SNP Alliance

The National Voice for Special Needs and Medicare-Medicaid Plans

A National Nonprofit Leadership Organization

Submitted via Federal e-Rule making Portal: http://www.regulations.gov

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Office of Inspector General
Department of Health and Human Services
Cohen Building, Rm 5527
330 Independence Ave, SW
Washington, D.C. 20201

Attention: OIG-0936-P

42 CFR Part 1001
RIN 0936-AA08

RE: Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefits Manager Service Fees

The SNP Alliance is grateful for the opportunity to provide comment to the U.S. Department of Health and Human Services Office of Inspector General regarding the proposed rule on revising the safe harbors to the federal anti-kickback statute for prescription drug rebates. We share the Administration's concern for rising drug costs and the impact of out-of-pocket expenses for consumers.

The SNP Alliance is a national, non-profit leadership association addressing the needs of high-risk and high-cost populations through specialized managed care. We represent over 390 special needs plans (SNPs) and Medicare-Medicaid demonstration plans (MMPs), with over 1.9 million enrolled members. Our primary goals are to improve the quality of services and care outcomes for the populations served, and to advance integration for those dually eligible for Medicare and Medicaid.

We do have considerable concerns regarding this proposed rule and oppose it as it is currently written. Our comments reflect not only our own reading of this proposed rule, but extensive discussion and input from our member health plans, aligned stakeholder and policy organizations, and consumer groups. Foremost, we believe the Proposed Rule is not only unlikely to achieve the policy objective that we share with HHS – to lower drug prices – and instead is likely to both increase costs and undermine the Administration's and states' goals of value-based care and integration for high-risk, high-cost Medicare beneficiaries. Our specific concerns can be summarized as follows:

- Increased cost for consumers in the form of both higher Part D premiums and higher net out-of-pocket costs, with few beneficiaries receiving meaningful out-of-pocket cost reductions from point-of-sale rebates;
- Negative impact to States' Medicaid managed care programs and Medicare-Medicaid integration initiatives, which will likely result in States carving-out Medicaid pharmacy benefits from comprehensive managed care programs, which would result in a LESS integrated environment for high-cost, high-risk and often vulnerable populations, including those dually eligible;
- The increase in over-all premium price resulting in health plans in low-premium or zero premium markets needing to "buy-down" premium costs, thus shifting rebate dollars away from additional supplemental benefits that are used to meet the needs of enrolled members;
- Unrealistic timeline of Jan 1, 2020 for implementation, given that comments are due April 8, Part D bids are due to CMS June 3 and most states will begin their fiscal years (and implement major changes to their managed care and Duals programs) July 1, 2019; and
- Unrealistic assumptions about drug manufacturer behavior in response to this proposed rule, and virtually no impact on over-all escalating drug pricing, which is driven by specialty drugs that often have neither competition nor negotiated rebates.

<u>Increased cost to consumers</u>

The Proposed Rule is based upon HHS' assumption that rebates have an inflationary influence on drug list prices and that these proposed revisions to the federal anti-kickback statute's safe harbors would cause prices to decrease by effectively eliminating rebates in their current form. Only one of the seven scenarios conducted by Milliman predicts manufacturers would reduce price. By the Centers for Medicare & Medicaid Services Office of the Actuary's (OACT's) own acknowledgement, Medicare premiums could go up by as much as 25 percent for millions of older adults and persons living with disabilities. While all beneficiaries would see higher premiums under the Proposed Rule, only some would see lower costs at the pharmacy counter. OACT estimates the Proposed Rule would fail to provide net out-of-pocket savings for the majority of Part D beneficiaries because most drugs prescribed in Medicare Part D *do not have rebates*.

