

ConnectedHealthInitiative

February 15, 2022

Christi A. Grimm
Principal Deputy Performing Duties of the Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-128-N; OIG-1117-N
Room 5527, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

RE: Comments of the Connected Health Initiative regarding *Solicitation of New Safe Harbors and Special Fraud Alerts*

Dear Ms. Flanzar:

The Connected Health Initiative (CHI) writes to respond to the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) annual solicitation of proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act, as well as developing new OIG Special Fraud Alerts.¹

I. Introduction and Statement of Interest

The Connected Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled healthcare system. For more information, see www.connectedhi.com.

II. Modernizing Enforcement of the Anti-Kickback Statute to Enable the Future Connected Care Continuum

Data and evidence from a variety of use cases continue to demonstrate how connected health technologies available today improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. These tools, including wireless health products, mobile medical device data systems, virtual care, telemonitoring-converged medical devices, and cloud-based patient portals, are revolutionizing American healthcare by securely enabling the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care. CHI's aggregation of numerous studies demonstrates

¹ HHS OIG, *Solicitation of New Safe Harbors and Special Fraud Alerts*, 86 FR 71611, (Dec. 17, 2021).

the improved outcomes and reduced costs associated with greater use of connected health innovations.²

Over time, HHS has taken important steps to better utilize digital and connected health technology in several components of Medicare, such as through the expansion of support for remote patient monitoring in the Physician Fee Schedule, as well as in key Medicare program Alternative Payment Models (APMs) like the Medicare Shared Savings Program (MSSP). Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. As a result, utilization of digital health innovations is disconcertingly low, despite their ability to drastically improved beneficiary outcomes as well as generate immense cost savings.

CHI notes its appreciation for steps taken by HHS in recent years to advance the use of connected health innovations use, such as CMS' steps to support remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) by Medicare practitioners by clarifying that RPM is not part of the Medicare Telehealth Services list and is not subject to Section 1834(m) of the Social Security Act's restrictions. CMS has established its support for a modality-neutral approach to direct interactions between patients and providers through its support for RPM codes and is poised to further expand this approach through its approach to Chronic Care Management, Transitional Care Management, and Personal Care Management Services.

While the important pro-digital health policy changes were made in the past, the pace of uptake for digital health innovations in the Medicare system continues to lag when compared to the well-established benefits and efficiencies this cutting-edge technology offers. As a community, we continue to support OIG's efforts to utilize advanced technology to augment care for every patient via modernizing safe harbors. With the congressionally mandated shift from fee-for-service to value-based care in Medicare's approach, OIG' efforts to improve its safe harbors, in coordination with other agencies, will be key in responsibly advancing the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

The healthcare system will not fully integrate these remote monitoring and virtual care technologies if current fraud and abuse regulations are not modernized, and a continued leading impediment to the uptake of digital health tools across healthcare systems is the anti-kickback statute (AKS) and its restrictions that do not contemplate efficiencies provided by digital health technologies. CHI agrees that the AKS is an important anti-fraud protection for Medicare; however, it has not kept pace with change within the healthcare industry. Instead, it may present barriers to innovation, and it is critical that there are considerations for new safe harbors. Many technology companies provide substantial financial and in-kind resources to support innovative care models. Under current fraud and abuse regulations, it is unclear the extent to which technology companies are able to contract directly with providers and manufacturers to address Medicare patients' needs. Existing waivers under the AKS and civil monetary penalties (CMP) for value-based arrangements are limited to participants in the Medicare Shared Savings Program or CMMI models. Many providers outside those programs would like to pursue opportunities to engage with technology companies to serve their patient populations. Because of the OIG's strict interpretation of the statute, it is risky for technology companies to enter into agreements to subsidize the costs of certain interventions for providers, even where those services would be medically necessary to reduce future health care costs.

² *Key Clinical Studies Demonstrating the Benefits of Connected Health Technologies*, (last visited Feb. 15, 2021), <https://bit.ly/2MblRou>.

III. CHI's Recommendations for the OIG's New Safe Harbors and Special Fraud Alerts

Generally, CHI supports the creation of AKS safe harbors that will responsibly facilitate greater acceptance and use of connected health innovations—be they hardware, software, or a combination of the two—throughout the continuum of care. We offer the following specific input on OIG safe harbors and special fraud alerts:

- a. *OIG Safe Harbors Should Enable All Entities that Enable Value-Based Care to Qualify as "Value-Based Enterprise"*

While the traditional value-based enterprise (VBE) is envisioned as clinicians, providers, or suppliers; we support digital health companies also being eligible for participation as a VBE due to their investment in and work surrounding the implementation of connected health technologies. Vendors of digital health technologies and services add significant value as VBE participants through their data analytics capacity and ability to access financial and other resources that are unattainable to many provider entities. The creation of innovative business arrangements that include digital health companies as active participants who can share in risk has the potential to impactfully move the needle and create improved outcomes at overall reduced costs. CHI recognizes that digital health technology companies' arrangements will still need to meet the other safe harbor requirements. However, by broadening the definition of a VBE, more patients will be able to benefit from a clinician, provider, or supplier entities' relationship with digital health companies, which will in turn improve patient outcomes.

