ConnectedHealth

October 26, 2018

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
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; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP* (83 FR 43607)

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) Request for Information (RFI) in which the OIG seeks to identify ways in which it might modify or add new safe harbors to the anti-kickback statute (AKS) 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]

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Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their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

[1] HHS OIG, *Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP*, 83 FR 43607 (August 27, 2018).

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, 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 the 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. We urge OIG to review CHI's aggregation of numerous studies that demonstrate 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).

[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.

However, key advancements are taking place. In 2017, CMS took several major steps to advance the uptake of connected health innovations across its programs. For example, in 2017 CMS promoted the flexible use of remote monitoring innovations in the Quality Payment Program (QPP). As part of the QPP's Merit-Based Incentive Payment System (MIPS) rules, CMS adopted an Improvement Activity (IA) that CHI proposed – titled *Engage Patients and Families to Guide Improvement in the System of Care* (IA_BE_14) – which incentivizes providers to leverage digital tools (any devices they use to collect PGHD do so as part of an active feedback loop) for patient care and assessment outside of the four walls of the doctor's office. CHI is especially encouraged that CMS has proposed the adoption of new remote patient monitoring and virtual check-in codes as part of the 2019 Physician Fee Schedule.

However, the health care 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, may present barriers to innovation, and considerations for new safe harbors are needed. 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.

Generally, we urge creation of AKS safe harbors that will responsibly facilitate greater uptake of connected health innovations – be they hardware, software, or a combination of the two – throughout the continuum of care in conjunction with the above-noted advancements in HHS policy (and others). We believe that the OIG could provide clarification on questions regarding AKS to reflect realistic engagement program requirements. Such clarifications should include:

- Creating an AKS safe harbor for value-based care arrangements and/or for research arrangements, allowing for the integration of innovative technology into the provision of value-base health care. This safe harbor could help to ensure that giving patients a device (e.g., a tablet) to communicate with a care team is not considered a beneficiary inducement; or that providing access to software-based platforms for data analytics or telemedicine is not violating the AKS.

- Clarifying, via an AKS safe harbor and revisions to the CMP, that utilization of a device with multiple functions does not violate the AKS and the CMP. Multi-function devices are essential in the successful and responsible utilization of connected health technology to improve outcomes and reduce costs. Yet existing AKS regulations and guidance are often interpreted to halt this type of innovation from reaching the patients who need it most, because devices that offer non-health care related functionalities may be viewed as beneficiary inducements or illegal kickbacks. This chilling effect causes patients and the health care system to lose the benefit of these devices. Multi-function devices offer the ability in clinical trials to validate the identity of trial participants. These devices 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. Patients are more likely to use a multi-function device, meaning that they can now get reminders to comply with discharge instructions or take medications on time, and providers are more likely to receive real-time, important information about a patient's status, such as blood pressure or heart rate. This seamless integration of health technology into patients' lifestyles is in alignment with the federal government's emphasis on capturing social determinants of health and treating each individual as a whole person. In developing such a safe harbor, we urge OIG to consider the imposition of objective enrollment and participation criteria, such as proven effectiveness of better outcomes and reduced cost savings, using data collected through rigorous research studies.

- 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,[5] written pursuant to the Cybersecurity Information Sharing Act of 2015.

[5] 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.

- Modifying the “promotion of access to care” exception to the CMP, to remove barriers to more beneficiary incentive programs within value-based arrangements. OIG should allow for inclusion of items or services other than those characterized as “preventive care” in the current regulation. This should include the use of devices that are multi-functional, such as devices that have health-related functions as well as non-health functions. These devices blend seamlessly into patients’ day-to-day lives and are used continuously by patients, even as they sleep – leading to increased patient usage and adherence. OIG should also allow for increased flexibility with respect to the contribution of technology resources to synthesize incoming patient data, identify trends, and test new care coordination modalities.

III. Conclusion

CHI appreciates the opportunity to submit comments to OIG and urges its thoughtful consideration of the above input. We look forward to the opportunity to further work with OIG and other stakeholders towards modernizing the approach to the AKS.

Sincerely,

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