ALLIANCE *for*
CONNECTED CARE

December 31, 2019

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Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5521
330 Independence Avenue, SW
Washington, DC 20201

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 Alliance for Connected Care (The Alliance) appreciates the opportunity to comment on proposed rules revising safe-harbors under the Anti-Kickback Statute and Civil Monetary Penalty (CMP) rules on beneficiary inducements. Our members support the goals of the Department of Health and Human Services' (HHS) Regulatory Sprint to Coordinated Care and thank the Office of the Inspector General (OIG) for its thoughtful proposals and questions.

The Alliance is dedicated to improving access to care through the reduction of policy, legal and regulatory barriers to the adoption of telemedicine and remote patient monitoring. The Alliance's membership brings together diverse industry leaders - from providers of direct patient engagement to physician consultation and remote monitoring, as well as the connected care technologies that are already facilitating the future of health care delivery.

Members of the Alliance for Connected Care have seen firsthand how expanded access to telehealth and remote patient monitoring can better coordinate care, create economic efficiencies, and drive better health outcomes. Greater utilization of connected care technologies is a natural outcome of shifts to more outcome-focused and value-based care models. We applaud HHS for its push to support more value-based care models and support efforts create more flexibility for care delivery within these models.

The Alliance encourages OIG to approach all regulation of digital health technologies in a platform and technology agnostic manner. It is critical that regulations drafted today do not hinder or prevent the next generation of digital health technologies that we are not yet able to predict.

The Alliance will focus its comments on four priority areas for telehealth and remote patient monitoring in the proposed rule.

- Request for comment on the possible exclusion of health technology companies from value-based safe harbors

- Implementation of the statutory exception for telehealth technologies for in-home dialysis as passed by Congress
- New opportunity to protect arrangements involving telehealth and remote patient monitoring under the care coordination safe harbor
- New safe harbor for patient engagement and support that could include telehealth and remote patient monitoring services

Request for Comment on an Exclusion of Health Technology Companies from Value-Based Safe Harbors

As part of its overarching structure for Value-Based Enterprise, OIG identifies companies that are providing mobile health and digital technologies to physicians, hospitals, patients, and others for the coordination and management of patients and their healthcare as eligible to participate. However, OIG also proposes to expressly prohibit many organization types, including pharmaceutical and device manufacturers from consideration as a Value-Based Enterprise Participant.

The Alliance agrees with OIG's assessment that it may not always be possible to consistently differentiate by organization type, as a mobile and digital health company could also be a device manufacturer. The Alliance shares this concern and appreciates OIG questions on how best to distinguish among entities that would be included or excluded from the definition on the basis of factors such as product type, company structure, heightened fraud risk, or other features.

Rather than create categories by organization type, the Alliance recommends that OIG tie its definition of value-based enterprise participant to the services rendered to the patient. The qualification for a digital health tool to fall under the safe harbor for value-based enterprise should require an ongoing service being delivered by a clinician – for which the digital health tool is a critical part. The digital health tool as a standalone item should not be covered under the safe harbor. It should instead be covered when included as part of an ongoing service (for which clinical outcomes will be measured) – a situation where it no longer has the same risks that OIG may associate with traditional medical devices. For example, a remote patient monitoring device by itself would be a device – but when part of a remote patient monitoring service, that device becomes part of the service and is then evaluated as part of the service being delivered. In this context, a device is supervised by a care provider who has a defined value-based plan and goal, and who will adhere to clearly defined care protocols. This said, we acknowledge that even this definition will not hold up to every situation. The next frontier in digital health – artificial intelligence will begin to blur the lines between a simple "dumb" device and a care management service that leverages digital health tools.

