



January 11, 2018

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8013

Re: **CMS-4182-P**

To Whom It May Concern,

The UAW Retiree Medical Benefits Trust (the "Trust") welcomes this opportunity to provide some feedback to the Centers for Medicare and Medicaid Services on its proposed rules in publication **CMS-4182-P**. We believe the proposals contain a number of provisions that could improve the Part C and D programs, as well as a few proposals that raise additional considerations.

Background on the Trust

The Trust is a Voluntary Employees' Beneficiary Association (VEBA) covering 680,000 UAW retirees and their dependents nationwide. About 78% of the Trust's population is covered by Medicare. For those enrollees in Medicare, the Trust offers through selected carriers a nationwide Part D plan, a nationwide MA PPO plan, and several local MA HMO plans. Each of these is considered an Employer/Union Group Waiver Plan (EGWP). The Trust's standalone Part D EGWP has 512,099 members. The Trust's MA membership was over 188,000 as of December 1, 2017.

Substitution of New-to-Market Generics Mid-year

The Trust supports the proposed changes to allow Part D plans to introduce new-to-market generic alternatives mid-year without advance notice to individual beneficiaries. Generic drugs provide new alternatives for therapy for beneficiaries, and at a lower price for purchasers, such as Medicare and the Trust, and a lower cost to the beneficiaries.

The Trust urges CMS to allow similar substitution in the case of a new-to-market biosimilar, or at least for an interchangeable follow-on biologic. These follow-on biologics offer the same opportunity for significant savings for purchasers.

The Trust would also like to take this opportunity to suggest that CMS consider other mid-year changes to be appropriate when implementing that change would prevent fraud, waste, and abuse. The Trust has been able to make such changes for its non-Medicare drug plans with desirable impacts. In cases of fraud, waste, or abuse by beneficiaries, prescribers, pharmacies, or even drug manufacturers, the ability to make mid-year changes quickly is crucial to the ability of Medicare and Part D plans to reduce unnecessary costs.

Follow-on Biologics for Low-Income Subsidy Recipients and for non-LIS Beneficiaries in Catastrophic Coverage

The Trust supports the proposal to consider follow-on biologics "generics" for the purposes of LIS beneficiaries and for non-LIS beneficiaries above the Catastrophic Coverage level. However, the

Trust also urges CMS to go a step further in clarifying the status of follow-on biologics in the coverage gap. The Trust (along with many others) have recently urged that follow-on biologics be considered “applicable drugs” in the coverage gap. Doing so would be compatible with the proposed definition of “generic drug,” which does not include follow-on biologics for all purposes of the word (as it would be “an applicable drug” in the coverage gap context).

Implementation of CARA “Lock-in” Procedures

The Trust welcomes the proposed rules for Part D to implement the Comprehensive Addiction and Recovery Act’s (CARA) provisions allowing plans to “lock” an enrollee into a particular pharmacy or prescriber. The Trust has used a similar strategy to great effect with its non-Medicare population and, it would be very helpful to have that tool available to the Trust’s Medicare population as well, as part of a comprehensive strategy to address this issue and aid the Trust’s enrollees who are seeking treatment for addiction.

The Trust seeks clarification on parts of the application of the rules to EGWPs. The Trust provides the drug plan for its enrollees prior to becoming Medicare eligible and then through an EGWP once they enter Medicare. For some of these enrollees, the Trust will have already engaged some manner of lock-in provision, and the enrollee will be on their way to recovery from addiction. As the enrollee transitions to the Part D plan, the Trust wants to be able to continue the success with that enrollee, either through adopting the same lock-in (which would be consistent for the enrollee) or by considering the prior lock-in as part of a new determination.