Absent behavioral changes by manufacturers, Medicare beneficiary savings would primarily flow to a smaller group of beneficiaries taking expensive, brand-name drugs that currently have significant competition and rebates – and for which potentially more affordable, but less-rebateable drug therapy options are available. Furthermore, as noted by one of the SNP Alliance health plan members, "the most expensive drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for those brand drugs with rebates." SCAN Health Plan did an internal analysis which showed that only 1% of their members would benefit from reduced costs at POS, and only 8% would indirectly benefit by slowing their progression through Part D Benefit phases.

<u>Impact to Medicaid and Medicare-Medicaid integration</u>

The Proposed Rule makes no mention of an assessment of the impact of the proposed revisions to the discount safe harbors on states' pursuit of Medicaid comprehensive managed care or integration

initiatives for Medicare-Medicaid enrollees ("dual eligibles"), including, and especially, those involving Dual Eligible SNPs (D-SNPs). While preliminary costs to states are calculated within the OACT estimate, the direct impact to state policymaking and priorities is not addressed; nor are the regulatory interplays or consequences for Medicare-Medicaid integration.

HHS acknowledges the Proposed Rule would not generate savings for Medicaid enrollees who already have zero to nominal out-of-pocket cost sharing for their prescription drugs, which make the implications of the new safe harbor for point-of-sale (POS) "drug discounts" unclear within the context of Medicaid. A central objective in proposing the rule — to reduce out-of-pocket costs — is not applicable to Medicaid. If Medicaid Managed Care is included in the Final Rule, we are concerned drug companies may be reluctant to offer rebates to Medicaid plans, driving up costs for the Federal government and the States. CMS's own actuaries estimate the Proposed Rule would increase Medicaid costs by $2 billion. Given the uneven playing field created between fee-for-service Medicaid and Medicaid Managed Care, as well as PACE and Duals Demonstration initiatives, States may be incented to move to reevaluate the inclusion of Medicaid pharmacy benefits in their comprehensive managed care and duals integration initiatives, which for some states is essential to pursuing comprehensive care coordination in their Medicaid programs. For complex care and chronically ill dually-eligible individuals, this will create confusion and create barriers to advancing integration, resulting in worse health outcomes and higher costs for the Federal government and the States, primarily through higher Medicare costs.

<u>Impact to smaller non-profit health plans and potential decrease to benefits for Medicare beneficiaries with significant costs and needs</u>

For many smaller non-profit health plans, including those special needs and Medicare-Medicaid integration plans (MMPs) serving Medicare beneficiaries with complex needs, chronic conditions, and high costs, the drug rebates negotiated are used to reduce beneficiary premiums or to enhance benefits. And in markets with low or zero premiums, these rebates also are used to offer members zero- or reduced premium Part D plan product and competitive prescription benefits. D-SNPs, in particular, use rebate dollars to reduce their part D premiums in order to reach the Part D Low Income Subsidy (LIS) Benchmark and offer LIS eligibles a zero-premium product. As Medicare Part D premiums rise by as much as 25 percent, if a D-SNP or MMP has a Part D premium in excess of this benchmark amount, it will undermine its program because its members would need to pay a Part D premium. Compounded with no retained rebate dollars for these payers to apply to premiums, supplemental benefits for underserved dual eligibles served by D-SNPs and MMPs may be negatively impacted, as would the Administration's and States' collective efforts to enhance alignment, further integration, improve care and lower taxpayer costs for those dually eligible.

<u>Unrealistic time-line</u>

We are concerned by a number of critical timing and operational issues, including the interaction with the looming June 3, 2019 Part D bid submission deadline for calendar year (CY) 2020 and states' varying fiscal year calendars, and believe the proposed Jan. 1, 2020 timeline is unworkable. It is questionable whether the OIG can finalize this rule in advance of the Part D bid deadline of June 3. Even if it can be

finalized, plans will not have the time to ascertain with sufficient reliability the effect on their bids. As such, the stability and reliability of the program during CY 2020 will be seriously undermined. It is likely that CMS would be forced to allow for re-submission of the bids, which would delay the release of needed information in advance of finalizing the bids, notifying the public of low-income benchmark plans, ensuring relevant and clear member marketing and communications materials (including evidence of coverage), and options for the upcoming Annual Enrollment Period.