We agree with OIG's stated goals of preventing abusive marketing practices, protecting independent clinical decision making about products, and reducing the risk of inappropriate cost shifting to federal health care programs. However, we believe that many of the considered solutions – such as the need for explicit definitions for an exclusion list – have the potential to go too far in limiting value-based enterprise

for health technology companies. Broadly speaking, digital health companies should be able to participate in value-based enterprise and share in risk-based arrangements—provided they are operating under the same outcome-based incentives as other participants. OIG should take steps to protect the independent judgement of the managing clinician working under a value-based arrangement, but does not need to intervene on a technology or service-specific basis.

Implementation of the Statutory Exception for Telehealth Technologies for In-Home Dialysis as Passed by Congress

The Alliance is pleased to see the implementation of important provisions created by Congress through the *Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act*. A key provision in the Act amended the Social Security Act to permit an individual with End stage renal disease (ESRD) receiving in-home dialysis to elect to receive their monthly ESRD-related clinical assessments via telehealth if certain conditions are met. In order to implement this provision, OIG created a new exclusion from the definition of "remuneration" under the Beneficiary Inducement CMP regulations.

The Alliance believes that implementation of this provision is crucially important, both for individuals with End-Stage Renal Disease (ESRD) and because of the precedent this Congressionally-mandated provision will set for other digital health exclusions under the CMP. OIG lays out three guiding principles for this exclusion – that the technology 1) contributes substantially to the provision of telehealth services related to the individual's ESRD, 2) is not of excessive value, and 3) is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes. Additionally, it articulates an underlying intent of preventing telehealth from being used as a beneficiary inducement. OIG also articulates consideration of instituting a limitation that the exception could "protect telehealth technologies that provide the beneficiary with no more than a *de minimis* benefit for any purpose other than furnishing telehealth services related to the individual's ESRD" and limited to Medicare Part B Services. Finally, OIG proposes a definition for "telehealth technologies" consistent with the definition of "interactive telecommunications system" found at 42 CFR 410.78 but it requests input on a wide range of other potential limitations on this definition.

The Alliance respects OIG's efforts to ensure that technology to support telehealth services not be of excessive value and not duplicative of existing technologies in the beneficiary's home. The Alliance has some concerns that the idea of limiting coverage to the *de minimis* benefit might create complications for patients with multiple health needs that could be fulfilled by the same device. We would encourage OIG to consider a scenario in which the same digital health tool could be used for the ESRD concurrently with a coordination/patient engagement arrangement. It would not be a good use of resources to set up a system in which the patient was prescribed two separate digital health tools, when one (perhaps slightly more expensive device) would meet all needs.

As a general principle, the Alliance supports implementation in as technology-neutral a fashion as possible, to facilitate the development of more efficient means of delivering the same services. The overarching description of a two-way interactive communication system meets this threshold. However,

we would caution OIG not to go into unnecessary detail about specific technologies or services – which seem likely to change over time. We also believe that a technology-neutral approach is also the best way to facilitate the further development of "bring your own device" type approaches that should create opportunities to lower costs and simplify services for beneficiaries.

With regard to the retrieval of devices at the end of an arrangement, we encourage OIG to rely on a risk-based standard that allows a great deal of provider flexibility. There may be many situations in which the value of the device does not warrant the cost of retrieval, or in which a secondary use for the device is not a realistic option. In value-based arrangements, under which the cost of the device comes out of the bottom line of the accountable organization, there is very little risk that the accountable organization will make a poor financial decision. Similarly, if the device was tied to a service delivered as discussed earlier in this letter, there would be little incentive for the value-based entity not to collect items of significant value at the termination of that beneficiary-service relationship.

New Safe Harbor for Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency

This proposed safe harbor would protect in-kind remuneration exchanged between qualifying VBE participants with value-based arrangements that satisfies all the proposed safe harbor's requirements. Unlike other provisions in the OIG rule, this safe harbor does not require parties to bear or assume downside financial risk. Because of that, OIG recommends additional protections and proposes to require that parties in a value-based arrangement establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured, and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population.

