

December 31, 2019

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

RE: *Multi-stakeholder Comments to the Food & Drug Administration on 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 (OIG-0936-AA10-P)*

We represent a diverse coalition of stakeholders that span the healthcare and technology sectors, all of whom support the expanded use of connected health technologies. We actively participate in the administration of healthcare through connected technologies and medical devices. A consistently growing body of evidence demonstrates that connected health technologies improve patient care, reduce hospitalizations, help avoid complications, and improve patient engagement (particularly for the chronically ill). These tools, increasingly powered by artificial/augmented intelligence (AI), leverage patient-generated health data (PGHD) and range from wireless mobile remote physiologic monitoring (RPM) products and medical devices, telehealth and preventive services, clinical decision support tools, and cloud-based chronic care management solutions. It is essential that these tools be utilized to address the rising costs of healthcare to both the public and private sector. We appreciate the Office of Inspector General's (OIG's) efforts to develop safe harbor protections under the Federal anti-kickback statute (AKS) for certain coordinated care and value-based arrangements and to add protections under the AKS and the civil monetary penalty (CMP) law.<sup>1</sup> OIG's efforts are essential to the success of the Department of Health and Human Services' (HHS) regulatory sprint to coordinated care.

Data and evidence from a variety of use cases continue to demonstrate how the connected health technologies improve patient care, prevent hospitalizations, reduce complications, and increase patient engagement, particularly for the chronically ill. These tools are poised to revolutionize American healthcare by securely enabling the exchange of health information and incorporating PGHD collected from outside of the doctor's office into the continuum of care. Over the last few years, HHS has worked to enable caregivers and patients the ability to better utilize connected health technology. For example, CMS has taken several major strides to advance the responsible uptake of connected health innovations across several Medicare programs, such as through the adoption of new RPM Current Procedural Terminology codes in its Physician Fee Schedule, as well as beginning to put Quality Payment Program incentives into place for the use of connected health technologies.

While we are encouraged by HHS' progress described above, the American health care system will not fully integrate connected health technologies if existing fraud and abuse regulations are not modernized. While we agree that the AKS is an important anti-fraud safeguard, it has not kept pace with the revolutionary changes being made to the healthcare industry, presenting barriers to the development and use of new connected health tools, and there needs to be consideration for new safe harbors. Existing waivers under the AKS and CMP for value-based arrangements are limited, stopping many of us from pursuing opportunities to utilize technology to serve patient populations, even where use of such technologies would be medically necessary to improve outcomes and to reduce future costs.

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<sup>1</sup> <https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf>.

Generally, we support 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. While many of our organizations are providing further and more detailed views to OIG on its proposed rule, we provide the following recommendations:

- ***A “Value-Based Enterprise” Should Include Non-Billing Non-Provider Entities, Including Digital Health Companies, as Permissible Participants in VBEs.*** Vendors of digital health technologies and services can add significant value as VBE participants through their data analytics capacity and ready access to financial and other resources that many provider entities are not likely to have. The creation of innovative business arrangements that include digital health companies as active participants who can share in risk has the potential to really move the needle on improved outcomes at overall reduced costs.
- ***OIG’s Proposed Patient Engagement Safe Harbor Should Clearly Provide for the Provisioning of Connected Health Technology, Including RPM Tools.*** We support 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” (1001.952(hh)). This language should make it clear that value-based care arrangements and research arrangements may allow for RPM tools and services 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.
- ***OIG Should Waive Cost-Sharing Requirements for Connected Health Technologies.*** Our experiences have clearly shown patient cost-sharing requirements to be a barrier to the uptake of connected health technologies used for care management and RPM. Therefore, we support OIG providing for the waiver or offset of cost-sharing obligations for care management and RPM use cases. These cases occur 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.
- ***OIG’s Safe Harbors Should Clarify that Multi-Function Equipment Complies with AKS.*** We call on OIG to 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).
- ***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. 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.

Sincerely,

Alliance for Connected Care

Biofourmis

College of Healthcare Information Management Executives

Connected Health Initiative

Consumer Technology Association

Diasyst

Kaia Health

Medical Alley Association

Medical Society of Northern Virginia

Optimize Health

Proteus

Reemo Health

Reflexion Health

Rimidi

rtNOW

Scope Data LLC

The Learning Corp.

The Omega Concern

Upside Health

ValidCare

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Vivify Health