ConnectedHealth

December 31, 2019

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

RE: Comments of the Connected Health Initiative regarding *Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements* (OIG-0936-AA10-P)

Dear Ms. Edwards:

The Connected Health Initiative (CHI) writes to respond to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) proposed rule in which the OIG created safe harbor protections under the Federal anti-kickback statute (AKS) for certain coordinated care and associated value-based arrangements, and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of "remuneration" in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.[1]

[1] HHS OIG, *Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*, 84 FR 55694, (October 17, 2019) (OIG RFI).

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Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their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.

CHI is a long-time active advocate for the increased use of innovative technology in the delivery of healthcare and engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, Morgan Reed, executive director of CHI and president of its convening organization ACT | The App Association, is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group (DMPAG), an initiative bringing together a diverse cross-section of 15 nationally recognized experts to identify barriers to digital medicine adoption and propose comprehensive solutions regarding coding, payment, coverage and more.[2] CHI is also a board member of Xcertia, a collaborative effort develop and disseminate mHealth app guidelines that can drive the value these products bring to the market. These guidelines also seek to increase the confidence that physicians and consumers can have in these apps and their ability to help people achieve their health and wellness goals.[3]

II. Modernizing 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 the improved outcomes and reduced costs associated with greater use of connected health innovations.[4]

Over time, HHS has taken important steps to better utilize connected health technology in several components of Medicare, such as through the expansion of the PFS' Telehealth Services List, as well as in key Medicare programs like the Medicare Shared Savings Program (MSSP).

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[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group

[3] http://www.xcertia.org/

[4] This CHI resource is publicly accessible at https://bit.ly/2MblRou.

Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS 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. CMS coverage of remote monitoring was relatively anemic until CY2018 when current procedural code (CPT® Code) 99091 was unbundled, covered, and activated reimbursement payment for remote physiologic monitoring (RPM) services through the collection and interpretation of physiological data digitally stored and/or transmitted by the patient to the physician or qualified healthcare professional. Furthermore, CMS took critical steps to promote flexible use of remote monitoring innovations in quality payment program (QPP). For example, as part of the QPP's merit-based incentive payment system (MIPS) rules, CMS adopted an Improvement Activity (IA) that CHI proposed – IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care) – which incentivizes providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office. The IA gives providers credit to ensure that any devices they use to collect PGHD do so as part of an active feedback loop. CHI was encouraged that CMS had assigned a high weight and linkage to what was then called "Advancing Care Information" bonus to this IA, signaling to providers that CMS acknowledged the important role connected health tools could play in improving health outcomes and controlling costs.

The following year (CY2019) CMS also activated and paid for three new remote RPM codes: (1) CPT Code 99453 (education and set up), (2) 99454 (supply and transmission), and 99457 (20 minutes of treatment management services). CMS has also ensured that RPM utilization by home health agencies, as well in key alternative payment models such as the Medicare Shared Savings Program (MSSP) and Medicare Advantage. Building on its activation and payment for three new remote physiologic monitoring [RPM] codes in the CY2019 PFS, CMS has continued to progress in making meaningful policy changes to the support the use of digital health tools in Part B, activating and paying for a new CPT Code (99458) to cover each additional aggregate 20 minutes of review of PGHD in a 30-day period; and in clarifying that CPT Codes 99457 and 99458 may be furnished by "auxiliary" (clinical) staff under general supervision by a physician or Qualified Health Care Professional (QHCP), allowing that clinical staff to be located in another facility than the one where the physician/QHCP is located. However, we still await CMS guidance on use of remote physiologic monitoring, with CMS now indicating that it will provide such guidance in a future "rulemaking." CMS has also continued to expand the Medicare Telehealth Services List, this year addressing the opioid crisis.

Furthermore, this year CMS' (CY 2020) QPP notably finalized its Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) participation framework that begins in the 2021 performance year. CMS has made a handful of modifications to its MIPS program to ensure that MIPS program participants may use digital health tools in meeting program requirements, both in Quality Measures and Improvement Activities. However, CHI continue to encourage CMS to clarify the role of digital health tools in Alternative Payment Models (APMs).

