April 5, 2019

Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Attention: OIG–0936–P
Cohen Building, Room 5527
330 Independence Avenue SW
Washington, DC 20201

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 Benefit Manager Service Fees

Dear Mr. Zajic:

Navitus Health Solutions is providing these comments regarding the 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 Proposed Rule.

As background, Navitus Health Solutions is a 100% pass-through, fully transparent, pharmacy benefit manager (PBM). Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits for over six million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business.

At Navitus, we agree with HHS's stated goal of trying to lower prescription drug costs for the millions of Americans who desperately need medications and trying to increase transparency in drug pricing, as these goals have been part of our corporate mission from the start of our company. We also agree that traditional PBM business models may drive up drug expenses by promoting higher cost agents in their quest to secure higher rebates from drug manufacturers because traditional PBMs often keep a portion of the rebates that they negotiate. In contrast, however, Navitus discloses the amount of all rebates it receives from manufacturers and passes 100% of all these rebates back to our clients. The result is Navitus does not rely on manufacturer drug monies for our company's revenue or profits. All of Navitus' decisions in regards to formulary and rebate management is for the benefit of our client payers.

Navitus agrees that rebates from drug manufacturers warp the incentives that PBMs are operating under, creating a market dysfunction where the goals of CMS and the Part D plans are not aligned with those of the PBMs providing services to the plans. For PBMs, the amount of rebates that are paid to Part D plans are often used as a rough measure of performance by the plans and their consultants in the process of PBM service acquisition and ongoing PBM services. However, higher rebates are not necessarily a good proxy for lower costs. We do not believe the proposed transition to point of sale rebates will help this situation. When PBMs choose drugs with higher rebates but higher costs over comparable drugs with lower overall costs, then the total costs can be significantly higher for the plans and CMS in spite of the higher rebates. A better solution would be to require any dollars paid by drug manufacturers to PBMs to be passed through to the Part D plans; thus, eliminating the misaligned incentives.

While Navitus understands the Administration's focus on rising prescription drug costs, we do not believe that the proposed rule will solve the issue of increasing drug prices. We are also concerned that the proposed rule will have unanticipated negative consequences for beneficiaries and health plans.

As a result, Navitus opposes the proposed rule and is providing comments on the following topics:

- **The Proposed Rule Will Result in Increased Costs for Part D Beneficiaries, Plans, and CMS**
- **Safe Harbors for Any Amounts Retained by PBMs from Drug Manufacturers Creates a Conflict of Interest**
- **The Proposed Rule Ignores Existing Transparent Model PBMs**
- **The Actuarial and Economic Analyses Yield Uncertain Outcomes from the Proposed Rule**
- **"Chargeback" Definition and Implementation of Price Reductions at the Point of Sale are Unclear**
- **The Proposed Rule Potentially Violates Federal Law**
- **The Timeframe for Compliance is Unreasonable**
- **The Proposed Rule Ignores the Role of Drug Manufacturers in Setting Drug Prices**
- **The Proposed Safe Harbor Should Include Claims with 100% Cost Sharing**

The Proposed Rule Will Result in Increased Costs for Part D Beneficiaries, Plans, and CMS. The elimination of rebates negotiated by PBMs through the proposed rule will negatively affect Part D beneficiaries' ability to access affordable prescription drugs and cause increased costs. The costs required to implement all of the changes under the proposed rule will also be significant and will ultimately fall on the beneficiaries, as this will require changes in processes, procedures, and other operational changes. Additionally, point-of-sale rebates will undermine the drug utilization tools used by plans to help beneficiaries and plans save costs and result in higher long-term costs.

Drug manufacturers pay rebates in order to increase sales volume. Currently, many considerations influence when a drug manufacturer will pay rebates. Those considerations include a PBM's formulary placement, overall drug volume, overall drug market share, changes in market share, and other factors related to the financial performance of a particular drug over time. All of these considerations boil down to the manufacturers trying to increase sales volume and revenue. If the rebates are not tied to a way for the manufacturers to receive increased sales volume, then there would not be any incentive for them to pay those rebates, regardless of whether they are paid at the point-of-sale or after a set period of time. Manufacturers will also be unwilling to provide meaningful discounts to PBMs if they are required to use a per unit discount determined in advance,[1] because the manufacturers will not know if the discount will cause an increase in sales volume.

