access to MTM Program Data to All Qualified Researchers*

  CMS should provide access to MTM data and all data currently available in the Chronic Conditions Warehouse for all qualified researchers from both the public and private sectors to independently evaluate MTM program outcomes and suggest improvements. The existing criteria by which CMS decides the merits of a research proposal are sufficient to determine whether a requestor should have access to research identifiable data, and should be consistently applied regardless of the researcher's institutional affiliation.

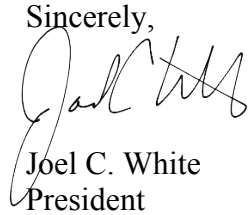
- *Include MTM Program Data in the Public Use File*

  Several of the MTM data elements collected by CMS, as outlined in the MTM Program Guidance and Submission Instructions, were not released as part of the Public Use File (PUF) last August. To the extent that additional accurate and reliable MTM program data is available, we urge CMS to include these data in future PUF releases.

Conclusion

Prescriptions for a Healthy America appreciates the opportunity to comment on the 2016 Call Letter and look forward to working with you to ensure seniors and the disabled are more adherence to their medications.

Sincerely,



Joel C. White
President
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