COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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February 19, 2019

Senator Bill Cassidy
520 Hart Senate Office Building
Washington, DC 20510

Senator Mark Warner
703 Hart Senate Office Building
Washington, DC 20510

Re: *The Patient Affordability, Value and Efficiency Act*

Dear Senators Cassidy and Warner:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we thank you for the opportunity to submit this comment letter in response to the draft version of the Patient Affordability, Value, and Efficiency Act ("PAVE Act").

COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the independent community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA's mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For more than 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

As the providers of care for the majority of Americans battling cancer, community oncologists are highly aware of the importance and promise of value-based care. COA is committed to increasing the quality of cancer care while decreasing costs, and we are working tirelessly to make the CMS Innovation Center's Oncology Care Model ("OCM") successful. We support value-based models that can positively impact prices and utilization and we applaud you for your interest in removing the statutory barriers to value-based care. We support the effort to add new clarity and flexibilities to pay for prescription drugs and medical devices based on their proven effectiveness. We look forward to working with you, the rest of the Congress, and the administration on moving our healthcare system towards lower costs and improved outcomes.

Value-Based Contracts Should Promote Better Outcomes

COA believes that value-based contracts ("VBCs") are important in all therapeutic areas, but particularly in cancer care where patients often face high-cost, complex treatment. To date, the lack of clarity and flexibility surrounding many safe harbors has fostered significant uncertainty for stakeholders and has limited their willingness to enter into innovative arrangements. COA believes that amending the Anti-Kickback Statute ("AKS") to add exceptions for value-based contracts and medication adherence support programs would promote greater development and adoption of these arrangements. We attach to this letter (*Appendix A*) the comment letter we submitted to the Office of the Inspector General, Department of Health and Human Services ("HHS") on October 26, 2018 in response to a request for information (*OIG—0803—N, Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Payments).*

Importantly, COA applauds HHS for its recently released ambitious proposal to overhaul the secretive drug rebate system and ensure patients receive the benefit of negotiated drug discounts. The Administration's proposal has the potential to directly lower drug prices and to reduce the incredibly negative influence of PBM middlemen. However, the draft changes to AKS safe harbor proposed through this rulemaking leave some unanswered questions about how the elimination of rebates would impact existing and future innovative contracting arrangements. Therefore, we are very pleased to see the proposed changes to the statutory exemptions envisioned in the PAVE Act as a decisive step to remove the legal barriers to value-based arrangements.

COA is working on important innovative thinking around the future of the OCM and the goal of patient-centric high-quality care. Our efforts around an "OCM 2.0" universal payment model include, among other priorities, the aim to move toward value-based pricing for drugs, including outcome-based and indication pricing, which the current system does not adequately support. To date, COA has held over 75 meetings with pharmaceutical companies to understand value-based contracting arrangements they have entered into internationally, as well as with commercial payers. Our intent is to include value-based drug arrangements directly into the OCM 2.0. To that end, COA believes that the PAVE Act would build a critical foundation to allow OCM practices and other oncology providers to focus on engaging with manufacturers around meaningful preidentified clinical or economic targets that can positively impact both prices and utilization.

In addition, as providers, we know all too well the impact on costs and quality of patient non-adherence to prescribed therapies, and we are happy to see an effort to exempt medication adherence support program and associated data collections from AKS. COA thinks that the AKS in its current form limits the ability for providers, manufacturers, and plans to help beneficiaries access tools to track the progress and effectiveness of their care. The new statutory exemption envisioned by the PAVE Act should have the flexibility to apply to any tools, technologies, or resources provided to beneficiaries with the goal of greater education, adherence tracking, and treatment effectiveness outside of the clinical setting.

The Stark Law and Promoting Care Coordination

Any changes to the AKS exceptions should be coordinated with Stark Law changes to ensure alignment and clarity. COA is very pleased to see that the PAVE Act tackles both by exempting value-based agreements for drugs and services from the physician self-referral statute. Currently, due to a lack of quality and cost transparency, many patients are not always aware of which providers achieve the best outcomes at the lowest cost, or which diagnostic facilities would lead to the lowest patient out-of-pocket ("OOP") costs. Due to complex compensation structures, providers may not be able to direct patients to low-cost, high-quality providers with affiliated entities due to the constraints of the Stark Law. Given the diverse range of services, diagnostics, and providers on which cancer patients depend on for their treatment plans, the lack of care direction can lead to higher treatment and patient OOP costs. The Stark law was created in a fee-for-service environment, and evolving payer and provider environment and increased financial risk necessitate improved care coordination. COA supports the statutory changes in the PAVE Act and expects it to help the adoption of value-based care reimbursement.

