



Ms. Susan Edwards
Office of Inspector General
Department of Health and Human Services
OIG-0803-N
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

RE: Identifying New Safe Harbors to the Anti-Kickback Statute
Submitted electronically to www.regulations.gov

Dear Inspector General Daniel Levinson:

Thank you for the opportunity to provide athenahealth's perspective to the regulatory barriers to coordinated care and, particularly, the Anti-Kickback Statute.

Over the last twenty-one years, athenahealth has built a network of over 115,000 clinicians who care for 106 million patients in both the acute and ambulatory settings. We provide electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices and hospitals. Consistent with our model in which all of our customers use a single instance of our cloud-based application, we have aspired to connect with partners across the care continuum to enable our clinicians to improve the quality of care they provide to the more than 110 million patients on our network. As the #1 Most Interoperable EHR by KLAS in 2017, we connect with over 26,000 health plans, 95% of US pharmacies and more than 1,200 non-athena sites.

Thanks in large part to private sector developed standards, interoperability can no longer be classified as a technological problem. Every ONC-certified EHR on the market has the ability to exchange information in a meaningful way with another certified EHR. Nevertheless, the industry lacks widespread *interoperation* of critical data due to misaligned business incentives.

As Administrator Seema Verma recently wrote in a blog, "CMS fully acknowledges that we cannot operate in a 'way-we-have-always-done-it' manner and hope for different results." athenahealth is convinced that the agency can play a role in breaking down the final barriers to data access through tweaks and modifications to existing regulations and policy. Consistent with its espoused values, CMS should seek to create a regulatory ecosystem that empowers the private sector to drive the next wave of innovation in healthcare because of the technology available, not in spite of it.

It is within that context that we answer the below question from the Request for Information regarding the Anti-Kickback Statute.

1. Promoting Care Coordination and Value-Based Care

A. Please tell us about potential arrangements that the industry is interested in pursuing, such as care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements that may implicate the anti-kickback statute or beneficiary inducements CMP. For example, we are interested in better understanding the structure and terms of the arrangement (e.g., categories/types of parties; how risk is allocated among parties; financial relationships involving potential referral sources and seekers created by the arrangement; and types of items and services provided by the arrangement). We are also interested in understanding how the

arrangement promotes care coordination or value-based care and how the arrangement prevents potential harms, such as increased costs, inappropriate utilization, poor quality of care, and distorted decision making.

To promote interoperability between disparate healthcare organizations, CMS should create a new carve out to Stark and Anti-Kickback laws to allow physicians to make and receive fair market value payments, which would be nominal, for the exchange of important and usable information for patient care. The new exceptions under the Anti-Kickback Statute and Stark Laws will allow for a true functioning market for the exchange of health information.

Fraud and abuse laws were written to prevent improper financial influence over referral decisions, but they did not contemplate a situation where the exchange of information in association with a patient referral could be valued separately from the actual referral of business. In most functioning marketplaces across the economy—finance, insurance, even auto parts—market participants in need of data are able to pay fair market value for the transmission of data, thereby supporting the creation and maintenance of the necessary technological infrastructure to enable the efficient, secure exchange of information. As a result, a sustainable market for information exchange emerges.

In healthcare, however, because the transfer of patient data occurs most frequently in the context of a care referral, any accompanying transfer of value is prohibited under the Stark Laws and/or the Anti-Kickback Statute. As a result, the owner/curator of quality data is obligated to assume the cost of electronic transfer of information to a recipient. The beneficiary of the work and the infrastructure investment necessary to curate that data and enable the secure and efficient transfer of the data—the recipient—is prohibited from paying fair market value for that work and investment. This paradigm, which forces the curator of data to pay for the privilege of sending data electronically to a recipient, operates as an effective economic disincentive to information sharing in healthcare. That disincentive, of course, burdens clinicians and impedes efficient delivery of high-quality care to millions of Medicare beneficiaries.

Success of value-based payment programs relies on the clinicians' ability to be held accountable for the cost and quality of care they deliver. Yet, clinicians regularly lack the necessary cost and clinical data to make decisions to improve health outcomes. This level of accountability depends on access to real-time data from other care settings. While this information sharing is critical for participation in CMS Quality Programs, such as MIPS and APMs, we believe the exception should extend beyond participation in such programs to promote widespread interoperability.

It is our experience that information exchange occurs best when there is a business case and problem to solve. We believe that new safe harbors to Stark and Anti-Kickback statute to allow for the fair market value payment for the exchange of health data will spur interoperability forward and allow the market to further realize the benefits of health IT on lowering costs and improving patient outcomes.

athenahealth looks forward to working together with you on these important issues. Please do not hesitate to reach out via email at gcarey@athenahealth.com or phone at 617-402-8516.

Sincerely,



Greg Carey

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athenahealth, Inc.