There is no reason to believe that prohibiting the current rebate structure and allowing only point-of-sale rebates would lead to lower drug prices for Part D beneficiaries or CMS. If the proposed rule is adopted and rebates payable to Part D plans and PBMs are prohibited,[2] then Part D plans may no longer have the rebate dollars available from drug manufacturers, but they will still need to pay for prescription drugs. As a result, the Part D plans may need to raise premiums and report higher costs to CMS in order to remain at the similar levels of profitability. At the same time, drug manufacturers will reap windfall profits by not needing to pay rebates and will be able to raise prices. This will increase the total costs of the drugs to CMS and beneficiaries, which is the exact opposite of the intent of the proposed rule.

Prohibiting PBMs and plans from receiving rebate payments also removes an important tool for negotiating lower costs, and the proposed rule offers no viable alternatives to replace it. PBMs act to consolidate the buying power of their clients, including Part D plans. If PBMs are prohibited from negotiating price concessions on behalf of Part D plans, as proposed, drug manufacturers will have a reduced set of forces pushing prices down.

Agreements between PBMs and drug manufacturers limiting drug price increases would also be prohibited under the proposed rule. As part of our negotiations with manufacturers, Navitus currently negotiates caps on the prices that Navitus will pay for specific drugs. As with other PBMs, manufacturers pay Navitus an amount equal to the amount by which the manufacturers' drug prices exceed the negotiated limit on price.

[1] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2363, proposed new subsection (dd).
[2] See *Proposed Rule -- Removal of Safe Harbor Protection for Rebates,* page 2363, proposed new subsection (cc).

These caps on drug prices would be prohibited "rebates" under the proposed rule, and their prohibition would result in less downward pressure on drug prices, leaving drug manufacturers more latitude to raise prices at will. This would continue to result in drug price inflation exceeding the Consumer Price Index.

If the proposed rule is enacted, drug manufacturers would likely keep prices at the highest levels that can be supported by market forces, which would very likely be higher than the negotiated prices we have today. It is also likely that drug prices will continue to increase over time, without anything to hold them down in place of the current PBM negotiating pressure. Additionally, the amount of the savings that are currently negotiated by PBMs for the benefit of Part D plans and Part D beneficiaries would, instead, be kept by drug manufacturers, who would no longer need to pay out rebates or offer price protection in order to remain on formularies managed by the PBMs and Part D plans.

Safe Harbors for Any Amounts Withheld by PBMs from Drug Manufactures Creates a Conflict of Interest. Under the proposed rule, PBMs may still retain money paid to them for "*services provided in accordance with a personal or management services contract"*[3] and "*PBM service fees".*[4] However, allowing PBMs to retain any money from drug manufacturers creates a conflict of interest. If CMS wants to remove the incentives for PBMs to encourage or enable higher drug prices, CMS should prohibit PBMs from retaining any money from drug manufacturers. Instead, all amounts that PBMs receive from drug manufacturers should be required to be passed back to the Part D Plans or to CMS.

If drug manufacturers are paying PBMs money that the PBMs keep, then the PBMs have an incentive that is not consistent with goals of lowering prices and overall costs. Instead, PBMs would have the incentive to keep manufacturers happy in order to continue receiving such payments from manufacturers. Manufacturers have the goal of increasing overall revenue, which normally means keeping their drugs on each formulary in a preferred status to increase sale volume for their drugs at the highest prices possible. Allowing drug manufacturers to continue to pay PBMs will allow the manufacturers to influence PBM decisions, implicitly or explicitly, including decisions to keep overpriced drugs on the formularies and continually enabling escalating drug prices. Regardless of what payments from manufacturers are labeled, they all impact PBMs' incentives unless they are fully passed through to the plans, Part D beneficiaries, or CMS and used to reduce overall drug prices.

While Navitus agrees with HHS and OIG's intent to create a pass-through, transparent pharmacy benefit model, it does not believe that the proposed rule would achieve this, as the proposed rule would allow for payments to PBMs from manufacturers to be shifted to service fees.[5] We believe that a better approach would be to continue to allow rebates but require that all payments from manufacturers including rebates, price protection dollars, and all other monies payable from manufacturers to PBMs be passed through to the Part D plans and then reported to CMS and used to reduce overall costs. This would allow for more information to be available in order to guide future decision making without disrupting the entire pricing structure in place for benefit plans in a way that could significantly increase prices.

In addition to rebates and price protection, Navitus currently passes through all amounts that it receives from drug manufacturers to its clients. Under the proposed rule, however, Navitus would effectively be prohibited from passing services-related fees through to its clients, which we believe is not in the best interests of the Part D plans that are our clients, CMS or Part D beneficiaries.

