April 8, 2019

Submitted electronically

Office of the Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: OIG-0936-P

Thank you for the opportunity to provide comments on the proposed rule, *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.*

The Council for Affordable Health Coverage (CAHC) is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. CAHC promotes policies that lower health costs through increased competition, informed consumers and more choices. Our members include medical providers, patient groups, insurers, pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and employers. To that end, because of our diverse membership and the wide implications of the proposed rule, our comments apply only to the proposed rule's effects on value-based arrangements (VBAs) for pharmaceuticals.

In the preamble, HHS states at ***III.A-Amendment to the Discount Safe Harbor***-(84 FR 2348):

> *"The Department is exploring value-based arrangements and their use in the sale of prescription pharmaceutical products. The Department does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCOs. We are interested in hearing from stakeholders about, and are soliciting comments on, the extent to which the proposed amendment and accompanying proposed safe harbor may affect any existing or future value-based arrangements. We request that any such comments specify how any currently protected arrangements or arrangements that might be protected under the proposed safe harbor are "value based."*

Comment:

CAHC has long supported policies that expand value-based arrangements (VBAs) in federal programs, including Medicare Part D. VBAs are gaining prominence in commercial sector drug benefits but are limited in how they can be utilized in federal programs.

Value-based care hinges on reimbursement based on patient outcomes. In order to successfully measure outcomes, coordination between the various sites of care and various caregivers, including the patient, is key. Additionally, when reimbursement is tied to outcomes, ensuring that patients are seen at high quality sites of care is also crucial. Value-based models eliminate the financial incentive to provide

additional services and replace it with an incentive to provide *quality* services. However, these models, which are designed to improve care and outcomes, may still implicate the Stark and the Anti-Kickback statutes.

For example, a physician participating in a VBA for a particular drug might need to refer the patient to a medical site to collect ongoing clinical data to track outcomes. That physician may have a financial stake in that particular site, which would trigger Stark, even if the referral presents no risk for increased payment to the physician. The Stark law should only be implicated when referrals result in additional payment as opposed to payment as part of value-based care arrangements. Furthermore, to encourage broader adoption of value-based arrangements, a clearly defined safe harbor from Stark should also be implemented.

VBAs rely on coordination between payers, providers, drug makers, technology companies and patients. The Anti-Kickback Statute (AKS) and Stark laws prevent such collaboration around value in federal programs, particularly as they relate to tying drug reimbursement with patient outcomes. These laws and subsequent regulations are intended to prevent fraudulent and abusive practices by prohibiting arrangements where organizations, individuals, and physicians could receive inappropriate payments for referring a product or service that would be paid for by federal health programs. Although the laws and regulations have historically been effective in capturing true misconduct, their broad and relatively inflexible approach has also had the unintended consequence of hampering the adoption of innovative arrangements and patient engagement efforts that can truly benefit consumers and the health care system.

Payment methodologies being considered in VBAs could include a form of retrospective payment from a manufacturer to the PBM or plan. Since the chargeback mechanism contemplated in the proposed rule would have to be set in advance and consist of a flow of funds from the manufacturer directly to the pharmacy, the result could be a disallowing of retrospective payment to the plan or PBM from a manufacturer for VBAs.

For example, an outcomes-based VBA between a manufacturer and PBM could establish a rebate be paid back to the PBM from the manufacturer if a drug does not achieve the labeled indication or a clinical outcome agreed to by both parties. These arrangements rely upon ongoing data exchange, measurement of results, and- if warranted- a payment. All occurring after the drug has been dispensed.

Overall results will not be known ahead of time, particularly if a payment is to be made to the PBM or the plan from the manufacturer, or what the amount may be.

<u>Recommendation:</u>

1. HHS should clarify value-based arrangements would be allowed within the discount safe harbor, if the terms of a VBA are established in advance, and allow for any VBA payments from manufacturer to PBM to occur even if the amount varies and is paid retrospectively, and
2. HHS should adopt three new safe harbors to the Anti-Kickback statute to facilitate value-based care.

CAHC supports broader adoption of VBAs in federal health programs and encourages the administration to ensure that any changes to the AKS via the removal or addition of any safe harbors explicitly protect VBAs. In the final rule, HHS should explicitly establish a new safe harbor protecting value-based

arrangements from the Anti-Kickback statute. CAHC defines a value-based arrangement as a written agreement in which the payment for medication(s) or other health care technologies is tied to: (1) the future performance of the goods/services; (2) the achievement of measurable and defined patient outcomes or clinical circumstances; (3) a patient's compliance with a medication regimen prescribed by a patient's health care provider; or (4) any other evidence-based outcome or circumstance.

Each VBA is inherently different and relies on care coordination as the crux to enable tracking of patient outcomes. As the definition above reflects, one arrangement might base payment on the clinical outcomes (i.e. blood pressure), another might base payment on behavioral outcomes (i.e. ER visit), and yet another might base payment on medication adherence (i.e. is the patient still refilling the drug?). The antikickback statute stands in the way of enabling care coordination and data sharing between the biopharmaceutical manufacturer, payer, healthcare provider and patient required to successfully carry out a VBA. Furthermore, CAHC believes that VBAs for prescription drugs should have a medication adherence/compliance component to them to ensure the outcome of the medication is a result of proper adherence and not due to non-adherence.

CAHC suggests three well-tailored safe harbors to the AKS be created to encourage prescription drug value-based arrangements in federal health programs:

1. **Safe Harbor for VBAs:** A value-based arrangement pursuant to a written agreement in which each participant agrees to assume varying levels of financial risk (including but not limited to rebates, discounts, price reductions, contributions, reimbursements, guarantees, patient care, shared savings payments, withholds, or bonuses or anything of value) based on—

    i. the future performance of the goods or services described in the arrangement;
    ii. the achievement of measurable and defined patient outcomes or clinical circumstances;
    iii. a patient's compliance with a medication regimen prescribed by the patient's health care provider; or
    iv. any other evidence-based outcome or circumstance as defined by the Secretary through notice-and-comment rulemaking.

2. **Safe Harbor for Medication Adherence Programs:** A medication adherence support program pursuant to a written agreement (including a program that is part of a value-based arrangement and any agreement with respect to the collection and use of derived adherence data and information) that establishes the protocol for a patient's substantial compliance with a covered medication regimen prescribed by the patient's health care provider under title XVIII, a federal health care program, or a state health care program.

3. **Safe Harbor for Donated Technology:** Expressly exempt investments necessary to implement a value-based pricing mechanism, including any investment in equipment and software necessary to monitor and assess compliance by a seller as reasonable and necessary to implement the pricing arrangement, and that such items are removed upon termination of the arrangement. In order minimize the risk of implementation activities being unlawful remuneration:

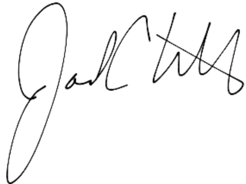
    i. A seller should not pay or reimburse a buyer for any information or data that the buyer is already collecting.

ii. A seller may reimburse a buyer for any additional costs incurred by the buyer that are necessary to implement a value-based pricing arrangement during the term of the arrangement.
iii. A seller can only reimburse a buyer for the costs of gathering the data that is necessary to achieve/monitor the clinical benchmarks for the value-pricing arrangement. The seller cannot pay for data gathering that is not necessary to the pricing.

Conclusion

Thank you again for the opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me at joel.white@cahc.net. CAHC looks forward to our continued work with the administration as you move forward to improve prescription drug affordability and access.

Sincerely,



Joel White
President