March 7, 2014

Submitted electronically via http://www.regulations.gov

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-4159-P: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Sir or Madam:

I write on behalf of the American Benefits Council ("Council") to provide comment on the proposed rules ("Proposed Rules") revising the Medicare Advantage ("MA") program ("Part C") and prescription drug benefit program ("Part D") regulations. The Proposed Rules were published in the Federal Register on January 10, 2013, by the Centers for Medicare and Medicaid Services ("CMS").

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to health and retirement plans that cover more than 100 million Americans. Many Council member companies sponsor retiree health benefits that rely on Medicare Advantage and Part D Prescription Drug Plans to provide affordable, high quality prescription drug coverage to retirees.

The Proposed Rules propose to implement changes to the Part C and Part D regulations to implement statutory requirements, strengthen beneficiary protections, exclude plans that perform poorly, improve program efficiencies, clarify program requirements, and improve payment accuracy.

We appreciate the opportunity to comment on the Proposed Rules. As discussed in greater detail below, we are concerned about the potential for the Proposed Rules to reduce choice and impose higher costs that ultimately would be borne by employers who provide retiree coverage and beneficiaries.

TIMELY ACCESS TO MAIL ORDER SERVICES

The Proposed Rules would establish fulfillment requirements for mail order services of three business days from receipt to shipment for prescriptions filled without requiring "additional review" and five business days for prescriptions requiring additional review before shipment. CMS indicates in the preamble that clarifying illegible orders, resolving third party rejections, and coordinating with multiple providers may qualify for the five business day fulfillment requirement. However, the proposed change at Section 423.120(a)(3) of the Part D regulations does not identify any circumstances that could qualify as needing additional review and affording mail service pharmacies five business days to fulfill the prescription. Moreover, CMS acknowledges in the preamble that some prescription orders may require clarification or additional steps to be taken that will extend beyond the five business day requirement, but the Proposed Rules make no provision for such contingencies.

The Council is concerned that proposed Section 423.120(a)(3) is too restrictive and jeopardizes the continued availability under Part D of cost-effective mail order benefits. Mail order pharmacies offer seniors the convenience of home delivery as well as lower cost-sharing. Mail order services also provide access to lower drug costs, which benefit both the Medicare program and plan sponsors of retiree benefits. We encourage CMS to expand the fulfillment requirements, given that CMS points out in the preamble that the industry standard for mail service deliveries ranges from seven to ten business days.

In considering whether to finalize fulfillment requirements for mail order services, we urge CMS to consider current industry standards as well as to allow for circumstances that are outside of the pharmacy's control. Such circumstances include, but are not limited to, drug shortages, problems with members' credit cards, and prior authorization requirements.

DRUG CATEGORIES OR CLASSES OF CLINICAL CONCERN AND EXCEPTIONS

The Council supports the proposed exceptions that will lift some restrictions on the protected class drugs that must be covered by Part D sponsors. We believe the proposed changes to sections 423.120(b)(2)(v) and (vi) of the Part D regulations strike an appropriate balance between protecting Medicare beneficiaries while allowing Part D sponsors more power to negotiate discounts and compete more effectively. The

Proposed Rules achieve this balance through a thoughtful analysis of existing Part D beneficiary protections and the clinical benefits, if any, achieved under the existing requirements on protected class drugs. We agree with CMS that requiring open coverage of certain categories and classes of drugs presents both financial disadvantages and patient welfare concerns for Part D as a result of increased drug prices and overutilization.

MEDICARE COVERAGE GAP DISCOUNT PROGRAM AND EMPLOYER GROUP WAIVER PLANS

The Council supports initiatives that increase transparency in cost and pricing, and therefore is supportive of the proposed change that would require Part D sponsors to disclose to employer group waiver plan ("EGWP") sponsors the projected and actual manufacturer discount payments attributable to the EGWP's enrollees under the Medicare Coverage Gap Discount Program ("Discount Program"). However, we are concerned about the potential consequences of this new reporting requirement in terms of higher premiums for EGWPs as Part D sponsors pass the increased administrative costs associated with this new reporting requirement on to EGWPs.

We also acknowledge the proposed change at Section 423.2325(h) of the Part D regulations, which would eliminate ambiguity and clarify that the discount calculation under the Discount Program will be based upon the Part D Defined Standard benefit for all EGWPs beginning in 2014. The Council notes that there has been much confusion regarding the application of discounts under the Discount Program to EGWPs since CMS issued the final rule in 2012, and the proposed change provides helpful clarification with regard to the issue.[1]

PAYMENTS TO PDP SPONSORS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE AND PAYMENTS TO RETIREE PRESCRIPTION DRUG PLANS

CMS proposes to revise the definition of "actually paid" for Part D as well as for the Retiree Drug Subsidy ("RDS") program in order to reconcile the definition with proposed changes to the definition of "negotiated prices" in the Proposed Rules. We note that CMS previously sought comments on whether to adopt the same definition of "actually paid" for the RDS program as it adopted for Part D in the final rule published on January 12, 2009.[2] CMS invited public comment on three theories that could support

[1] 77 Fed. Reg. 22,072 (Apr. 12, 2012).

[2] 74 Fed. Reg. 1494 (Jan. 12, 2009).

CMS having and exercising the discretion to adopt a different policy for RDS than for the Part D program with respect to the way drug costs must be reported and therefore not require pass-through pricing for the RDS program.

