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False Claims Act Settlement with eClinicalWorks Raises Questions for Electronic Health Record Software Vendors

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Summary

On May 31, 2017, the US Department of Justice announced a Settlement Agreement under which eClinicalWorks, a vendor of electronic health record software, agreed to pay $155 million and enter into a five-year Corporate Integrity Agreement to resolve allegations that it caused its customers to submit false claims for Medicare and Medicaid meaningful use payments in violation of the False Claims Act.

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On the Subject

Communications, Media & Internet
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In Depth

The ***US Department of Justice (DOJ)*** announced on May 31, 2017, an agreement (Settlement Agreement) settling allegations in the DOJ's Complaint-in-Intervention (Complaint) that eClinicalWorks (ECW), a vendor of electronic health record (EHR) software, caused its health care provider customers to submit false Medicare and Medicaid claims for meaningful use payments in violation of the False Claims Act (FCA). Under the Settlement Agreement, ECW agreed to pay approximately $155 million to resolve the allegations without admitting liability and an ECW software developer and two project managers agreed to pay additional amounts. ECW also entered into a five-year Corporate Integrity Agreement (CIA) with strict compliance oversight and reporting obligations and costly obligations to provide the latest version of ECW's EHR software (including related implementation and training services) to each of ECW's current customers free of charge.

The groundbreaking settlement has sent shockwaves through the health information technology (HIT) industry and may be a sign of increasing FCA actions against vendors of EHR technology (CEHRT) certified through the HIT certification program of the Office of the National Coordinator of HIT (ONC). HIT vendors should review, and consider improvements to, their systems and other procedures for identifying, responding to and correcting software design and quality issues that call into question EHR software's conformity to applicable EHR certification criteria or present patient safety or clinician usability risks. HIT vendors should also review existing customer referral and marketing arrangements compliance with the Anti-Kickback Statute.

The following sections discuss the key elements and implications of the Complaint, Settlement Agreement and CIA.

Allegations

The DOJ's Complaint included two categories of allegations. The predominate allegations concerned false statements concerning ECW's EHR software, but also included certain allegations regarding improper payments (*i.e.*, kickbacks) to referral sources in violation of the Anti-Kickback Statute.

False Statements

First, the DOJ (and the whistleblower) allege that ECW made material false statements and concealed material

facts from its certifying body about the extent to which ECW's EHR software met the 2011 Edition and 2014 Edition of the ONC's EHR certification criteria. For example, according to the Complaint, to pass certification testing related to implementation of the RxNorm standardized drug vocabulary in the EHR software's e-prescribing functionality, ECW modified its EHR software by hardcoding only the RxNorm standardized drug codes for the 16 drugs tested by the certification body's publicly available test scripts and not any other drugs.

The EHR software needed to be certified as CEHRT under the criteria in order for ECW's physician practice customers to properly achieve meaningful use under the Medicare and Medicaid EHR Incentive Programs, commonly known as the "Meaningful Use Programs." Physician practices cannot earn incentive payments for using paper medical records or legacy EHR systems that are not CEHRT. By achieving meaningful use of CEHRT, physician practices could receive Medicare EHR Incentive Payments of up to $43,720 per physician or other Medicare eligible professional, or up to $63,750 of Medicaid EHR incentive payments per Medicaid eligible professional.

In addition, after earning incentive payments, practices could subsequently avoid reimbursement penalties under the Medicare Physician Fee Schedule by achieving meaningful use of CEHRT. However, the Complaint did not address any Medicare reimbursement penalties that were not applied because of providers' false meaningful use attestation. Currently, physicians participating in Medicare may use CEHRT to avoid reimbursement penalties under the Medicare Merit-Based Incentive Payment System (MIPS) launched this year by the Centers for Medicare and Medicaid Services and other Medicare Quality Payment Programs.