Changes for Manufacturer Rebates and Pharmacy Price Concessions at Point-of-Sale

CMS has called for comments from EGWP about the discussed changes to manufacturer rebates and pharmacy price concessions. As the (in ERISA terms) sponsor of a large Part D EGWP, the Trust wants to respond to this call. However, due to the complexity of described changes, the Trust is uncertain about the impact at this time. The Trust urges CMS to delay any ultimate implementation of changes until further analysis by both CMS and by relevant stakeholders can be completed. The Trust urges CMS to conduct an analysis of the impact of the rebate and price concession changes it is contemplating on the trends that CMS has noted, and an analysis of the impact on beneficiaries as a result of moving through the coverage phases more slowly.

Introduction of the Preclusion List

The Trust is generally supportive of the introduction and proposed use of the “preclusion list” in MA and Part D. The Trust appreciates that CMS plans to retain the provisional period as part of the restrictions on prescribers appearing on the preclusion list, as it will ensure that the beneficiaries have access to needed medications. In implementing the preclusion list, the beneficiary should be held harmless (unless they too have committed some manner of fraud).

Because of concerns for the beneficiaries, the Trust has a few suggestions on certain parts of the proposed preclusion list rules. First, in reinstituting the requirement for a valid NPI on drug claims, the Trust requests that CMS ensure that the beneficiary is not held responsible for the price of the drug in the event of an invalid NPI.

Second, in implementing the preclusion list in MA, CMS has proposed to remove the requirement that MA plans ensure that all providers of services covered under Parts A and B of Medicare be enrolled with Medicare as a provider. This requirement is not mutually exclusive with the preclusion list, however. The Trust is supportive of the prohibition against covering any provider claims coming from

providers on the preclusion list. Yet, the Trust is concerned that removal of the provider enrollment requirement from MA creates the opportunity for beneficiary disruption. In several different circumstances, an MA enrollee is able to disenroll from the MA plan back to Original Medicare. With the provider enrollment requirement, the beneficiary would not experience any loss of continuity of care from that change for covered A and B services. However, without that requirement, disruption would be now possible for any beneficiary moving from MA to Original Medicare.

“Marketing” Definition Change

The Trust supports the proposed change to the definition of “marketing” and the introduction of “communication” as the overarching category. This change is logical and aligns “marketing” closer to its lay sense.

Increased Flexibility in Plan Design for Medicare Advantage

The Trust supports the proposed increased flexibility through CMS’ re-interpretation of the uniformity of benefit provisions for Medicare Advantage plans. The Trust appreciates the potential opportunities in working with its MA carrier partners in developing benefit plan options for those with common chronic medical conditions.

Definitions of “retail pharmacy” and “mail order pharmacy”

In the proposed rules relating to the “any willing pharmacy” requirements under Part D, CMS introduces an amended definition of “retail pharmacy” and a new definition of “mail order pharmacy” in order to address the situation where a traditional retail pharmacy begins to offer drugs through mail order delivery. The Trust has a concern with these definitions as we do not believe that they achieve their purpose. These definitions would apply to all the different aspects of a Part D plan, including determination of the appropriate cost-sharing for a given supplier. By relying on the assigned cost-sharing for a particular pharmacy in determining its type in the definition, plans are left in a logical circle about which cost-sharing to assign. The Trust urges CMS to adopt different definitions that do not depend on the cost-sharing attached to the pharmacy.

On the topic of retail pharmacies engaging in mail order delivery, the Trust has concerns about the situation of a retail pharmacy filling prescriptions that cross state lines. The Trust has encountered fraudulent claims in situations where beneficiaries received prescriptions by mail that they never requested from a pharmacy in another state and from a provider in yet another state.

Conclusion

The Trust appreciates the opportunity to comment on the proposed rule. Overall, the Trust is supportive of what CMS has proposed. The Trust is eager to have new formulary tools and at-risk beneficiary management tools. The Trust is also eager to consider what kinds of innovative plan designs might be possible for particular medical conditions in its Medicare population.

Sincerely,



Francine Parker
Executive Director
UAW Retiree Medical Benefits Trust