April 8, 2019

The Honorable Alex Azar
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Daniel R. Levinson
Inspector General, Department of Health and Human Services
Room 5527, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Re: OIG-0936-P

Submitted Electronically via www.regulations.gov

Dear Secretary Azar and Inspector Levinson:

I am writing on behalf of the National Association of Health Underwriters (NAHU), a professional association representing more than 100,000 licensed health insurance agents, brokers, general agents, consultants and employee benefits specialists. We are pleased to have the opportunity to provide comments in response to your proposed rule titled "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 Benefit Manager Service Fees," (OIG-0936-P) published in the *Federal Register* on February 6, 2019.

The members of NAHU work daily to help millions of individuals and employers of all sizes purchase, administer and utilize health insurance coverage. Our expertise lies in the technicalities of health-plan purchasing and administration, and the real-world challenges plan sponsors and individual beneficiaries face when buying and then utilizing their health insurance benefits, including their prescription drug coverage. Our members include thousands of agents who specialize in the private Medicare marketplace and serve individual Medicare beneficiaries directly. Thousands more work with employer-sponsored plans that cover Medicare Advantage beneficiaries through employer group waiver plans. However, all of our members and all of their clients struggle with high medical care costs and the high cost of prescription drugs, as well as their direct consequence – rising health insurance premiums. While this proposed rule does not directly affect the private market beyond the Medicare sphere, the assumption is that it will indirectly impact prescription drug costs for all Americans. It is from this perspective that we offer you the following comments on the proposed rule.

NAHU members appreciate the Administration's bold initiative to lower the cost of prescription drugs, particularly at the point of sale for Medicare beneficiaries. High prescription cost-sharing rates have a significant impact on the budgets of many seniors, particularly those who take a large number of prescription medications and those who need access to high-cost and specialty drugs. The enormous expense of these medications can lead to prescription-drug-adherence issues amongst the Medicare population, which then impacts both beneficiary health and wellness and long-term Medicare claim costs. We recognize the value in the goals behind this proposal, which would eliminate the current broad safe harbor for prescription drug rebates and replace it with two new and targeted safe harbors focusing on providing rebate savings during certain point-of-sale purchases and also for pharmacy benefit manager (PBM) service fees. The important priorities behind this proposed rule include reducing out-of-pocket costs for seniors, lowering private Medicare plan premiums and reducing federal Medicare spending, and these are all goals NAHU members share. However, as with any significant policy change, practical concerns arise, including the following issues that NAHU members would like to raise for your consideration as you move forward.

The Potential for Premium Increases and Reduction of Supplemental Benefits

While changing the current rebate structure for Medicare Advantage and Medicare Part D issuers to a point-of-sale delivery mechanism will lower beneficiaries direct costs at the pharmacy, NAHU members are concerned that the rule does not adequately address the problem of corresponding potential increases to plan premiums and the potential loss of significant supplemental Medicare Advantage plan benefits. Eliminating rebate payments in Medicare Part D could lead to cost adjustments by manufacturers and PBMs, resulting in Part D and Medicare Advantage insurers no longer receiving their current rebate revenue stream. Issuers currently use at least a portion of their manufacturer rebates to offset plan premiums, and there is already market-based evidence that if that changes, monthly costs for plan participants would rise. For example, our members report that in 2019 Silverscript offered a stand-alone Part D plan in certain markets known as the Allure Plan that passes rebates onto the customer at the point of sale. Premiums are quite high, however, and hover around $80 a month. While the cost of the beneficiary's drugs are less expensive, particularly if the customer has many prescriptions or takes high-cost drugs, the overall plan premiums are much steeper than market alternatives.

For Medicare Advantage prescription drug plans (MA-PD plans), rebate funds paid to health insurance issuers are also used to provide beneficial supplemental benefits like dental, vision and hearing coverage, nutritional assistance and in-home care options. According to a recent analysis by Avalere Health, on average, $0-premium MA-PD plans would experience a 28% reduction in resources available to finance supplemental benefits. Such a reduction could translate to an average annual $228 decrease in funding available per beneficiary for these plans to provide additional services. NAHU members know that consumers value and derive great health benefits from the supplemental services MA-PD plans currently offer, and that these benefits are particularly attractive and helpful to some of Medicare's most

vulnerable beneficiaries. Over the past two years, the Trump Administration has done much to encourage Medicare Advantage plan innovation and benefit improvements, particularly those designed to improve outcomes for high-risk individuals. Accordingly, as you work to finalize this proposal, NAHU asks that you also work to find a balance so that seniors do not save costs in one crucial area only to face increased charges and benefit reductions in other equally important areas.

Impact on Medicare Advantage Employer Group Waiver Plans

NAHU members also request that the Administration consider the potential impact of the proposed rule on the approximately 4.3 million Medicare Advantage beneficiaries who enroll in their coverage through an employer group waiver plan (EGWP). We are particularly concerned about those enrolled via employer group plans that self-fund these benefits. Self-funded EGWPs routinely use the rebate funds they receive following participant drug purchases to later offset the premium costs of the coverage they provide to these Medicare beneficiaries. The proposed rule would require point-of-sale rebates for these self-funded employer-sponsored plans too. Our concern is that EGWP sponsors will take one of two courses of action if this proposal, as drafted, applies to their plans beginning on January 1, 2020. One would be to discontinue the EGWP offering due to the increased compliance and cost burden; the other would be to raise premiums for all enrollees by the amount received in rebates. Neither of these two options would be a good outcome for the millions of Americans happily covered under EGWPs.