Although there is no mention of requiring pass-through pricing for the RDS program, we are concerned that the proposed change would impose such a requirement on the RDS program. Such a change is neither warranted nor required. Although included in the Part D statute, the RDS program has a unique statutory structure that makes clear that Congress did not intend to require identical treatment of qualified retiree prescription drug plans and Part D plans. To do so would thwart Congress' intent in creating the RDS program – to encourage employers to continue their retiree prescription drug plans. In fact, CMS has acknowledged that the Part D and RDS programs are "mutually exclusive."[3] Moreover, key reasons cited by CMS for requiring Part D plans to report pass-through prices (e.g., to avoid advancing Medicare beneficiaries through the Part D benefit phases more quickly, and to contain increases in low income subsidy payments by the Government) have no applicability to the RDS program. Finally, because retiree plans do not have specific responsibility for negotiating prices or establishing pharmacy networks, pharmacy discounts obtained and retained by plans' pharmacy benefit managers ("PBMs") are not appropriately defined as administrative costs of the retiree plans, particularly where in many cases the retiree plan may have bargained for an arrangement that locks in prices at a guaranteed level. Under such arrangements, the PBM, while it may retain any positive differential between the pass-through and the lock-in price, is also responsible for any negative differential between the pass-through and the lock-in price.

We urge CMS not to finalize the proposed change to "actually paid" in order to reconcile definitions of negotiated prices under the Part D and RDS programs. CMS previously sought comments on whether to adopt the same definition for both programs and, based on filed comments, did not adopt the same definition for the RDS program. Nothing has changed since then that would warrant changing the RDS program definition now.

ANY WILLING PHARMACY

We are concerned by the Proposed Rules' proposed change that would require Part D sponsors to offer preferred pharmacy status to any willing pharmacy. Such a change would eliminate Part D sponsors' ability to bargain for favorable negotiated prices with

[3] *See* 74 Fed. Reg. at 1518.

pharmacies in exchange for the increased patient volume that preferred pharmacies expect. This will in turn result in higher drug costs for Part D sponsors and therefore higher costs for the Medicare program as well as for beneficiaries.

The proposed change would also increase Part D sponsors' administrative costs as it would require sponsors to develop standard terms and conditions for network participation that list all combinations of cost sharing and negotiated prices possible for retail settings under the plan. It also represents an unnecessary and unwarranted interference into negotiations between Part D plan sponsors and pharmacies. As such, the proposed change is a complete reversal of CMS' prior position on preferred pharmacies as expressed in the preamble to the 2005 Part D final rule:

> Ultimately, however, it is at Part D plans' discretion how they will establish pharmacy networks—including the offering of contracting terms and conditions that are different than standard contracting terms and conditions and the establishment of preferred pharmacies provided they meet our pharmacy access standards, non-discrimination provisions, and other applicable requirements under Part D.

70 Fed. Reg. 4194, 4250 (Jan. 28, 2005). Similarly, CMS stated:

> We believe that our policy of permitting cost-sharing discounts for preferred pharmacies, as codified in § 423.120(a)(9), strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs.

70 Fed. Reg. at 4254.

A recent study of Part D preferred pharmacy networks showed that, on average, Part D plans with preferred networks have lower premiums than those without preferred networks, and have similar Star Ratings as Part D plans without preferred networks.[4] Thus, preferred pharmacy networks produce real cost savings for Part D sponsors, the Medicare program, and beneficiaries, and provide the same quality service as non-preferred pharmacy networks. The Proposed Rules' changes would have the effect of eliminating preferred pharmacy networks and the cost savings they produce.

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[4] AvalereHealth, "2014 Premiums and State Ratings for Medicare Part D Prescription Drug Plans with Preferred Pharmacy Networks", December 2013.

PREFERRED COST SHARING

The Council is concerned by the Proposed Rules' proposed restrictions on the use of preferred networks and cost sharing would limit the flexibility and potential savings Part D sponsors' could bargain for when seeking favorable negotiated prices with pharmacies in exchange for the increased patient volume that preferred pharmacies expect.

The Proposed Rule's proposed requirement that Part D sponsors must offer beneficiaries and the Part D program lower negotiated costs on *all* drugs in return for lower cost sharing. The Proposed Rule also indicates that CMS is considering the imposition of a required minimum level of savings over the costs available at retail cost-sharing rates and limitations on how broadly cost sharing should be applied to a Part D sponsor's formulary. These changes would constrain Part D sponsors' bargaining and may result in lower savings for Part D sponsors and, therefore, higher drug costs for Part D sponsors and therefore higher costs for the Medicare program as well as for beneficiaries.

Under the current regulatory scheme, a Part D sponsor's ability to reduce cost sharing is contingent upon one condition, "In no case shall such a reduction result in an increase in payments made by the Secretary under Section 1860D-15 of the Act to a plan."[5] The Proposed Rules indicate that CMS "implied [in the original Part D proposed rulemaking] that any assessment of whether the condition was met would be a matter of actuarial equivalence analysis."[6] Rather than clarifying the statutory requirement and prior regulation, the Proposed Rules' proposed changes represent a departure from established practice.

Additionally, the Proposed Rule's proposed changed to preferred cost sharing would increase Part D sponsors' administrative costs because they would require sponsors to develop new and limited combinations of cost sharing and negotiated prices possible for retail settings under the plan. It also represents an unnecessary and unwarranted interference into negotiations between Part D plan sponsors and pharmacies.

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[5] 42 U.S.C. § 1395w-104(b)(1)(B).

[6] 79 Fed. Reg. 1918, 1975 (Jan. 10, 2014).

Thank you for considering these comments submitted in response to the Proposed Rules issued with regard to the Medicare Advantage and Medicare Prescription Drug Benefit programs.

If you have any questions or would like to discuss these comments further, please contact me at (202) 289-6700.

Sincerely,

Kathryn Wilber
Senior Counsel, Health Policy