As a result, the DOJ alleges that ECW caused its customers to receive unearned EHR incentive payments by submitting false attestations of meaningful use of CEHRT. Based on the Complaint, it appears that the DOJ did not pursue ECW's physician practice customers for the unearned incentive payments, in part, because ECW's customers "unknowingly" submitted false attestations (reasonably believing that the ECW EHR software was properly certified as reported on the ONC's website) and the FCA requires the government (or the whistleblower) to establish that false claims were submitted knowingly.

Kickbacks

While the Complaint spends over eight pages detailing conduct involving certification of ECW's EHR software and meaningful use incentive payments to providers, DOJ only spent one page describing certain marketing arrangements for which ECW allegedly kickbacks to influential customers to induce them to recommend ECW's EHR software in violation of the Anti-Kickback Statute. ECW paid the purported kickbacks through a referral program, site visit program and a reference program.

According to the Complaint, under the referral program, ECW paid current customers as much as $500 for each provider they referred who executed a contract with ECW with payments to customers totaling almost $144,000. Under the site visit program, ECW paid customers to host prospective customers and payments varied based on the number hosted and whether the hosted prospect licensed ECW's software. The Complaint stated that under the reference program, ECW paid current customers as much as $250 to serve as references for the ECW software and speak to prospects. The reference fees varied based on number of references spoken to and whether the prospect licensed the ECW software.

Based on the scant details about the three ECW programs included in the Complaint, it is unclear exactly what DOJ's objections were to these arrangements. In particular, the site visit and reference programs could be viewed as typical and commercially reasonable marketing arrangements for information technology that involve customers providing actual marketing services in exchange for the payment. In addition, the Complaint seems to indicate that DOJ included the allegations about these programs because they resulted in more customers submitting claims for meaningful use incentive payments related to EHR software that did not meet the certification criteria, which was the main focus of DOJ's Complaint.

In addition, the Office of the Inspector General (OIG) of the US Department of Health and Human Services has for years consistently stated that marketing payments technically implicate the Anti-Kickback Statute, but has also recognized that payment for marketing services are commonplace, and in fact, unavoidable without banning marketing activities entirely. Various advisory opinions and other guidance set forth a multi-factored facts-and-circumstances analysis for distinguishing between proper and improper marketing activities outside the Anti-Kickback Statute safe harbors. The analysis examines the nature of the payment, the type of marketing activity (*i.e.*, active or passive), the type of item or service marketed, the intended audience, and the identity of the marketer and his or her relationship with the intended audience. However, the presence or absence of any of these factors does not necessarily mean that an arrangement violates the Anti-Kickback Statute.

Ongoing CIA Requirements

In addition to the large monetary settlement payment, ECW agreed to comply with novel requirements in the CIA, which are discussed below, for a five-year term. These significant CIA requirements appear based on modifying the "independent monitor" model typically used in quality of care CIAs.

Free Upgrades

The CIA requires ECW to provide, without charge, to current customers the latest version of the ECW EHR software that includes software updates that correct noncompliance with EHR certification criteria and the latest updates to any drug database supported by the EHR software used by the customer without charge. ECW is also not permitted to charge for implementation and training services for the updated version.

Free Data Transfer

The CIA requires ECW to transfer an existing customer's data without penalties or service charges to the customer or the customer's designated successor vendor.

Corporate Compliance Program

Like CIAs required as part of other FCA settlement agreements, the CIA with ECW requires ECW to implement an effective corporate compliance program that includes a full-time compliance officer, compliance committee, code of conduct, written compliance policies and procedures, a training program and a compliance hotline or other disclosure program.

The written policies must address a wide range of topics, including, without limitation: compliance with EHR certification criteria and other federal health care program requirements applicable to HIT; compliance with the Anti-Kickback Statutes; software standards and practices (which are discussed below); development and implementation of software modifications to address patient safety issues; adhering to "all applicable aspects of the ONC Safety Assurance Factors for EHR Resilience (SAFER) guides;" staffing of an EHR usability team to address screen and workflow design and other EHR usability issues, an EHR patient safety team and an EHR certification compliance team; and notifying customers of patient safety and certification issues.

