Consumer Technology Association™

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

December 30, 2019

Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P, Room 5521
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

BY ELECTRONIC SUBMISSION

Re: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, And Civil Monetary Penalty Rules Regarding Beneficiary Inducements

The Consumer Technology Association (CTA®) appreciates the opportunity to submit comments in response to the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) proposals regarding the federal Anti-Kickback Statute (AKS) provisions for certain coordinated care and associated value-based arrangements between or among clinicians, providers, suppliers, and others that squarely meet all safe harbor conditions.

As North America's largest technology trade association, CTA® is the tech sector. Our members are the world's leading innovators—from startups to global brands—helping support more than 18 million American jobs. CTA® owns and produces CES®—the largest, most influential tech event on the planet.

On the policy front, CTA's® Health and Fitness Technology Division strives to advance the use of consumer-based technology enabled health solutions to deliver better health outcomes and reduce overall healthcare costs. The Division, which includes some of the most well-respected thought leaders in the health care and technology sectors, provides policy advocacy, health care market research, and standards initiatives that advance the appropriate use of consumer technologies in the health care context. Many of our members are leaders in the digital health economy and can provide HHS a unique perspective.

Consumer Technology Association™

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

Unlike most trade associations, CTA® is accredited by the American National Standards Institute (ANSI) as a Standards Development Organization (SDO), and we have long history of voluntary national standards development. Among the wide range of topics addressed by our standards program are health, fitness & wellness, video, and drones. Both CTA® members and non-members can participate in the standards program. Just as significantly, CTA® partners with other standards developers and organizations to develop joint documents and information sharing.

GENERAL COMMENT

CTA® appreciates OIG's continued leadership in adding new safe harbors and modifying existing safe harbors to the Anti-Kickback Statute to protect remuneration exchanged under certain value-based arrangements. OIG's approach will help move the current healthcare system away from rewarding high volume healthcare not tied to quality to one based on value and patient outcomes. Many of our members proactively engage in value-based arrangements through innovative and patient-centered solutions. While we commend OIG's focus on value-based arrangements, we are concerned that OIG's proposal to exclude specific industries from Anti-Kickback Statute safe harbor protection could limit the availability of impactful technology and solutions that are part of many of these innovative arrangements.

OIG's Proposal May Exclude Key Technology Producers from Safe Harbor Protection

OIG defines a value-based enterprise (VBE) participant as an individual or entity who engages in at least one value-based activity as part of a value-based enterprise. The definition excludes pharmaceutical manufacturers; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); or a laboratory. OIG has voiced concerns that these entities may misuse the safe harbor to offer remuneration to practitioners and patients to market their own products. These entities could then create "value-based arrangements" that require clinicians or patients to use a particular product over others that may be more appropriate. Ultimately, OIG believes that these entities "are less likely to be on the front line of care coordination and treatment decisions."

OIG is considering the possibility of excluding other entities—specifically medical device companies—from acting as VBE participants entitled to safe harbor protection. OIG believes companies that make "mobile health and digital technologies" can be considered VBE participants under the proposed rule. The agency, however, is concerned about the risk that some companies

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

that manufacture medical devices covered by federal healthcare programs (particularly implantable devices used in a hospital or ambulatory surgical center setting), might misuse value-based arrangements to disguise improper payments for care coordination really intended as kickbacks to purchase the medical devices they manufacture. This concern stems from past enforcement experience, including large False Claims Act settlements involving kickbacks paid to physicians, hospitals, and ambulatory surgery centers to market various medical devices. In some cases, these improper schemes resulted in patients getting medically unnecessary procedures. OIG also has longstanding concerns about physician-owned distributorships in which financial incentives are offered to their physician-owners that may induce those physicians to perform more procedures (or more extensive procedures) than medically necessary—and to use devices the physician-owned distributorship sells in lieu of other, potentially more clinically appropriate, devices.

As a result, OIG is considering how to define the term "medical device manufacturer" from several approaches, including: (1) incorporating the definition of "applicable manufacturer" from the Physician Payments Sunshine Act; (2) relying on the products that a manufacturer produces (any manufacturer of an article that requires premarket approval by FDA or is classified as a medical device); and (3) basing the definition on whether the product manufactured by the company is eligible for separate or bundled payment from a federal healthcare program or is used in a test eligible for separate or bundled payment.

OIG is particularly interested in whether the definition could "exclude medical device manufacturers [from safe harbor protection] without limiting beneficial digital technologies." CTA® cautions that any definition of "medical device manufacturer" that excludes such a manufacturer from qualifying as a VBE participant may unintentionally impact the availability and use of mobile and digital health technologies and solutions that OIG itself has stated provides benefit to value-based arrangements.

