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"I have never let my schooling interfere with my education.."
-Mark Twain

District One
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THE TECHNOLOGY ISSUE

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Legal risks of health care technology: Learning from the $18.25M Athenahealth, Inc. settlement

by Lawrence W. Vernaglia and Stephanie J. Schwartz

UPSET YOU DIDN'T GET TAKEN TO THE SUPER BOWL BY YOUR VENDORS THIS WINTER? MAYBE YOU SHOULD BE GLAD YOU DIDN'T.

Long term care facilities and their owners and managers face risks when accepting gifts, trips, benefits, or other perks from current or potential vendors.

The January 2021 settlement of $18.25 million paid to the federal government by Athenahealth, Inc. (the "Vendor"), a Massachusetts-based electronic health records ("EHR") developer, is one of the more recent examples of how sales and marketing arrangements can be viewed negatively by enforcement authorities. While this case was brought against a health care information technology vendor (thus coming within the scope of this issue of *New England Administrator)*, the case offers a broader cautionary tale for providers entering into business arrangements with third-party vendors and of when sales strategies can get parties in trouble.

The allegations against the Vendor involved three marketing arrangements in which the company allegedly engaged between January 2014 and September 2020.[1] These schemes, detailed below, allegedly involved illegal kickbacks paid to potential clients, existing clients, and competitors in exchange for referrals to and/or continued business with the Vendor. These allegedly illegal kickbacks were alleged to have resulted in false or fraudulent claims (because they were tainted by the kickbacks) that were ultimately submitted by the Vendor's clients to federal health care programs—specifically, the EHR incentive programs provided under Medicare and Medicaid.

EHR incentive programs were first established under the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") and, with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), were replaced by the Merit-based Incentive Payment System ("MIPS"), which analyzes several quality measures in determining Medicare payment adjustments.[2] Health care providers attest to using certified EHRs to satisfy these programs' requirements, in order to receive incentive payments and/or avoid payment reductions as part of the programs.

With more financial arrangements between providers and third parties comes greater risk of conduct that potentially violates federal law, including the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"), the violation of which could result in significant fines, civil monetary penalties ("CMPs"), and exclusion from participating in the federal health care programs (among other consequences).

The AKS, 42 U.S.C. § 1320a-7b(b), prohibits the knowing and willful solicitation or receipt of any remuneration, in cash or in kind, in exchange for referrals or the purchase of items or services for which payment may be made in whole or in part under a federal health care program. An AKS violation results in a felony conviction that brings with it a maximum fine of $100,000 or a maximum prison sentence of 10 years (or both), as well as the potential imposition of a CMP of up to $104,330 (as adjusted for inflation, effective January 17, 2020, see 45 C.F.R. § 102.3 (2019) (citing 42 C.F.R. § 1003.310(a)(3) (2019))). The FCA, 31 U.S.C. §§ 3729-33, imposes liability where a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" (among other types of conduct). Significantly, the standard to establish intent (i.e., "knowingly") under the FCA includes "reckless disregard" for the truth or falsity of the claim, which has proven to be a rather low bar. Each claim that violates the FCA results in a civil penalty between $11,665 and $23,331 per claim (as adjusted for inflation, effective June 19, 2020, see 28 C.F.R. § 85.5 (2020)), plus three times the amount of damages the federal programs sustain. Providers may also be excluded from participation in the federal health care programs, for a period of time or permanently, and may face CMPs of up to $20,866 (as adjusted for inflation, effective January 17, 2020, see 45 C.F.R. § 102.3 (2019) (citing 42 C.F.R. § 1003.210(a)(1))).

It is often alleged that it is a violation of the civil FCA to submit a claim that has been rendered illegal because it resulted from an AKS violation, even when the underlying conduct is not charged criminally. Here, the government alleged that by engaging in conduct under its three marketing

arrangements that allegedly violated the AKS, the Vendor and its clients would have submitted (or caused to be submitted) claims to a federal health care program (i.e., claims for enhanced payments under the EHR incentive programs and MIPS) in violation of the FCA.[3] Below, we will discuss these alleged marketing programs and the conduct that was argued to have rendered them illegal, to provide a view of the key risks to consider when entering into arrangements with third-party vendors, including health care technology companies.