Quality Assurance Program with Software Standards and Practices

The CIA requires the compliance program to include a quality assurance program with software standards and practices, which are "professionally recognized software development, quality assurance, and risk management standards and practices appropriate to the nature and purposes of EHR systems (including supporting clinical decision-making and the provision of medical care to patients)." As part of the quality assurance program, ECW must proactively monitor information about potential software defects, usability problems and other issues that may present patient safety or EHR certification issues.

Health Care Provider Payment Sunshine

The CIA requires ECW to post on its website reports of the cumulative value of payments by ECW to health care providers after the effective date of the CIA.

Retention of SQOO

The CIA requires ECW to engage an independent Software Quality Oversight Organization (SQOO) to develop the software standards and practices in consultation with ECW and assess the "effectiveness, reliability and thoroughness of" ECW's: internal quality control systems designed to address patient safety, certification, usability and other EHR issues; policies, procedures and practices for addressing EHR issues; adherence to software standards and practices and other requirements; other quality assurance program requirements of the CIA; and policies, procedures and practices to ensure that ECW customers are notified of their rights under the CIA. In contrast to OIG's past approach in selecting the "independent monitor," here, ECW is required to "seek input" from OIG on selecting an appropriately qualified SQOO within 60 days. If ECW is unable to retain an SQOO that OIG approves of within this time, OIG will select the SQOO.

Retention of Independent Review Organization

ECW must retain an independent review organization (IRO) to conduct an arrangements review, which includes a review of (1) ECW's systems, processes, policies and procedures relating to arrangements involving the offer, payment, solicitation or receipt of anything of value between ECW and any actual or potential source of health care business or referrals (Systems Review) and (2) a review of 50 randomly selected "Focus Arrangements,"

which are arrangements between eCW and any actual source of health care business or referrals to eCW that involves, directly or indirectly, the offer, payment or provision of anything of value (Transactions Review). As part of the Transactions Review, the IRO will assess whether ECW has complied with certain procedures and other requirements of the CIA for Focus Arrangements.

Implications for HIT Vendors

The settlement amount and extensive CIA requirements provide a clear signal that CEHRT vendors may experience increased scrutiny by the government, as well as whistleblowers, for compliance with the EHR certification criteria because CEHRT may enable health care providers to earn incentive payments or other enhanced reimbursement (or avoid decreased reimbursement) under federal health care programs. The CIA makes clear that the government is not only concerned about improper reimbursement to health care providers, but also patient safety issues caused by defective software and poor usability as well as kickbacks to referral sources. Vendors should consider the following responsive steps:

- Development and implementation of a compliance program that reflects the elements of an effective corporate compliance program set forth in DOJ and OIG compliance program guidance for the health care industry;
- Development and implementation of policies, procedures and practices for addressing EHR certification criteria, patient safety and EHR usability considerations into the ongoing software development and design process;
- Development and implementation of procedures for employees, customers and other persons to report patient safety, usability and compliance issues to vendor management and procedures for promptly tracking, monitoring and resolving the issues;Identification, review and prompt resolution of any currently known or suspected EHR certification criteria compliance issues and patient safety issues;
- Evaluation of current showcase or reference site arrangements, referral arrangements and other marketing arrangements outside the Anti-Kickback Statute safe harbors with persons in a position to generate new customers and new business to determine whether they reasonably comply with OIG guidance regarding marketing arrangements;
- Development and implementation of policies, procedures and practices for complying with the Anti-Kickback Statute, including policies for evaluating whether marketing arrangements with referral sources comply with the Anti-Kickback Statute; and
- Implementation of a comprehensive training program to address the range of health care regulatory compliance matters addressed by the CIA and foster a culture of health care regulatory compliance.

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