Investments in digital health topped $8.5 billion in 2018 and that number is expected to be surpassed in 2019.[1] Many of those investments come from medical device manufacturers. We believe that the unintended consequence of OIG's proposed approach would be to arbitrarily limit available digital medical solutions.

[1] https://rockhealth.com/reports/2019-midyear-digital-health-market-update-exits-are-heating-up/; https://www.geekwire.com/2019/digital-health-investments-hit-time-high-8-6b-2018/; and https://www.geekwire.com/2019/digital-health-investments-hit-time-high-8-6b-2018/.

OIG Should Not Exclude Specific Entities or Industries from VBE Participation

Manufacturers that produce medical devices, DMEPOS, or other solutions should not be excluded from participating as VBE participants. Manufactures play an important and evolving role in care coordination and in the expansion of digital medicine. These stakeholders are on the frontlines of producing innovative technologies such as mobile health, remote monitoring, data analytics, patient portals, and other healthcare technologies that OIG itself lauds for holding "promise for improving care coordination and health outcomes through monitoring of real-time patient data and detection and prevention of health problems."

OIG must appreciate that the traditional medical device technology industry is highly dynamic and undergoing great change. This includes disruptive new entrants into the marketplace as well as significant mergers, acquisitions, and divestitures. Tracking this change would take a near-daily assessment and analysis of the entire medical industry to have a clear understanding regarding which companies market "medical devices," "DMEPOS," or other "health technology."

As discussed above, part of OIG's concern is based on its enforcement history but seems to disregard equally valid concerns with hospitals, physicians, and other providers. OIG's own website profiles various perpetrators of healthcare fraud including providers, physicians, hospitals, home health companies, and skilled nursing facilities, and others who OIG says can serve as VBE participants.[2] In fact, the government's primary fraud and abuse laws—the Anti-Kickback Statute and the Physician Self-Referral Law—are not aimed specifically or exclusively at medical technology or drug manufacturers, DMEPOS suppliers, or others not eligible to qualify as VBE participant. Instead, the focus is on improper activity across the healthcare delivery spectrum.[3] OIG's concern about historic settlements "involving kickbacks paid [by medical device makers] to physicians, hospitals, and ambulatory surgery centers" appears not to consider how the Anti-Kickback Statute creates two-way criminal liability—making it a felony to offer and pay as well as to *solicit and receive* a kickback. OIG should have the same concerns about both the alleged offerors and payors as well as the solicitors and recipients of kickbacks.

CTA® encourages OIG to continue focusing its efforts on developing safeguards to protect against the types of behavior that would create fraud and abuse risks, including many of the safeguards OIG

[2] https://www.oig.hhs.gov/fraud/strike-force/; https://www.oig.hhs.gov/fraud/enforcement/criminal/index.asp.
[3] *See, e.g.,* DOJ Press Release, "United States Files False Claims Act Complaint Against South Dakota Neurosurgeon and Physician-Owned Distributorships," Nov. 14, 2019, *available at* https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-south-dakota-neurosurgeon-and.

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

proposes in the rule—such as prohibiting abusive marketing practices (e.g. requiring a physician's prescription for any value-based arrangement involving the use of a particular technology), protecting providers' independent clinical decision-making authority, or otherwise limiting the risk of over or underutilization of care. This could also mean requiring a VBE's governing body to implement additional monitoring, reporting, and data submission requirements within the VBE.

Patient Engagement and Digital Support Tools

OIG proposes a new safe harbor that would protect arrangements under which a VBE participant provides a patient with tools and supports intended to improve quality, health outcomes, and efficiency. As proposed, the safe harbor would protect patient tools and supports intended to improve care coordination. Tools could include supports for patient safety (at home or during care transitions) or that permit better communication with providers. OIG cites health-related technology and monitoring tools and services, like wearable monitoring devices or trackers to collect key information for treatment or disease monitoring.

OIG has warned that device manufacturers could use these support tools "to market their products or divert patients from a more clinically appropriate item or service, provider, or supplier." We reiterate our position that OIG should not exclude any one industry sector or type of entity from protection under the safe harbor—but instead focus on program integrity safeguards that would prohibit inappropriate behavior. To illustrate our point, OIG proposes to prohibit in-kind items used for patient recruitment or for marketing items or services to patients. It is also considering requiring, as determined by a patient's provider: (1) a direct connection between the patient tools and supports and the coordination and management of care; and (2) a direct connection to adherence of a treatment regimen or disease management plan. These kinds of requirements may presumably limit the risk of misuse and abuse of the safe harbor by focusing on the types of improper behavior with which the OIG is concerned. Simply excluding entities or whole industries from VBE participation, however, would not necessarily prevent inappropriate conduct.