The first program that the government alleged violated the AKS was the Vendor's "Concierge Event" program. Through this incentive program, the Vendor "provided existing potential clients with all-expense-paid trips to sporting, entertainment, and recreational events."[4] The Vendor allegedly provided these gifts to executives, providers, and other stakeholders in order to induce them to purchase the Vendor's EHR products. The exchange of in-kind remuneration (with no demonstrated educational component) for the purchase of a product that would be used to attest for EHR incentive programs was argued to be a violation of the AKS.

The second Vendor program that allegedly violated the AKS was the Vendor's "Client Lead Generation" program, which was in place from January 2014 to September 2020. Under this program, the Vendor allegedly induced its existing clients to refer new clients by offering and making payments for each referral. The payments included (but were not limited to) $200 for meetings with prospective clients that arose from a referral, $3,000 per doctor referred after a successful referral of an ambulatory practice, and $10,000 for each referred inpatient hospital program.

The third program addressed in the com-

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Older individuals can combat loneliness

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loneliness may be due to people becoming socially disconnected in a variety of ways. She describes loneliness as "a subjective feeling or sensation that tests one's health risks."

Simply living alone or in a state of isolation can also be as harmful to one's health as just plain feeling lonely.

Hawkley asks, "At what point do you say that somebody is lonely? A teenage boy, alone on a Saturday night may experience a very different kind of loneliness than does an elderly man without a spouse or partner to communicate with, nor hasn't spoken to anyone for days." Loneliness can mean different things to different people, whether young or old.

Scientists need to measure the condition known as loneliness in an encompassing way where they can define it as either slightly, moderately, or extremely lonely and as a way of clarifying its treatment plan. The researcher Sheldon, offers several correlates on loneliness that can be identified as psychologic, economic, and physiologic, and that contributes heavily to loneliness in the adult population. He further clarifies how "the infirmed, the widow, and the single man over eighty and living alone are highly prone to experiencing loneliness."

Those who are well enough to live without assistance for performing their activities of daily living were, surprisingly, most lonely. Others who may be bedfast and who have a caregiver to help tamp down the sense of isolation may do better.

A reprint letter dated 1859 and written by Florence Nightingale, said that "pets are excellent companions for those who are confined with long term illness."

In several studies on the value of animals as pets, especially with older individuals, it was suggested that the most common reasons why people love having a pet was to combat feeling lonely and to add quality to family life. For the isolated, pets hold an even greater importance for the elder's mental state. One can always rely on a pet to always be available and non-judgmental. Pets are considered, by many owners, as members of a family and can play a major part in an older person's existence.

A final thought: I realize that feeling good may be the last thing on our minds as the pandemic grinds on in America. Countless researchers say pursuing happiness and a happy outlook can give us the resilience to get through it.

According to the researcher Laura Santos, professor of psychology at Yale University, "We need to focus on happiness, more now, not less." Therefore, when you are feeling sad and lonely, try singing my favorite Beatles song, "Here Comes the Sun."

Bob Armstrong

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strong Consulting, and assumed receivership of six failing assisted housing facilities. Three years of that and Bob was truly ready for retirement.

Now Mr. Maine lives in Georgia, but certainly has left his mark in the Pine Tree State and in New England. Bob is a Certified Fellow of ACHCA, and has been a proud College member for over 30 years.

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Health care technology's legal risks

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plaint as a potential AKS violation was the Vendor's "Conversion Deals" program. Conversion Deals were alleged arrangements entered into by the Vendor and competitor enterprises that were terminating their EHR offerings. In exchange for payments from the Vendor, these competitors would allegedly refer its clients to convert to the Vendor's products.

The United States' allegations toward the Vendor led to negotiations that ultimately resulted in the $18.25 million (plus interest) settlement announced on January 28, 2021. In the settlement, the Vendor neither denied the United States' claims nor admitted wrongdoing. In the Department of Justice ("DOJ")'s press release announcing the settlement, Acting Assistant Attorney General Brian Boynton for the DOJ's Civil Division declared that "[t]his resolution demonstrates the department's continued commitment to holding EHR companies accountable for the payment of unlawful kickbacks in any form."

New technology is increasingly important in the delivery of health care services. However, as this settlement demonstrates, it is just as important to know the legal risks of engaging with third-party technology vendors and to recognize aspects of these arrangements that should be avoided. Payments in cash or in kind that are offered in exchange for referrals or purchases present severe risk of being viewed by the government as in violation of the AKS, and senior care providers should conduct careful analyses before entering arrangements to avoid the significant consequences associated with such violations.