The Proposed Rule Ignores Existing Transparent Model PBMs. The proposed rule appears to assume that all PBMs use traditional "spread" pricing, where a percentage of rebates is retained by the PBM, and assign blame for high drug prices to all PBMs and rebates provided by drug manufacturers. However, transparent, pass-through PBM models that align to the best interest of payers that purchase their services are already being employed in the industry.

[3] See *Proposed Rule -- Removal of Safe Harbor Protection for Rebates,* page 2363, proposed new subsection (h)(5)(vi).
[4] See *Proposed Rule -- Removal of Safe Harbor Protection for Rebates,* page 2363, proposed new subsection (dd).
[5] Ibid.

As noted above, Navitus uses a transparent, pass-through model, and passes all rebates it receives back to its clients. As a transparent PBM, Navitus also provides its clients with all of the information they need to make benefit decisions necessary to achieve the lowest possible overall costs. Our model removes the incentives to make decisions that result in higher drug costs. When combined with our focus on delivering the lowest-net-cost medications, our clients experience lower year-over-year drug trend, decreased per-member-per-month (PMPM) drug expenses, and reduced overall pharmacy costs. We believe that this model already achieves what the proposed rule intends to make happen and propose that if both (a) transparency and (b) the passing through of all drug manufacturer payments to Part D plans or CMS were required, that would solve most of the issues that result from the current rebate structure in drug pricing.

The Actuarial and Economic Analyses Yield Uncertain Outcomes. There is no guarantee that removing the safe harbor protection for rebates negotiated by and paid by PBMs would influence a drug manufacturer's pricing strategies and lead to lower drug prices. The analyses conducted are based on uncertain predictions as to how drug manufacturers, PBMs, and health plan sponsors will change their strategic behavior in response to elimination of the Safe Harbor Rule.

The proposed rule fails to address how it will achieve the intended goal of reducing prescription drug costs. In fact, the proposed rule acknowledges that there is much uncertainty related to the extent of the proposed rule's impact. The Department of Health and Human Services ("Department") states that "[i]t is difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response."[6] The Department further acknowledges the "uncertainty" of the analyses conducted by CMS's Office of the Actuary (OAS), Wakely, and Milliman in determining the impact the regulation would have on drug manufacturers and drug prices.[7] Before making systemic changes to the current system and potentially causing unpredictable and significantly worse outcomes, it may be best to gather additional information by forcing transparency in the current system.

"Chargeback" Definition and Implementation of Price Reductions at the Point of Sale are Unclear.[8] The proposed rule does not indicate how price reductions will be calculated or administered at the point-of-sale. It is unclear whether the proposed rule contemplates the point of sale discounts to be provided through wholesaler chargebacks or if they will be provided through PBMs. Additionally, although the proposed rule states that "the reduction in price must be completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale," the proposed rule fails to clearly indicate whether such discount applies to the beneficiary's cost sharing amount or to the health plan and beneficiary liability combined.[9]

The proposed rule also appears to suggest that even if a chargeback amount is fixed in advance, pharmacies are able to adjust cost sharing independently. However, this cannot be accurate, as the PBM must calculate the cost sharing at the time the claim is adjudicated based on the rate contracted with the pharmacy, the beneficiary's formulary, benefit design, and level of benefit accumulators.

While Navitus opposes the "chargeback" structure and point-of-sale rebate processes proposed, if CMS enacts the proposed rule, Navitus would recommend that CMS continue to leverage existing PBM / Third Party Administrator (TPA) infrastructure for administration of the price reductions. By using the infrastructure already in place, rather than require development of an entirely new pharmacy-based infrastructure that will not further CMS' stated goal of transparency, the PBM would function as the chargeback administrator and would process the claim and seek reimbursement of the chargeback from the drug manufacturers. The amount of the chargeback would then be transferred to the dispensing pharmacy with the plan payment due based on the net cost of the claim. The combined amount of the point-of-sale discount, and the benefit liability would be paid to the pharmacy.

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[6] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2355.
[7] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2357.
[8] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2349.
[9] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2363, proposed new subsection (cc)(1)(iii).

The Proposed Rule Potentially Violates Federal Law. The proposed rule potentially violates Medicare Part D statute's noninterference clause, which states that negotiations between drug manufacturers and pharmacies and PDP sponsors may not be interfered with considering the plain meaning of the statute.[10] A plain reading of the applicable statute seems to prohibit the type of interference that this removal of the safe harbor would cause.