Government Pricing and Reporting Requirements

COA applauds you for recognizing that several existing government pricing and reporting laws may be deterring manufacturers from entering into VBCs or from pursuing more aggressive and meaningful outcomes as part of these arrangements. In cancer care, we believe that there is room to align around important clinical and economic outcomes that could lead to significant improvements in quality of care and life for our patients, so we welcome the proposed changes to Medicaid "best price" ("MBP") requirements in the PAVE Act.

Current requirements around reporting discounts on drugs means that manufacturers are required to report pricing data to the federal government to determine Medicaid rebates, Medicare Part B average sales price ("ASP"), and the 340B Drug Pricing Program ceiling price. These outdated requirements were not designed to be compatible with value-based contracting and have served to dissuade drug companies from pursuing innovative arrangements. COA is very pleased to see the proposed amendment to the statutory definitions of MPB to exclude payments made pursuant to value-based contracts.

As oncology providers, we would like to ensure that any changes that incentivize VBCs for drugs provide incentives for value- and outcome-based arrangements for both pharmacy and medical benefit drugs. In addition to the MBP impact, manufacturers of Part B products are concerned that substantial price concessions under VBCs would reduce ASP, and in turn, Medicare Part B reimbursement rates for their products. Relatedly, CMS may substitute Average Manufacturer Price ("AMP") for ASP under certain conditions.

It is COA's understanding that the PAVE Act's proposed changes to the statutory definition of MBP should also exempt VBCs from the ASP statute and protect manufacturer's ASP calculations, and that the omission of an ASP exclusion was simply an oversight in the PAVE drafting process. ***We underscore that it is essential to exclude drugs purchased through value-based arrangements from ASP in addition to MBP and AMP determinations.*** COA salutes these efforts to reconcile the various statutory pricing requirements through new exemptions under MBP, AMP, and ASP reporting to minimize unintended consequences for discounted drug prices as part of value-based arrangements. This will promote greater participation from drug manufacturers and increase innovative arrangements that can reduce costs and improve patient care.

Conclusion

COA looks forward to continuing to serve as a resource to policymakers on thoughtful reforms dedicated to promoting value, efficiency, and lowering the cost of cancer care. Community oncology providers have been active in pioneering oncology payment reform for years and are now working on the next-generation, value-based models that include payment for cancer drugs based on value to patients and the health care system.

Please do not hesitate to have your staff engage COA in any discussions about specifics of the PAVE Act and or value-based drug contracting/arrangements in general. We look forward to changes to the draft PAVE Act, especially regarding to our comments about ASP exclusions, and lending COA's support to the introduced PAVE Act.

We appreciate your leadership and vision in this area.

Sincerely,

Ted Okon
Executive Director

COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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October 26, 2018

Submitted electronically via www.regulations.gov

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: *OIG—0803—N, Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Payments*

Dear Ms. Edwards:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we thank you for the opportunity to submit this comment letter in response to the Office of Inspector General's ("OIG") Request for Information regarding the Anti-Kickback Statute ("AKS") and Beneficiary Inducement Civil Monetary Payments (OIG—0803—N) ("AKS RFI).

The Community Oncology Alliance ("COA") is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to independent community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. For more than 15 years, COA has built a national grassroots network of community oncology practices to advocate for public policies that benefit cancer patients. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, mid-level providers, oncology nurses, patients, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees.

As the providers of care for the majority of Americans battling cancer, community oncologists are highly aware of the importance and promise of value-based care. COA is committed to increasing the quality of cancer care while decreasing costs, and we are working tirelessly to make the CMS Innovation Center's ("CMMI") Oncology Care Model ("OCM") successful, while working on the next-generation model, which we refer to as the OCM 2.0. We support value-based models that can positively impact prices and utilization and we applaud the administration for its interest in removing regulatory barriers to value-based care.

Below are the recommendations we hope will be considered as potential reforms to the AKS are pursued.

Promoting Care Coordination and Value-Based Care

COA commends the administration for exploring factors that influence stakeholder participation in value-focused, innovative payment models. We believe these types of arrangements are important for all patients, but particularly for those battling cancer, who often face high-cost, complex treatment. Although the AKS includes certain exceptions and safe harbors intended to protect coordinated care arrangements, the lack of clarity surrounding many safe harbors has fostered significant uncertainty

for stakeholders and has limited their willingness to enter into these types of arrangements. We believe specific guidance around how the administration would apply the AKS to specific situations concerning value-based programs could help promote greater development and adoption of these arrangements. Given the challenges the AKS poses to the transition from volume to value, clearly defined exceptions should be created in a way that increases transparency and clearly defines specific parameters for stakeholders.