As noted above, CMS has taken major strides forward in supporting the use of connected health innovations such as RPM by Medicare practitioners, notably clarifying that RPM is not part of the Medicare Telehealth Services list and therefore is not subject to Section 1834(m) of the Social Security Act's onerous and backwards-facing 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. Therefore, the CHI also encouraged CMS to align its DME payment policies, accordingly, including in establishing and demonstrating medical necessity.

While the progress described above represents important pro-digital health policy changes that are long overdue, 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 CMS' efforts to utilize advanced technology to augment care for every patient. With the congressionally mandated shift from fee-for-service to value-based care in Medicare's approach, CMS' efforts to further advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

However, the healthcare system will not fully integrate these remote monitoring and virtual care technologies if current fraud and abuse regulations are not modernized. The healthcare sector has evolved significantly since the enactment of the AKS in 1972. 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 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.

III. CHI's Recommendations for the OIG's Proposed Revisions to Safe Harbors Under the Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CPM) Rules Regarding Beneficiary Inducements

Generally, the 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's RFI:

A. OIG's Definition of "Value-Based Enterprise" (VBE) Should Be Inclusive of All Entities that Enable Value-Based Care, Rather Than Seeking to Categorically Exclude Certain Legacy Categories of Stakeholders

In the OIG's proposed rule, it references value-based enterprises to include "[a] network of individuals and entities that collaborate together to achieve one or more value-based purposes."[5] The OIG's Rule also notes that VBEs must agree to collaborate for the purposes of "(i) put[ting] the patient at the center of care through improved coordination (ii) increas[ing] efficiencies in the delivery of care, and (iii) improv[ing] quality of care and health outcomes for patients or populations."[6] While the traditional 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 can and do 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. The 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' relationships with digital health companies, which will in turn improve patient outcomes.

[5] § 1001.952(ee)(1)

[6] § 1001.952 (ee)

Notably, OIG's proposed definition of a VBE participant explicitly excludes a "pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies [DMEPOS]; or a laboratory,"[7] (which OIG states are "less likely to be on the front line of care coordination and treatment decisions"). OIG's concerns are based on such entities abusing safe harbor protections to market their products or require a clinician or patient to use a certain product when another may be more appropriate. Should OIG's proposal be finalized without changes, such entities would categorically not receive AKS liability protection through OIG safe harbors for patient engagement support. Furthermore, they would not be able to provide outcome-based payments with certainty that such payments would 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 reconsider this proposal, which, unless altered to permit DMEPOS manufacturers, distributors, and suppliers would exclude countless Americans from the benefits of connected care. This action would be counter to HHS' goal of enhancing a connected care continuum that is not limited to the provider setting. We believe that OIG shares our concern based on its discussion in the proposed rule regarding whether and how to define a "medical device manufacturer" without inadvertently limiting 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 or the two), including DMEPOS manufacturers, can and do 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 an 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 is 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 proposal, many CHI members would find themselves potentially classified as both medical device, DMEPOS manufacturers, and/or pharmaceutical manufacturers. The CHI advises against OIG basing its VBE definition and scope decisions on "historical enforcement" by attempting to fit these new market players into backwards-facing categories. 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.

[7] OIG RFI at 55703.

Rather than unequivocally excluding industry categorizations from being VBE participants, OIG 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. Such an 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's Should Permit for the Identification of Target Populations as Appropriate, Rather Than Categorically Excluding Certain Patient Groups.

OIG's RFI raises the possibility of limiting the reach of value-based arrangements to those that serve patients with chronic conditions.[8] CHI urges OIG to also enable value-based arrangements to assist patients as well, and believes that limiting their availability to those with chronic conditions would be a disservice to countless Americans. HHS (most recently through its final CY2019 and CY2020 Physician Fee Schedules) has already validated that the use of connected health technologies, such as RPM, should not be limited to patients with chronic conditions due to the demonstrated ability of such technologies to improve care widely and reduce costs. Scenarios past chronic condition treatment, such as post-surgical monitoring, are also primary use cases for RPM. Connected health technologies can and should be integral in *preventing* disease.

