THE COUNCIL
The Council of Insurance Agents & Brokers

April 8, 2019

Via Electronic Submission – www.regulations.gov

Mr. Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Attn: OIG-0936-P
Room 5527, Cohen Building
330 Independence Ave SW
Washington, DC 20201

RE: File Code OIG-0936-P
Amendments to "Safe Harbors" under Anti-Kickback Statute

Dear Mr. Zajic:

The Council of Insurance Agents and Brokers ("The Council") appreciates this opportunity to comment on the Inspector General's ("OIG") proposed revisions to safe harbors under the Medicare and Medicaid anti-kickback statute (the "proposal").[1] We applaud the OIG's efforts to modernize these rules to reflect today's prescription drug distribution model and to provide real savings for beneficiaries at the point of sale.

By way of background, The Council represents the largest and most successful employee benefits and property/casualty agencies and brokerage firms. Council member firms annually place more than $300 billion in commercial insurance business in the United States and abroad. Council members conduct business in some 30,000 locations and employ upwards of 350,000 people worldwide. In addition, Council members specialize in a wide range of insurance products and risk management services for business, industry, government, and the public.

Council members' focus, not surprisingly, is on the employer-sponsored healthcare market and controlling costs therein. Although this proposal is limited in scope to public healthcare programs, it implicates several principles backed by our members to add transparency to the prescription drug supply chain and bring down drug costs for all payers.

Specifically, we support the following features of the proposal:

[1] Office of the Inspector General (OIG), Department of Health and Human Services (HHS), 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*, 84 Fed. Reg. 2340 (Feb. 6, 2019).

- Delivering discount benefits to ultimate payers, not middle men;
- Standardizing contract terms related to pharmacy benefit manager (PBM) services and compensation; and
- Requiring additional regular disclosures by PBMs to health plans with which they contract regarding their business arrangements with drug manufacturers.

In response to some of the requests for information raised in the proposal regarding additional transparency measures and improving PBM accountability to the plans on whose behalf they negotiate, the Council generally advocates for more clarity and accessible information regarding business relationships and pricing arrangements throughout the drug supply chain.[2] Specific measures related to this proposal that may advance this overall policy goal include:

- Disclosure by PBMs to public programs and private plans of rebate/discount amounts and other revenue paid to the PBM or related third parties based on the plan sponsor's drug utilization;[3]

- More transparency around pass-through arrangements through which payers do – or do not – receive rebate or other "discount" dollars paid to PBMs by manufacturers;

[2] Our members emphasize that rebates/discounts are only one piece of the drug pricing discussion. The drug supply chain generally is rife with complex contractual arrangements, ever-changing terminology, and opaqueness regarding pricing and payments. Additionally, not all plans or plan sponsors are similarly situated with respect to their PBM arrangements (e.g., contract terms, services, pass-throughs and other benefits differ). Our members therefore urge policymakers to bear in mind and address challenges that may have a comprehensive impact on the system, including more access in general to understandable information they and their clients need to *fully* understand and assess their costs and contractual relationships.

[3] Currently, PBMs may disclose and pass along "base rebates" to plan sponsors, but several other categories of payments have been re-labeled or re-categorized in PBM contracts as non-rebates and thus are not passed on (e.g., those associated with IMS national programs, market share performance programs, access payments, non-disadvantage arrangements, administrative fees, inflation protection programs, among others). Such changes in terminology, Council members believe, are a response by PBMs to some employers' demands for 100% rebate pass-throughs.

To the extent rebates are restricted or go away entirely, some of our members are concerned that confusing contract terminology and opaqueness of manufacturer-PBM payment arrangements could get even worse. Moreover, they note, potential monetary conflicts of interest between PBMs and the plans with which they contract, and ubiquitous efforts to drive market share, are a function of distribution chain dynamics and are not limited to payments labeled as "rebates."

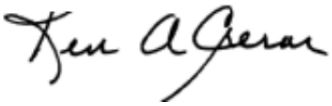
- An auditable structure that allows plan sponsors to have a complete picture and conduct more fulsome analyses of their drug-related costs and contractual relationships;

- Standardized PBM contract terms regarding prescription drug prices and distribution channel payment streams/arrangements (including actual services being provided) that are understandable by plans sponsors and their consultants; and

- Robust competition in the PBM space, which – we believe – is at least partially facilitated by improved disclosures/information access throughout the drug supply chain.[4]

Again, we appreciate this opportunity to comment and appreciate your continued efforts to address these important issues.

Respectfully submitted,



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[4] At least some of our members are concerned that elimination of rebates may lead to even more concentration in the PBM market (with the "big three" players – Express Scripts, CVS, and Optum – able to still offer better discounts to clients vis-à-vis smaller PBMs and by removing one lever smaller market participants have to pursue innovative solutions and spur competition), which could actually drive costs up because the few remaining PBMs may choose not to pass on revenue from manufacturers to patients and/or plan sponsors.