The Timeframe for Compliance is Unreasonable. Under the proposed rule, changes are anticipated to go into effect on January 1, 2020. Compliance with this deadline would be extremely difficult, as it does not give stakeholders adequate time to implement the changes required under the proposed rule. At Navitus, contracts with numerous clients would need to be amended. In addition, changes would need to be made to restructure current rebates arrangements into discount arrangements with many drug manufacturers. Navitus' formularies would also need to be revised in response to any pricing strategy responses by drug manufacturers, and Navitus' overarching strategy would need to be changed to adjust to the changes in the proposed rule. This aggressive timeline is nearly impossible to meet given that plan sponsors must also engage in drug manufacturer negotiation well in advance of the plan year for 2020. Even the alternative deadline of January 1, 2021, would be difficult to meet. If the proposed rule were to go into effect, stakeholders would need much more time to implement the changes required under the proposed rule.

In addition, if point-of-sale price reductions are administered through wholesaler chargebacks and a new process is required to implement calculation of point-of-sale transactions, additional time would be needed to change industry operations to incorporate changes to the financial fields used in the remittance process and create an entirely new set of processes to implement the point of sales rebate structure and related payments.

The proposed rule also sets unreasonable expectations with respect to the amount of time for PBMs to implement the changes it proposes. The proposed rule severely underestimates the amount of time to implement the changes and modify business practices by stating that the "Department estimates that this would result in affected businesses spending an average of 20 hours reviewing their policies and determining how to respond, divided equally between lawyers and managers…"[11] We anticipate the time that we would need to spend in response to enactment of the proposed rule would exceed that amount by several orders of magnitude.

The Proposed Rule Ignores the Role of Drug Manufacturers in Setting Drug Prices. The proposed rule unfairly targets PBMs as the cause of increasing drug prices and ignores the role drug manufacturers play in rising drug costs. In an attempt to divert attention away from their role in increasing drug costs, drug manufacturers have suggested that PBMs have caused the drug manufacturers to raise prices of drugs due to the current rebate system in place. However, available evidence shows that there is no correlation between rebates negotiated between PBMs and drug manufacturers and the list price of drugs set by drug manufacturers. According to a study conducted by Visante, drug manufacturers are increasing prices of drugs irrespective of any negotiated rebates.[12] The study shows that for drugs that have had higher than average increase in price growth for treatment of conditions like rheumatoid arthritis, multiple sclerosis, and anticonvulsants, there have been relatively low rebates. In contrast, for drugs that have had lower than average price growth, there have been relatively high rebates. In addition, according to OIG's June 2018 report, entitled "Increases in Reimbursement for Brand-Name Drugs in Part D," it was found that even after taking into account rebates of drug manufacturers, the reimbursement rate for brand name drugs in Part D still increased by 62% over a 4-year period.[13] By removing the ability of PBMs to negotiate rebates and

[10] 42 U.S.C. § 1395w-111(i) (emphasis added), "*NONINTERFERENCE In order to promote competition under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.*"

[11] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2354

[12] See "No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories." PCMA, April 2017. www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf

[13] "Increases in Reimbursement for Brand-Name Drugs in Part D." U.S. Department of Health & Human Services, Office of Inspector General, June 2018. oig.hhs.gov/oei/reports/oei-03-15-00080.pdf

price protection on behalf of their clients, the proposed rule would provide a windfall to drug manufacturers as the pressure from PBMs to keep over-all costs reduced would be removed.

The Proposed Safe Harbors Should Include Claims with 100% Cost Sharing if Enacted.[14] In response to the request for comments on how the safe harbor would apply during periods of 100% beneficiary cost sharing, Navitus agrees that the new safe harbor should protect reductions in price for prescription pharmaceutical products without regard to what phase of the benefit the beneficiary is in, including periods of the benefit where there may be 100% beneficiary cost sharing. Attempting to exclude periods of the benefit where there may be 100% beneficiary cost sharing adds unnecessary complexities and creates an opportunity for loopholes to be exploited for PBMs or plan sponsors to extract remuneration from drug manufacturers without benefiting the beneficiaries.

Thank you for the opportunity to provide feedback on this proposed rule. If we can provide any additional information for your rule-making process, please let us know. Please also let us know if you would like to meet with us at any of our facilities in Madison or Appleton in Wisconsin, in Austin, Texas or in Phoenix, Arizona.

Sincerely,

Paul M. Page
General Counsel
Navitus Health Solutions

[14] See *Proposed Rule - Removal of Safe Harbor Protection for Rebates,* page 2348.