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Be aware of health care technology's legal risks

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Under the statute, AKS violations may be asserted against recipients, as well as offerors, of improper remuneration. Providers should be cautious about accepting benefits from vendors or potential vendors in connection with sales and marketing activities. This case stands for the proposition that the DOJ is willing to proceed in a case where the alleged kickbacks related to the purchase of an "overhead" technology. Would the government have proceeded against the vendor in the absence of the EHR Incentive that provided enhanced government compensation when the vendor's technology was utilized? The technology in question was not separately reimbursable by a federal healthcare program, but there were special governmental payment incentives to using such technology.

The broad language in the complaint and settlement suggests that flashy sales strategies may be targeted for enforcement activity in other scenarios as well. Providers who may be on the receiving end of offers of entertainment, travel, or cash from vendors should carefully consider the potential reach of these laws in prohibiting such activities. Many providers have established policies prohibiting acceptance of gifts or trips from vendors. Others have established more nuanced rules, allowing limited meals and business courtesies, including allowing participation in sporting or recreational activities, where meaningful business discussions and relationship-building take place. Such encounters are not inherently unlawful, but settlements such as this one show that the government takes a hard line when it believes that the sales techniques may influence health care purchasing decisions.

So if you watched the Super Bowl from your living rooms (like we did), don't feel bad. It might have saved you a lot of trouble!

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Endnotes

[1]Complaint at 2, United States v. athenahealth, Inc., Nos. 17-cv-12125-ADB, 17-cv-12543-ADB (2021).

[2]Complaint at 3, athenahealth, Inc., Nos. 17-cv-12125-ADB, 17-cv-12543-ADB; Quality Payment Program Overview, Quality Payment Program, https://qpp.cms.gov/about/qpp-overview (last visited Feb. 21, 2021).

[3]It is important to note that arrangements that violate the AKS and result in significant fines, penalties, and other consequences do not necessitate that a given vendor's products be separately reimbursable or separately covered. That is, an arrangement involving kickbacks for a product that relates only to overhead costs for the provider (rather than claims for reimbursement submitted to the federal health care programs) may violate the AKS just as the arrangement discussed in this Article allegedly did.

In a 1999 Advisory Opinion written by the Office of Inspector General ("OIG"), the OIG stated that in deciding whether to prosecute arrangements that potentially violate the AKS, it considers a variety of factors, including whether the items purchased are separately reimbursable under the federal health care programs. Advisory Op. No. 99-3 (U.S. Dep't of Health & Human Servs., Office of the Inspector Gen. (1999)). There is greater risk of a kickback violation when separately reimbursable items are involved in an arrangement, but the risk of violation and enforcement is not forgone when the product involved solely contributes to providers' overhead costs rather than toward claims for reimbursement. See id. For example, in a case concerning an arrangement involving syringes, the District Court for the District of Connecticut found that although "syringes are typically not separately reimbursable by a federal health care program and… hospitals are reimbursed for providing a service, not for the equipment included in doing so," this "does not foreclose a showing that 'payment may be made' under a federal health care program" and that the OIG could seek enforcement action under the AKS. MedPricer.com, Inc. v. Becton, Dickinson & Co., 240 F. Supp. 3d 263, 273-74 (D. Conn. 2017).

Common examples of arrangements involving products that contribute to a provider's overhead costs and are not separately reimbursable concern medical devices used during procedures. While the purchase and sale of these products do not involve separate reimbursement under the federal health care programs, improper remuneration may still result in severe consequences. One case, concerning conduct in 2017, involved the sale of implantable devices to be used in surgeries; although the claims resulted in a settlement of the allegations and no admission of liability, the settlement agreement recognized that where the purchase or use of the devices themselves is not submitted for reimbursement, the arrangement may nonetheless be considered a violation of the AKS that could also contribute to various false claims. Settlement Agreement at 2, United States v. Asfora, No. 4:16-cv-04115-LLP (D.S.D. 2019).

[4] Complaint at 2, athenahealth, Inc., Nos. 17-cv-12125-ADB, 17-cv-12543-ADB.

Brady's TB12

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mas, Brady sleeps with the room temperature at exactly 65 degrees Fahrenheit to promote recovery.

The book also contains photos and explanations of pliability exercises and an extensive collection of recipes. While "The TB12 Method" was written in a vernacular, conversational style with some blatant promotion of other related TB12 products, the actual method itself holds a considerable amount of useful information about overall health and performance.

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