



January 8, 2021

The Honorable Ami Bera, M.D.  
United States House of Representatives  
1727 Longworth House Office Building  
Washington, DC 20515

Re: Stark/Anti-Kickback/MBP Modernization RFI

Dear Representative Bera:

America's Physician Groups (APG) would like to write to express our support for your work and that of your fellow Innovation Caucus members in simplifying and modernizing the Stark and Anti-Kickback statutes. As you work to craft legislation to that effect, we were grateful to receive correspondence asking for stakeholder input on the finalized CMS and OIG rulemaking on Stark and Anti-Kickback and any suggested policy and legislative ideas to modernize these laws. We are pleased to offer the following feedback on the recently released Physician Self-Referral (Stark) Law Final Rule with ways that it could be strengthened to better support value-based arrangements and providers.

### **About America's Physician Groups**

APG is a national professional association representing over 300 physician groups that employ or contract with approximately 195,000 physicians that provide care for nearly 45 million patients. Our tagline, "Taking Responsibility for America's Health," represents our members' vision to move away from the antiquated fee-for-service (FFS) reimbursement system where clinicians are paid "per click" for each service rendered rather than on the outcomes of the care provided. Our preferred model of accountable, risk-based, and coordinated care avoids incentives for the high utilization often associated with FFS reimbursement. APG is committed to Medicare Advantage and the flexible, affordable, and efficient care it provides for seniors.

### **Recommendations**

**We agree with the full financial risk exception within the final rule that applies to value-based arrangements between VBE participants in a VBE that has assumed full financial risk for the cost of all patient care items and services.** As one of the leading proponents of the movement from volume to value, actions that support the ability of healthcare providers to accept financial risk, to achieve greater financial incentives for providing high quality care at lower costs, is something we support wholeheartedly.

**We would, however, ask that the caucus take into consideration the scope of the other three exceptions included in the final rule.** While we are confident that the majority of those whom would seek to apply for the new exceptions included in the final rule are fully engaged in value-based care and acceptance of risk, there should be some caution applied to ensure that these exceptions are not written and applied in such a broad fashion that some healthcare entities and providers that do not fully qualify as accepting some or full downside financial risk, or are not in true value-based arrangements, find themselves qualifying for some of the new exceptions, thus weakening the overall performance of these models and slowing the move toward value-based care. For instance, the Indirect Compensation Arrangements that Include a Value-based Arrangement exception seems at first glance to be so broad as to qualify many providers or entities with an exception that may not truly be value-based providers.

**Our members also believe that consideration to be given to whether those entities that are listed as being excluded from these exceptions are appropriately barred from consideration as participants.** One excluded set of entities that stands out is the set of entities involved in data analytics and technology. Organizations engaged in value-based arrangements are at the forefront of innovative care solutions, such as addressing behavioral health through technology that helps to encourage greater patient engagement. These emerging dynamics within value-based care must be encouraged and recognized. Excluding them from participation through this final rule hurts innovation at a time when our healthcare system needs it the most.

The Personal Services and Management Contracts and Outcomes-Based Payment Arrangements Safe Harbor policy establishes additional regulations aimed at protecting outcomes-based payment arrangements. The policy requires outcome measures be used to quantify quality improvements; reductions in payor costs; or both. The new policy excludes any payments made by pharmaceutical manufacturers, distributors, or wholesalers, PBMs, laboratories, compounding pharmacies, certain device manufacturers, distributors, wholesalers, and DME suppliers. **We believe that this policy as written is unclear for providers and fails to recognize pharmacists who participate in managed care or provide direct clinical work and are involved in outcomes-based payments and quality improvements.** Pharmacists and optometrists may be actively participating members of the care teams within these value-based entities, allowing for innovative care plans that can serve patients in a multitude of ways. Crafting exceptions within the Stark Rule that allow innovative care planning to develop is essential in the overall growth of value-based arrangements.

Thank you for your attention to the above comments. Again, we thank you for your continued support for, and attention toward, value-based care and the organizations engaged in moving our healthcare system away from volume and toward value. We look forward to continuing to work with you throughout this process. Please feel free to contact Valinda Rutledge, Senior Vice President, Federal Affairs, ([vrutledge@apg.org](mailto:vrutledge@apg.org)) if you have any questions or if America's Physician Groups can provide any assistance as you consider these issues.

Sincerely,



Donald H. Crane  
President and CEO  
America's Physician Groups

cc: Representative Mike Kelly, Representative Ron Kind, Representative Tony Cárdenas, Representative Roger Marshall, M.D., Representative Markwayne Mullin, Representative Brad Wenstrup, D.P.M.