April 8, 2019

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

Submitted via electronic submission system

Re: Proposed rule modifying discount safe harbor of federal Anti-Kickback Statute
Reference file code OIG-0936-P

The Association for Community Affiliated Plans (ACAP) appreciates the opportunity to provide comments to the Secretary of Health and Human Services regarding the proposed rule reference file code OIG-0936-P, as published in the Federal Register, 84 Fed. Reg. 234063 (Feb. 6, 2019), modifying the discount safe harbor of the federal Anti-Kickback Statute.

ACAP is an association of 64 not-for-profit, community-based managed care organizations (MCOs) located in 29 states and providing coverage to over 20 million Americans enrolled in Medicaid, Children’s Health Insurance Program (CHIP) and Medicare Advantage Dual-Eligible Special Needs Plans (D-SNPs). ACAP’s member plans all have state Medicaid contracts. Nationally, ACAP plans serve approximately one-half of all Medicaid managed care enrollees. Twenty-two of our plans are D-SNPs, 23 of our plans are Medicare Long-Term Services Plans (MLTSS), and 13 of our plans participate in Medicare-Medicaid (MMP) Financial Alignment Demonstrations.

ACAP member plans are different from other MCOs operating in the U.S. They provide a unique service by partnering with states and communities to serve the neediest and most vulnerable. Unlike commercial plans, ACAP members do not have a profit motive or shareholders to whom they must provide justification and value. They reinvest savings directly into reduced premiums, expanded and more comprehensive services, and improved health outcomes for their beneficiaries. In this manner, ACAP members serve as a safety net within the U.S. health insurance system. They are willing and able to provide coverage to the high-cost, high-risk patient populations that other MCOs prefer not to enroll. ACAP refers to ACAP members as “Safety Net Health Plans” in light of this vitally important role they play. ACAP’s mission is to support and serve as an advocate for Safety Net Health Plans in order to improve the health of lower income and vulnerable populations across the nation.

ACAP’s member plans lead the way in addressing the opioid epidemic, finding innovative ways to address social determinants of health, reforming the way health care is delivered
and financed in the U.S., and breaking down the longstanding barriers between physical and behavioral health care. Safety Net Health Plans ensure the highest-quality health care through an ongoing commitment to transparency, quality measurement and continuous quality improvement and have routinely been featured in the top tier of Medicaid plan ratings developed by the National Committee for Quality Assurance (NCQA).

ACAP is submitting this letter in order to share the perspective and feedback of its member health plans. ACAP is also submitting this letter to impart two specific recommendations:

1. First, that the Secretary exclude Medicaid from the scope of the rule because the rule will impose significant costs and other consequences on Medicaid plans, states, and Medicaid beneficiaries without significant benefits; and

2. Second, that the Secretary delay implementation of the rule until further study of its effects can be conducted, until Congress can take action to address other inputs into drug costs that the rule leaves unaddressed, or both, and until plans and other stakeholders have additional time to adjust their contracting to address the rule.

ACAP’s comments and recommendations are explained in more detail below.

**ACAP applauds the Secretary’s goals of addressing rising drug costs, curbing list prices, and reducing financial burdens on beneficiaries**

ACAP applauds the Secretary for seeking to address the effect of rising list prices for prescription drugs on Medicare and Medicaid and the beneficiaries those programs seek to serve. As the Secretary is aware, drug manufacturers have continued for years to raise list prices beyond normal adjustments needed to keep pace with inflation or to account for increased production costs. As a result of these uncontrolled price increases by manufacturers, prescription drug expenditures represent an increasing burden on federal and state health care programs and their beneficiaries, both to the extent that beneficiaries share in drug costs through out-of-pocket expenses as well as the effect rising drug costs can have on increased premiums and reduced services. A study that ACAP commissioned by The Menges Group in November 2018\(^1\) indicates that high-cost medications represent a rapidly increasing proportion of Medicaid prescription drug spending. For example, costs for prescription drugs with an average pre-rebate cost of $1,000 or more rose from 19 percent of all Medicaid pre-rebate spending in 2011 to 44 percent in 2017. Increasingly, Medicaid MCOs bear the burden of rising drug costs to Medicaid; Medicaid MCOs’ share of Medicaid-paid prescriptions rose from 22 percent in federal fiscal year 2011 to 72 percent in fiscal year 2017. Prescription drug expenditures rose from 15.6 percent of Medicaid MCOs’

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premium revenues during calendar year 2015 to 16.1 percent during calendar year 2016 alone.