OIG can better enable value-based care by ensuring that any entity enabling value-based care to provide outcome-based payments with certainty that such payments will not violate the AKS. Noting our support for including companies that make mobile health and digital technologies in the scope of a VBE entity, CHI strongly urges OIG to ensure that it does not exclude countless Americans from the benefits of connected care, consistent with HHS' goal of enhancing a connected care continuum including, but not limited to, to the provider setting. We believe that OIG shares our concern based on its past acknowledgement that its defining of a "medical device manufacturer" should not inadvertently limit the availability of the mobile and digital health technology that would provide benefit to value-based arrangements.

CHI notes that companies producing medical devices (either software, hardware, or some combination of the two), including DMEPOS manufacturers, play a significant and frontline role in providing for a fully connected care continuum that includes different settings outside of the provider's location. These technologies include -- but are not limited to -- patient portals that provide data analytics and remote patient monitoring systems, which are essential ingredients to effective and efficient care coordination through monitoring real-time patient data for those diagnosed with disease, as well as in the early detection and prevention of disease. We urge OIG to reduce confusion that would be caused by its declaration that pharmaceutical and DMEPOS manufacturers and laboratories are "less likely to be on the front line of care coordination and treatment decisions" by updating its discussion to reflect the role all of these entities play in today's care coordination.

The connected health technology market is rapidly evolving, with a melding of traditional categorizations within the medical industry taking place due to startups identifying new market niches, acquisitions, etc. Under OIG's current rule, many CHI members find themselves potentially classified as medical devices, DMEPOS manufacturers, and/or pharmaceutical manufacturers. This will result in further inconsistency with Congressional intent for the AKS and the Physician Self-Referral Law that focuses on conduct rather than organizational categorization.

Rather than unequivocally excluding industry categorizations from being VBE participants, OIG, through its safe harbors, should instead not exclude any certain entities from this scope and should focus its rules on behavior representing fraud and abuse in violation of the AKS. This approach would be consistent with many of the proposed safe harbors in OIG's proposed rule addressing marketing (e.g., requiring a prescription for use of a certain technology in a value-based arrangement) and clinical decision-making (e.g., allowing physicians to select technology from outside of the value-based arrangement if appropriate), among others. CHI believes that appropriate reporting and transparency requirements from the value-based arrangement, paired with objective enforcement, can largely make these safeguards feasible.

b. OIG Should Waive Cost-Sharing Requirements for Connected Health Technologies.

CHI stakeholders' experiences clearly demonstrate patient cost-sharing requirements to be a barrier to the uptake of connected health technologies used for care management and RPM. We support OIG providing for the waiver or offset of cost-sharing obligations for care management and RPM use cases where the cost-sharing waiver or offset of obligations is part of a value-based arrangement, particularly where the costs of collection exceed the amount to be collected, with reasonable and objective fraud and abuse measures.

c. OIG Should Exempt its Durable Medical Equipment Annual Certification Requirement for Remote Patient Monitoring.

CHI urges OIG to ensure that DMEPOS enabled by internet connectivity and new, innovative features be permitted to meet CMS' requirement for face-to-face encounters. Care providers can leverage connected health technology to obtain DME PGHD for continual evaluation and treatment of conditions. Such capabilities negate the need for an annual demonstration of medical necessity through their ongoing collection and transmission of PGHD. Therefore, CMS should mitigate or eliminate, through safe harbors, this annual certification requirement when remote patient monitoring tools, whether physiologic or therapeutic, can demonstrate medical necessity.

d. OIG Should Enable Patient Access to Digital Health Equipment and Software Platforms.

As clinicians remotely monitor patients at home who may have COVID-19 and other acute and chronic conditions, there are ongoing concerns that any equipment or access to software platforms provided free of charge may inadvertently trigger liability under the AKS. CHI requests that HHS OIG clarify that providing access to software-based platforms for PGHD analytics or telemedicine at no/low cost does not violate the AKS. Additionally, the operative definition for "remuneration" in this statutory provision, at 42 U.S.C. 1320a-7a(i)(6), is broad, and we recommend that the HHS OIG also provide clear guidance that giving patients a device to

communicate with a care team is not considered a beneficiary inducement. These clarifications will enable the provisioning of RPM, telehealth, and other tech-driven healthcare tools without triggering AKS liability.

- e. *OIG Should Enable Access to Devices with Multiple Functions to Reflect Modern Use of Digital Health Tools in Care Delivery.*

We call on OIG to clarify that utilization of a device with multiple functions, such as a smartphone or e-tablet, does not violate the AKS and the CMP when it is primarily used for managing a patient's healthcare, including the social determinants – e.g., finances, scheduling, and transportation – that impact a patient's health. Multifunction devices are essential to the successful and responsible application of connected health technology to improve outcomes and reduce costs. However, many existing interpretations of the AKS regulations and guidance prohibit such devices from reaching the patients who need it most. Multi-function devices offer the ability in clinical trials to validate the identity of trial participants and allow health care functionality to be integrated into the other digitized aspects of a patient's life, such as their email and text message communications, personal finances, or navigation, making patients more likely to use a multi-function device, while also giving providers real-time information about a patient's status (e.g., blood pressure or heart rate).

IV. Conclusion

We appreciate the opportunity to provide input on the OIG's solicitation of new safe harbors and special fraud alerts as it begins to develop new regulations.

Sincerely,



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