MEDICAL ALLEY ASSOCIATION

October 26, 2018

Via Electronic Submission to www.regulations.gov
(Docket No. OIG-0803-N)

Daniel R. Levinson
Inspector General
Department of Health & Human Services
330 Independence Avenue SW, Room 5250
Washington, D.C. 20201

Re: Request for Information Regarding Anti-Kickback Statute and Beneficiary Inducements CMP

Inspector General Levinson,

Thank you for the opportunity to share our comments and suggestions regarding modifications to the Anti-Kickback Statute and other existing restrictions on beneficiary inducements. Ensuring patients receive the highest quality of care for the lowest possible cost is the top focus and concern of our members. Reforming or eliminating existing barriers to value-based arrangements and care coordination is critical to accomplishing this goal and we applaud HHS' emphasis on doing so.

The Medical Alley Association champions and facilitates an environment that enables the health technology and care community to innovate, succeed, and influence the evolution of healthcare. Developing new ways to improve patient care at lower costs is the key driver of the innovation done in Medical Alley. Our members have always been at the forefront of healthcare delivery and value-based care is no different. Their shared experience and expertise have helped us develop and frame our comments below.

Eliminate Barriers to Care Coordination and Value-Based Arrangements

Improving outcomes while reducing costs for patients should be the primary factor when contemplating changes to healthcare regulations. This requires a comprehensive look at what regulatory barriers are currently slowing or outright stopping healthcare innovators from achieving this. A few key changes can be made to existing law that would enable, and speed, the development of value-based arrangements and accurately measure the full value of the arrangement, resulting in lower costs and improved outcomes for patients, while maintaining important protections against fraud and abuse.

Value-based arrangements (VBAs) are ultimately judged on whether the parties sharing resources and accountability are able to achieve a particular outcome, while also improving cost efficiency. Under the current regulatory structure, parties contributing to care coordination may still run afoul of the law. This is because it could be viewed as improper remuneration, as it may influence referral patterns or indirectly relate to the volume of services delivered.

Another issue holding back VBAs is a set of definitions that are not useful in the context of truly value-based care. These include seemingly innocuously sounding concepts such as 'Fair Market Value' (FMV), which is the amount the Anti-Kickback Statute requires all services to be charged and priced. A major

challenge with using FMV in a value-based context is that, because the healthcare market is new to these types of arrangements, it is difficult to find offerings to serve as benchmarks. The result is that by moving ahead and pricing services or products as what they determine to be FMV, stakeholders would take on enormous legal risk. This is something many are understandably unwilling to do; patient care and innovation suffers as a result.

HHS itself has seemingly recognized the limitation of FMV by excluding it (and "volume and value of referrals") from the Medicare Shared Services Program (MSSP) and other, similar Center for Medicare & Medicaid Innovation (CMMI) waivers. HHS should extend waivers available to those participating in these programs, or the Accountable Care Organizations (ACO) program, to those implementing VBAs regardless of whether they are participating in these or other specific Medicare programs. Providing this flexibility for arrangements that meet value-based healthcare criteria will result in improved patient outcomes while reducing their overall cost of care.

Similarly, the time horizon necessary to properly capture the full value of the arrangement is extremely important. If too short of a time horizon is used, the VBA will appear to only increase the cost of care to the patient. Should too long of a time horizon be used, more uncertainty will be introduced into the measurement of spending and outcomes, making them all but useless. For these reasons, flexibility should be given to use time horizons that fit the purpose, arrangement, clinical nature, data availability, and other similar factors.

<u>Modify Existing, or Create New, Safe Harbors to Allow for Use of Devices for Remote Patient Monitoring</u>

Patient care does not stop at the clinic door. Successful treatment and recovery often require patients to adhere to a course of treatment or regular check-ins from doctors or nurses. A patient improperly following their doctor's orders, neglecting to adequately track needed indicators, or a provider's inability to consistently reach a patient to check-in can have serious negative consequences, such as costly re-hospitalizations or other serious health issues.

Remote patient monitoring is one way to combat the negative health consequences from the traditional means of patient care outside of a clinical setting. These technologies and services allow providers to track patient compliance to a course of care and vitals – particularly whether a patient is taking the drugs that have been prescribed in the right amount and at the right time or following discharge from a hospital after surgery – as well as the patient's general health and overall well-being. Unfortunately, the current statute often serves as a barrier to arrangements that enable a provider to bundle services with the products needed for effective remote patient monitoring.

This barrier extends beyond the traditional physician/patient relationship. Patient compliance or adherence devices, as well as mobile apps or other reminder type services, serve as a valuable tool for other stakeholders – such as manufacturers – to improve patient outcomes and advance patient care. Data from these devices enables collection of real-world evidence and will support physicians to better tailor a course of care a specific patients, based on the experience of other patients. Applying the knowledge gained from what worked – or hasn't – for other patients (in a secure, unidentifiable manner), particularly in terms of compliance and adherence, is key to the success of many VBAs.

In a VBA, the parties have already determined that the product is valuable as part of the course of treatment. The existing discount safe harbor has narrow technical requirements that must be met for a proposed arrangement to fit within it. Part of this is due to the requirement that all items in the bundle

be reimbursed by the "same methodology" – a term around which there is no consensus. This results in a review of the facts and circumstances of each arrangement which, due to these being inherently subjective and inconsistent, likely would lead to a stakeholder deciding potential criminal prosecution is not worth the effort to design and implement an innovative VBA.

Modifying the aforementioned existing safe harbors, or creating a new one, to allow for remote patient monitoring and other services to be offered alone or packaged with other device therapies as part of a VBA is a critical part of improving patient outcomes and reducing costs, the very goal of value-based healthcare.

Ensure Existing Safe Harbors Allow for Proper Adoption of Needed Cybersecurity Upgrades

The use of Electronic Health Records (EHRs) is now ubiquitous in patient care. While this development has improved patient care, it has brought its own set of challenges. These include interoperability problems between different EHR companies and health providers, physician unhappiness and burnout, and protection of the patient data contained in the EHR. This final challenge is perhaps the most critical to resolve in order to ensure patient safety and develop more effective methods of coordinated care.

Protecting patient data is critical for any player in the healthcare industry. Failure to do can have catastrophic consequences for patients. Although the primary concern is with EHRs, the development of the digital health field has broadened the need for appropriate data protection. For example, many health IT companies have platforms that connect to medical devices, which enables the improved delivery of cost-effective collaborative care. The successful, secure transfer of data is vital to the success of many new methods of patient care and analysis. Proper cybersecurity systems, however, can be – and often are – expensive and difficult to manage.

The most effective way to address this issue is to revise and extend the existing exceptions for donation and financial support of EHR software, connected medical devices, related technologies, and training, to specifically include technology related to cybersecurity. Since, as noted above, cybersecurity systems can be challenging to effectively execute without the requisite knowledge and experience, many recipients of EHR software under the existing exception may be vulnerable to security breaches. Additionally, parties may be using outdated connected medical devices which are vulnerable and in need of security updates. Advancement in patient care and the development of new heath technology solutions should not be hampered by regulations preventing deployment and proper functionality of cybersecurity protections by those who know it best. Making this small change to the existing law would provide better care for patients and enhanced protection of their data.

Thank you again for the opportunity to share our thoughts and suggestions. Please let me know if we can provide anything further.

Sincerely,

Shaye Mandle
President & CEO
Medical Alley Association