OIG is also contemplating a requirement that offerors of patient tools and supports must take reasonable efforts to retrieve an item or good furnished as a tool or support. OIG suggests it would set a minimum value for the item/good above which offerors would be required to make reasonable retrieval efforts (for example, $100, $200, $500, etc.) while limiting retrieval for tools and supports that are practicable to recover (i.e., not fixtures). We support OIG's proposal to limit any such retrieval efforts to patient engagement tools and supports that are above a certain threshold value.

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

Establishing those thresholds should take into consideration fair market depreciated values for similar items, products, and articles.

Safe Harbors Should Clarify Multi-Function Equipment Exclusion

CTA® urges OIG to clarify that devices with multiple functions do not violate the AKS or the Civil Monetary Penalties Law (CMP) when it is primarily used for healthcare purposes. Increasingly in our interconnected health, medical and consumer product ecosystems, medical devices are being produced that have multiple functions. Multi-function devices offer the unique ability to report medical device data from a user virtually wherever and whenever possible. Data captured and reported may including both health-related information as well as other aspects of an individual's life, that while not directly health-related may nevertheless impact health. Near real-time information about a patient's activities is often as valuable as physiologic information (e.g., weight, blood pressure, or heart rate).

OIG Should Allow Donations of Cybersecurity Technology and Supportive Services

CTA® supports the creation of an AKS safe harbor to allow donations or subsidies for cybersecurity technologies—including hardware, software, or combinations thereof, in addition to in-kind expertise/services and other support. As the healthcare sector evolves technologically with greater emphasis on interoperability, so do threats faced by providers, insurers, vendors, and patients. OIG should do its best to incentivize the sharing of sophisticated cybersecurity technology and support.

Inducements

CTA® urges OIG to carefully consider how to ensure that it does not stifle innovative healthcare provider arrangements for care coordination implemented via remote patient monitoring technologies. It is logical to assume that any professional that risks potential civil and criminal exposure under AKS will likely avoid entering complex arrangements—no matter a particular arrangement's potential to improve patient outcomes and reduce costs. In fact, many current arrangements designed to increase the adoption of digital medical services may arguably constitute improper "beneficiary inducements" under the CMP—making it difficult for healthcare providers and technology stakeholders to collaborate to improve patient health and outcomes. OIG should reexamine what constitutes an inducement and help healthcare organizations and providers better

understand these complex regulations by offering FAQs, guidance, or web-based access to additional information.

OIG Should Institute Waivers for Cost-Sharing Obligations Related to Care Management Services

In OIG's 2018 Request for Information, stakeholders expressed their challenges with the collection of small beneficiary cost-sharing (i.e., co-pay amounts) associated with "care coordination services."[4] A Kaiser Family Foundation report describes how relatively small amounts of cost sharing are associated with reduced use of care, including a reduction in the provision of necessary services.[5] Some of our members have reported that cost sharing (even de minimis amounts) may act as a barrier to the adoption of new technologies. Patients tend to show a general reluctance to adopt new and unfamiliar services when faced with increased out of pocket costs—regardless of the efficacy of the new service.

A 2016 Congressional Budget Office policy article on cost-sharing rules noted that "[i]Increases in cost sharing expose people to additional financial risk and may deter some enrollees from obtaining necessary care, including preventive care, that could limit the need for more expensive care in the future."[6]

We recommend OIG consider instituting safe harbor protection for waivers for cost-sharing associated with new technologies such as digital medicine that include care coordination functionality and remote patient monitoring. Such safe harbor protections would be consistent with the program goals to establish greater coordination and care. Co-pays should not be the reason patients turn away from needed care.

* * * * *

CTA® thanks OIG for this opportunity to comment, and we welcome discussing these issues in more depth. In the meantime, if you have any questions, please do not hesitate to contact us.

[4]OIG should properly streamline definitions as opposed to creating new ones such as "care coordination services." The Centers for Medicare and Medicaid Services (CMS) recently updated the Physician Fee Schedule to improve payment for care management and care coordination under the title of "Care Management Services." These include several non-face-to-face physician services such as Transitional Care Management, Chronic Care Management, Behavioral Health Integration, Interprofessional Consultation, and Remote Physiologic Monitoring (84 FR 62685). Keeping a consistent taxonomy would help sustain baseline definitions and understanding between complimentary HHS programs.
[5]https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.
[6]https://www.cbo.gov/budget-options/2016/52235.

Consumer Technology Association™

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

Respectfully submitted,

Consumer Technology Association

Michael Petricone
Senior Vice President, Government and Regulatory Affairs

René Quashie
Vice President, Policy and Regulatory Affairs, Digital Health

Kinsey Fabrizio
Vice President, Member Engagement, Health and Fitness Technology

1919 South Eads St.
Arlington, VA 22202