ACAP member plans’ prescription drug management efforts yield savings for Medicaid
As the Secretary has observed, neither existing law nor implementation of this proposed rule will prevent drug manufacturers from continuing their practice of uncontrolled drug price increases. The burden of controlling drug spending often falls on the shoulders of MCOs, especially Safety Net Health Plans. ACAP’s national study of MCO prescription drug benefit management programs indicates that those efforts yield large-scale savings for the MCOs and their states and beneficiaries. Average net (post-rebate) cost per MCO-paid Medicaid prescription during 2017 was $37, only 73 percent of the average net cost of Medicaid prescriptions paid in the fee-for-service (FFS) setting during 2016, which was $50. In 2017, generic drugs represented 88 percent of MCO-paid Medicaid prescriptions versus 84 percent in the FFS setting. Moreover, rebates are driving those savings for MCOs, states, and beneficiaries. In 2017, Medicaid managed care rebates comprised 51 percent of initial Medicaid payments to pharmacies. And, while pre-rebate prescription drug cost spending rose from 8.0 percent to 9.6 percent of all Medicaid expenditures between 2011 and 2016, post-rebate prescription drug cost spending remained relatively flat, rising from 4.3 percent to just 4.7 percent during the same period. Accordingly, MCOs’ prescription drug benefit management efforts are among the most successful current measures holding in check uncontrolled drug price increases by manufacturers.

Exclude Medicaid because Medicaid beneficiaries do not benefit and are likely harmed
For many of ACAP member plans’ beneficiaries—a population that includes Medicaid-Medicare dual-eligibles, patients receiving the Medicare Part D Low-Income Subsidy (LIS), and Medicaid beneficiaries—out-of-pocket drug costs do not present the concern that the Secretary raises in the preamble to the proposed rule. Medicaid and Medicare LIS beneficiaries have little to no cost-sharing or out-of-pocket expenses for prescription drugs. Other beneficiaries of ACAP member plans also have limited exposure to out-of-pocket expenses for prescription drugs, for example, due to maximum out-of-pocket cost provisions or low drug costs. However, even for those beneficiaries with the highest drug costs, the proposed rule would appear to do little to address their needs. The Congressional Budget Office has reported that specialty drug spend rose in Medicare Part D from $8.7 billion in 2010 to nearly $33 billion in 2015 and doubled to almost $10 billion under the Medicaid program during the same period. These drugs accounted for 30 percent of all Part D and Medicaid spending in 2015 even though they represented just 1 percent of all
prescriptions.\textsuperscript{2} Significantly, manufacturers typically offer no rebates on specialty drugs, other than those required by law, so the costs of specialty drugs would be unaffected by implementation of the proposed rule. Accordingly, ACAP believes that most of its member plans’ beneficiaries, and particularly Medicaid and Medicare LIS beneficiaries, would not benefit from the proposed rule.

At the same time, ACAP member plans, their states, and their beneficiaries would likely be significantly harmed by the proposed rule, because eliminating rebates that Medicaid MCOs negotiate on behalf of states and plans will result in higher costs to both. Many states currently rely on MCOs and their pharmacy benefit managers to negotiate supplemental rebates on MCO drugs.\textsuperscript{3} Furthermore, many ACAP Safety Net Health Plans’ contracts with pharmacy benefit managers provide for transparent pass-through rebates to the plans.

As the Secretary knows, its own Office of the Actuary (OACT) as cited in the proposed rule preamble estimates that the proposed rule will increase Medicaid costs by nearly $2 billion, if not more. OACT’s estimate assumed that manufacturers would retain just 15 percent of current rebates and offer the remaining 85 percent in new point-of-sale discounts or lowered list prices. If manufacturers do not lower prices—and several have already indicated that they will not in response to this rule, as discussed further below—Medicaid costs would grow even more. Additionally, the Secretary’s actuaries as stated in the proposed rule preamble further estimate that any savings from lowered list prices through the implementation of the proposed rule could be exceeded by lost rebate revenue to states. These higher costs and reduced rebates could lead to reduced Medicaid services to beneficiaries.

Furthermore, because the proposed rule aims to preserve Medicaid Drug Rebate Program (MDRP) rebates and any supplemental rebates that states negotiate for themselves, the proposed rule increases incentives for states to carve out pharmacy benefits from their Medicaid managed care programs, which would harm patient care without providing a benefit to beneficiaries. Pharmacy carve-outs in Medicaid managed care—when states take control of formularies away from pharmacy and therapeutics (P&T) committees and instead