Within this section, OIG indicates that it is considering, and it solicits comments on limiting the definition of "target patient population" to patients with a chronic condition, or alternatively, limiting any or all of the proposed safe harbors that use the target patient population definition to value-based arrangements for patients with a chronic condition. The Alliance strongly disagrees with this proposal, as the most critical opportunity to address many chronic conditions is prior to diagnosis. We seek to preserve the judgement of the treating clinician on potential risk factors and the need for preventative care coordination tools to be deployed in response to a wide range of health risks. In addition to chronic disease, social risk factors identified could include communication or transportation related concerns that create avoidable health outcomes. The risk of abuse for these low-cost tools is low, and frankly, most digital care coordination tools could be reimbursed hundreds of times over before reaching the cost of one avoided inpatient visit.

Regarding evaluation of care coordination programs, the Alliance recognizes the importance of tracking and evaluating care coordination arrangements. OIG states that it does not consider measures related to patient satisfaction or convenience to be valid measures for the purposes of this requirement. While OIG may not consider convenience to be a valid measurement by itself, the Alliance would contend that any utilization outcome that is tied to convenience would be worth evaluating. For example, if a care

coordination effort that leveraged telehealth had greater patient utilization and adoption than one which did not – that would be a valid measurement of the care coordination arrangement because it would have clear implications for the efficacy of care coordination tool.

We believe that the OIG proposal that a value-based arrangement be set forth in writing, with specific evidence-based, valid outcome measures against which the recipient would be measured to be a sufficient enforcement tool to ensure parties demonstrate efficacy. Allowing the parties in the agreement to set the performance goals and outcomes expected allows greater flexibility in the design of these measures, rather than OIG offering more prescriptive guidelines on what these measures should be. We encourage OIG to allow the participants in a value-based enterprise to design interventions and outcome measurements that best fit the needs of their patients.

New Safe Harbor for Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency

This proposed safe harbor protects patient engagement tools or supports to in-kind, preventive items, goods or services, or items, goods, or services such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health, that have a direct connection to the coordination and management of care of the target patient population.

Provided that participants are engaged in a value-based enterprise with clear goals and agreements, we believe OIG should allow significant flexibility with regard to the waving or reducing of cost-sharing obligations. As noted above, there are many circumstances in which cost-sharing requirements could reduce utilization and positive health outcomes. Physicians have reported that they have found themselves in a position of having to "sell" remote monitoring to patients because of the co-pays, even when it is the physician's belief that the tool is necessary for the patient's wellbeing. Cost-sharing requirements that make it more difficult for patients in a value-based enterprise to utilize tools designed to prevent avoidable, high cost conditions, address barriers to care, etc. would be counter to the stated goals of HHS and OIG in designing and implementing value-based arrangements.

As you know, even relatively small levels of cost sharing are associated with reduced use of care, including necessary services.[1] Requiring the patient to subsidize the provision of a necessary medical tool – particularly when it is known to the clinician that the tool will lower overall costs – undermines the recommendation of the clinician and discourages adoption. These tools include telehealth and remote patient monitoring services, communication-focused devices, and access to software-based platforms related to care delivery. In a value-based arrangement, participants should already be properly incented to avoid unnecessary utilization and keep total costs down.

[1] https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/

As previously mentioned, the Alliance encourages OIG to rely on a risk-based standard that allows a great deal of provider flexibility with respect to the retrieval of devices at the end of an arrangement. We believe collection requirements could become burdensome, particularly if applied to items that are not of high-value or reusable by the provider. In value-based arrangements, where the cost of the device comes out of the bottom line of the accountable organization there is very limited risk that the organization will make a poor financial decision. Similarly, if the device was tied to a service there would be little incentive for the value-based entity not to collect items of significant value at the termination of a beneficiary-service relationship.

Thank you for your consideration, we look forward to working with you on this important effort. Please contact Chris Adamec at 202-640-5941 or cadamec@connectwithcare.org with any questions.

Sincerely,

Krista Drobac
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