Without clarity from OIG as to the definition of "target populations," a serious risk of regulatory confusion exists that would prevent many organizations from helping target populations without chronic conditions based on liability concerns. Further, payors responsible for payment in a value-based arrangement should not be prohibited from being a part of the target population identification and selection process.

Instead of categorically excluding patients and stakeholders from the scope of a value-based arrangement, CHI calls on OIG to enable value-based arrangements to help any target population, and that payors are stakeholders able to be a part of value-based arrangements. Appropriate reporting, transparency, and auditing safeguards will prevent fraud and abuse while enabling the flexibility needed to create new and innovative value-based arrangements.

[8] OIG RFI at 55702.

C. OIG's Proposed Patient Engagement Safe Harbor Should Clearly Provide for the Provisioning of Connected Health Technology, Including RPM Tools.

The CHI supports OIG's proposal to create a new safe harbor "for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency".[9] This language should make it clear that value-based care arrangements and research arrangements may allow for connected health tools and services, such as RPM, to be provided at low/no cost without triggering AKS. OIG should ensure that that giving patients a device to communicate with a care team is not considered a beneficiary inducement; and that providing access to software-based platforms for PGHD analytics or telemedicine at no/low cost does not violate the AKS. We also urge OIG's approach to be focused on conduct, rather than a legacy categorization, consistent with our comments above.

CHI also supports OIG's proposed requirement that offerors of such patient tools make reasonable efforts to retrieve an item or good furnished to the patient once the patient is no longer in the target patient population, the VBE no longer exists, or the offeror is no longer a VBE participant.[10] We support limiting the retrieval requirement to those tools that are above a certain *de minimus* value threshold and that are practicable to recover.

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

The 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.

[9] § 1001.952(hh)

[10] OIG RFI at 55729.

E. OIG's Safe Harbors Should Clarify that Multi-Function Equipment Complies with AKS.

The CHI asks that OIG clarify, via an AKS safe harbor and revisions to the CMP, 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. Multi-function devices are essential in the successful and responsible application of connected health technology to improve outcomes and reduce costs, however, existing AKS regulations and guidance are often interpreted to 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 communication, personal finances, or navigation, making patients more likely to use a multi-function device while giving providers real-time information about a patient's status (*e.g.*, blood pressure or heart rate).

F. OIG Should Enable Donations of Cybersecurity Technology and Services.

We support creating an AKS safe harbor for the donation or subsidizing of cybersecurity technologies (hardware, software, or some combination of the two, including multi-functional hardware) and/or services. Creating an AKS safe harbor for the donation or subsidizing of cybersecurity technologies (hardware, software, or some combination of the two) and/or services. Like other critical infrastructure sectors, the healthcare sector faces increasing cyber-based attacks, both in quantity and in sophistication, which ultimately places patients at greater risk. CHI notes such a step has been endorsed by the Health Care Industry Cybersecurity Industry (HCIC) Task Force Report,[11] written pursuant to the Cybersecurity Information Sharing Act of 2015. Therefore, the CHI is encouraged by OIG's proposed safe harbor in 1001.952(jj) would assist in addressing the healthcare sector's increased risk of cyber-based attacks, both in quantity and in sophistication, which ultimately places patients at greater risk.

[11] Health Care Industry Cybersecurity Industry (HCIC) Task Force Report (June 2017) at p. 35, *available at* https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

G. OIG Should Eliminate its Durable Medical Equipment Annual Certification Requirement for RPM.

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 eliminate this annual certification requirement when RPM tools can demonstrate medical necessity.

IV. Conclusion

We appreciate the opportunity to provide input on the OIG's proposed rule and request that our views be considered as OIG moves forward to finalize its rule.

Sincerely,

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