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\item \textsuperscript{3} As Georgetown University Center for Children and Families research professor Edwin Park has observed, currently, only a handful of states fully carve out the outpatient drug benefit from Medicaid managed care plans and directly negotiate their own supplemental rebates for both FFS and Medicaid managed care. Several states have no directly negotiated supplemental rebates at all and rely wholly on Medicaid managed care plans to obtain any supplemental rebates. Most other states only directly negotiate supplemental rebates for beneficiaries in FFS, for a limited number of drugs or drug classes in managed care, or both. \textit{See} E. Park, How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs, available at \url{https://ccf.georgetown.edu/2019/01/09/how-to-strengthen-the-medicaid-drug-rebate-program-to-address-rising-medicaid-prescription-drug-costs/}.
\end{itemize}
administer them on a bureaucratic level removed from direct patient care—have posed a consistent threat to patient care for years. A study ACAP commissioned by the Lewin Group in 2007 concluded that carve-in approaches are associated with positive utilization management and patient care practices, whereas pharmacy carve-outs create a range of operational and patient care challenges. While most states currently allow MCO P&T committees to administer formularies for the benefit of patients, the proposed rule provides strong temptation for state Medicaid agencies to carve out pharmacy benefits from Medicaid managed care, to administer those benefits on a FFS basis, and thereby to maximize the volume and formulary placement states can offer to manufacturers in exchange for supplemental rebates.

States have already begun to look for ways to compensate for the revenue they will lose as a result of this proposed rule. For example, Pennsylvania recently announced a mandatory statewide implementation of a bureaucratically controlled state level formulary for Medicaid MCOs and cited this proposed rule as one of the reasons for its implementation. ACAP fears that more states will pursue a carve-out strategy in anticipation of receiving less rebate revenue as a result of the proposed rule. This trend would undermine the ability of Safety Net Health Plans to manage effectively the continuity and quality of care provided to their patients. Such harm to patient care would be for no good reason because Medicaid beneficiaries would not benefit from the proposed rule’s ostensible focus on reducing out-of-pocket costs in the first instance.

Because Medicaid beneficiaries have little to no out-of-pocket expenses and would not benefit from the proposed rule, and because Medicaid managed care plans, their states, and their beneficiaries are likely to be significantly harmed by the proposed rule, ACAP recommends that the Secretary exclude Medicaid from the scope of any final rule.

**Delay implementation for further study, Congressional action, and contract adjustments**

ACAP believes that the Secretary and all stakeholders could benefit from additional time to study the proposed rule and its potential effects. As the Secretary is aware, the projections of the Department’s actuarial consultants, including OACT, cast significant doubt on the assumptions that the proposed rule would reduce overutilization, reduce costs for federal programs, or reduce premiums or out-of-pocket expenses for most beneficiaries. Since the publication of the proposed rule, drug manufacturers have cast further doubt on those assumptions. Under direct questioning of Senator Charles Grassley, chair of the Senate Finance Committee, whether they would lower list prices in response to the

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implementation of the proposed rule, none of seven manufacturer CEOs at a committee hearing on February 26 would commit to doing so. Several of those manufacturers subsequently offered at least to consider lowering list prices if the proposed rule were extended by legislation to all commercial lines of insurance, leading to the introduction of legislation in the Senate (S. 657) to do that. In the meantime, however, surely the Secretary and all stakeholders must seriously reevaluate the actuarial projections in the proposed rule’s preamble that assumed drug manufacturers would reduce list prices or offer similar reductions in price in point-of-sale discounts through the proposed new point-of-sale safe harbor.

ACAP recognizes that the Secretary’s authority regarding the Anti-Kickback Statute is limited to regulatory safe harbors that reach health care paid for at least in part by a federal health care program, and the Secretary has no authority to alter either the statutory exemptions to the statute or the scope of the statute to reach commercial insurance. As the Secretary is aware, Congress is also considering legislation that will address many other prongs of drug pricing more comprehensively, including legislation to incentivize greater introduction of generic drugs and other potential changes to drug pricing. Given the prospects that Congress will act to change inputs to drug pricing affecting out-of-pocket expenses, as well as the more extensive hearings and budget scoring that such legislation will engender, the Secretary and other stakeholders could benefit from the additional insight into the potential effects of this rule in an environment that includes additional testimony, hearings, and analyses by Congress, states, and others.

Not least, ACAP asks the Secretary to consider that ACAP’s member plans as well as others operate on multi-year contracts that are already in place or are currently being negotiated. The currently proposed schedule for implementation would significantly disrupt a contracting cycle involving plans, states, manufacturers, and others that must take into account both this rule as well as evolving guidance from other rule makers, including CMS. Delaying the period of implementation until further study and Congressional consideration can take place will allow stakeholders to adapt contracts to any final rule.

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ACAP is prepared to assist with additional information, if needed. If you have any questions, please do not hesitate to contact Jennifer McGuigan Babcock at 202-204-7518 or jabcock@communityplans.net.

Sincerely,

/s/
Margaret A. Murray
Chief Executive Officer