Specifically, COA believes that in order to realize the potential benefits of value-based, risk bearing payment models, participants in all new payment models implemented by CMS and the CMS Innovation Center (e.g., OCM) should be granted similar flexibilities and exemptions offered under the Medicare Shared Savings Program ("MSSP"). Current requirements around reporting discounts on drugs, including those obtained through innovative value-based contracting measures, limit the effectiveness of these types of arrangements. Various reimbursement structures tied to Average Sales Price ("ASP") and Medicaid Best Price inhibit the testing of innovative value-based care coordination models involving performance-based drug arrangements that tie drug prices and costs to outcomes and other metrics.

We highly recommend that specific, clear exemptions be made to allow for testing models involving performance-based drug arrangements that tie drug prices and costs to outcomes and other performance metrics. COA has held over 50 meetings with pharmaceutical manufacturers to discuss incorporating performance-based arrangements into the OCM 2.0. We believe that these types of arrangements will tie drug prices to value in a manner that will lower overall drug expenditures.

Patient Support and Beneficiary Incentives

The AKS limits the ability for providers, manufacturers, and plans to help beneficiaries access tools to track the progress and effectiveness of their care. For example, the AKS restricts providers from providing complimentary services or tools that may incentivize or steer beneficiaries towards specific entities and/or settings of care. This outdated policy limits access to important technology and resources that can improve patient care. COA commends efforts to recognize the value of beneficiary adherence tools, including CMS' 2016 AKS rule, which focused on local transportation services and low-cost tracking or support tools. However, restrictions on free or subsidized patient tools, such as a smartphone, continue to serve as barriers that inhibit beneficiaries from accessing improved care. OIG and the Department of Health and Human Services ("HHS") can further reduce undue restrictions on beneficiaries' ability to adhere to care, including allowing the use of a physician, plan, or manufacturer-provided smartphone or tablet. These tools can provide care communication platforms and/or the means to transmit care-related data to help patients track and manage their health. These subsidized tools can provide flexibility to allow for greater education, adherence tracking, and treatment effectiveness outside of the clinical setting.

OIG has indicated that the utilization of services with "low-risk" of fraud or abuse will generally be exempt from AKS violations but has yet to provide additional information or insight into the range of items and services that might fall under such a classification. OIG should provide greater specificity around what activities OIG considers "low risk" and/or when OIG might provide exceptions that would further promote beneficiary adherence. This should include a comprehensive list of tools or categories of services to help providers, manufactures, and plans to consider how they can improve the quality of care and patient outcomes. Given the risk involved, OIG and CMS should consider allowing wide deference to patient support tools connected to value-based or outcomes-based payment or care strategies, assuming both parties can align on the type and quantity of the support.

The Intersection of the Stark Law and the AKS

Any future changes to the AKS or Stark Law exceptions and safe harbors should be aligned to ensure compliance is not overly burdensome. Recent HHS guidance concerning the AKS has granted additional flexibility to payment and care arrangements that are unlikely to create unnecessary utilization or increase the costs to government programs. However, it is problematic that such flexibility does not extend to the Stark Law.

Due to a lack of quality and cost transparency, many patients don't know which providers achieve the best outcomes at the lowest cost, or which diagnostic facilities would lead to the lowest patient out-of-pocket ("OOP") costs. Given the diverse range of services, diagnostics, and providers which cancer patients depend on for their treatment plans, the lack of care direction can lead to higher treatment and patient OOP costs. Due to complex compensation structures, providers may not be able to direct patients to low-cost, high-quality providers with affiliated entities due to the constraints of the Stark Law. This is the case even where those providers may actually lead to lower overall spending and improved outcomes. Therefore, COA recommends that HHS consider altering the definition of referral to consider the ultimate impacts of the referral on total costs and patient outcomes. This change would bring the Stark Law in line with the AKS, while ensuring that providers are able to coordinate their patients' care through the careful selection of team members who can deliver quality care in a cost-efficient manner.

Conclusion

COA looks forward to working closely with policymakers on thoughtful reforms dedicated to promoting value, efficiency, and lowering the cost of cancer care. Community oncology providers have been active in pioneering oncology payment reform for years and are now working on the next-generation, value-based models that include payment for cancer drugs based on value to patients and the health system.

We appreciate the opportunity to provide insight and comments and, as always, welcome the opportunity to discuss any of our comments with the OIG, HHS, or CMS.

Sincerely,

Ted Okon
Executive Director