Timing and Marketplace Stability

The proposed timeline of this regulation and its potential impact on market stability also gives NAHU members some concern. Currently, the proposed rule is slated to take effect on January 1, 2020, and would impact plans now in the pipeline for filing and approval for marketing to seniors during the annual election period (AEP) from October 15 to December 7, 2019. The Administration did recently provide some guidance to health insurance issuers about how they should address potential changes to the rebate structure in their 2019 plan bids. It announced an optional reinsurance demonstration project for 2020 and 2021 and directed issuers to follow the requirements outlined as per the Anti-Kickback Statute and safe harbors that are in place at the time of the submission timeline. However, NAHU members are concerned that this guidance may not provide for enough of a transition period and that January 1, 2020, is too soon for full implementation. We believe that forcing implementation for the upcoming plan year will have an unnecessarily detrimental impact on available plan options and rates for 2020. As the Administration itself notes on page 77 of the proposed rule, it "is difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response" and, on page 110, that will be "difficult to predict manufacturer and Part D plan behavior in response to this regulation." We are concerned that by forcing plan issuers to adapt to the principles outlined in what is just a proposed rule while they are in the middle of preparing their products and pricing for the year ahead, the response of Part D plans could be even higher rates for 2019 that might otherwise be necessary along with corresponding market uncertainty. As a result, NAHU recommends that, when finalizing this proposal, the Administration should consider delaying implementation until January 1,

2021, to give time for all stakeholders to make all necessary adjustments and accommodations during the product development period, not after the fact.

The potential legal uncertainty of this rule, as drafted, is another reason why NAHU suggests that the Administration consider delaying implementation until at least January 1, 2021, as well as revisiting issues with affected stakeholders during the finalization process. NAHU is aware that many stakeholders feel that in addition to the regulatory safe harbors that accommodate for the current prescription drug rebate structure with MA-PD and Part D plans, the statutory exception to the Anti-Kickback law provided in 42 USC § 1320(b)(3) is a relevant issue. This exception protects "a discount or other reduction in price obtained by a provider of services or other entity under a federal healthcare program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a federal healthcare program." While NAHU understands and does not necessarily dispute the Administration's contention outlined on page four of the proposed rule that this exception does not apply to the prescription drug rebates as currently offered in the MA-PD and Part D marketplace, we anticipate that other entities may not agree and thus this rule may be challenged. Other recent health-policy regulations tested in federal court have resulted in marketplace disruption and uncertainty for all stakeholders. The ones most gravely affected by the instability caused by a challenged regulation are the health insurance consumers who have purchased products affected by the contested rule. Since our members are currently addressing such fallout with consumers who have been affected by other recent regulations that are in the process of being challenged, NAHU would like to avoid a similar fate for MA-PD and Part D beneficiaries. While there is no way to prevent a substantive regulatory challenge definitively, NAHU hopes that the Administration will give serious weight to the negative impact a challenged rule has on consumers and the overall marketplace and make every attempt to avoid that fate for this particular proposal.

Providing Greater Price Transparency and Accountability

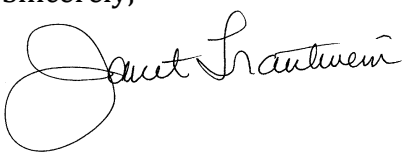
While NAHU strongly advocates a delay in implementation of this proposed rule and revisions made in consult with affected stakeholders, we understand the Administration's desire for more immediate action to address what is a genuinely monumental problem. Accordingly, NAHU suggests that the Administration spend time during the 2020 plan year studying both the value of current rebates and how rebate funds are used and distributed today, which is not always transparent. Perhaps a final rule could require a higher degree of rebate transparency and accountability at the manufacturer, PBM and plan levels. We understand that contract issues are at play here and that complete transparency may be impractical, but a higher degree of federal accountability about the amount and use of rebate funds could be required and then used to inform future policy efforts. When NAHU members list their chief concerns regarding the issues tackled by the proposed rule, they include the lack of clarity as to how and where rebate money flows precisely under the current regulatory framework, how potential changes to rebates will impact pricing and plan design moving forward, and how proposed changes will affect negotiating

positions and pricing in other markets. Greater transparency and data could help inform all of these concerns.

Conclusion

The members of NAHU sincerely appreciate the opportunity to provide information to you about the proposed rule and its potential impact on prescription drug costs and Medicare coverage options. If you have any questions about our comments, or if NAHU can be of assistance as you move forward, please do not hesitate to contact me at either (202) 595-0639 or jtrautwein@nahu.org.

Sincerely,



Janet Stokes Trautwein
Chief Executive Officer
National Association of Health Underwriters