Further, the Proposed Rule does not include reference or consideration of the roles of CMS and States in managing, regulating and overseeing Medicare Part D and Medicaid managed care, respectively, or their shared role in managing, regulating and overseeing the Duals Demonstrations, including the MMPs and aligned Medicaid MCO/D-SNP plans. The Proposed Rule also does not accompany rulemaking by CMS on a host of open and unanswered regulatory questions, including related to Medicare benefit design parameters, LIS calculation, beneficiary access and rights, the Star Ratings program, data reporting, beneficiary marketing and communications, reconciliation, administrative burden, and interaction with other programs—as has been the case for other significant policy and programmatic changes. For example, how are POS rebates to be explained in the evidence of coverage for D-SNP members, which are dual eligibles and thusly have no required cost sharing. The potential for beneficiary confusion and dissatisfaction, particularly given the net increase in out-of-pocket costs, also is not discussed. This issue would be compounded by the increased in the true out-of-pocket cost threshold for certain SNP members, and may undermine the significant beneficiary satisfaction the Medicare program has enjoyed under this Administration.

<u>No significant impact to over-all drug prices</u>

Despite all the related chaos and confusion to the implementation of this Proposed Rule, there will be little impact to overall drug prices and costs will continue to rise. As noted above, the majority of drugs with the greatest expense are not impacted by rebates, and thus will not see beneficiary out-of-pocket cost reductions under the Proposed Rule. According to the OACT estimates, even if drug manufacturers apply 85 percent of current drug rebate levels to lower drug prices, cost increases over the next 10 years will STILL include $58 billion in additional premiums; $197 billion in additional taxpayer costs; and an additional $137 billion in national drug spending. Therefore, the ostensible objectives for the proposal will not be achieved.

Further, removing rebates in their current form creates neither a mechanism nor assurances that lower list prices would follow. Drug manufacturers alone set and change the list prices for their products. The analyses in the Proposed Rule presume manufacturers *do not* meaningfully change their pricing strategies to match the Administration's stated goals. OACT assumes price reductions would not occur significantly, instead predicting the Proposed Rule would provide manufacturers the opportunity to *increase* their prices and provide *fewer* price concessions. Though not based on the output of any modeling, OACT further assumes manufacturers will moderate future product price growth; should that assumption not materialize in practice, the actuary's sizable estimates of increased beneficiary and taxpayer costs would be significantly higher.

Summary

The SNP Alliance desires to work with the Administration and Congress to achieve our shared goals of lowering drug prices and reducing out-of-pocket costs, reform the current drug rebate system, and to address the escalating cost of medications which seriously impacts many of the people served by our member health plans. We oppose the Proposed Rule in its current form and recommend it be withdrawn in full and HHS work with healthcare stakeholders and thought leaders on alternatives to lower drug prices and reduce out-of-pocket costs.

If the rule is not withdrawn, however, at a minimum, we recommend HHS consider the following be addressed in any Final Rule:

- Exclude Medicaid and to permit Part D plans and pharmacy benefit managers acting on their behalf to administer the new model;
- Delay implementation until, at least, January 2021 and, if Medicaid is not excluded from the rule, HHS should explore options – via existing waiver processes – outside of the Anti-kickback safe harbor that may allow states to choose whether to adopt the new model or keep its existing system. If adopting the new model, CMS could issue guidance to states that choose to "opt in" to permit states to implement in line with their next earliest fiscal year start (e.g., July 1, 2021); and
- Retain the existing safe harbor for rebates but narrow it to prohibit rebates calculated as a percentage of a drug's list price (i.e., so as to continue to allow rebates that facilitate fixed-prices for drugs).

Thank you for this opportunity to comment. We remain committed to working with the Administration to better serve vulnerable, high-risk and high-cost beneficiaries, and look forward to future opportunities to work with HHS to achieve this goal.

Respectfully submitted;

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