

“Meaningfully Useful” Risk Mitigation Strategies for Providers Following the eClinicalWorks Settlement

IN SHORT

The Situation: Recently, a leading electronic health records (“EHR”) vendor entered into a \$155 million settlement with the government to resolve allegations under the False Claims Act, and the United States Department of Health and Human Services’ (“HHS”) Office of Inspector General (“OIG”) reported that the Centers for Medicare and Medicaid Services (“CMS”) paid an estimated \$729 million in Medicare EHR incentive payments from 2011–2014 that did not comply with federal requirements.

The Impact: There is heightened governmental scrutiny, and increasing liability, surrounding EHR meaningful use criteria and meaningful use incentive payments.

Looking Ahead: Health care providers should implement mitigation strategies to reduce regulatory risks with their EHR vendors and be prepared to respond to governmental audits of meaningful use attestations.

The Health Information Technology for Economic and Clinical Health Act (“HITECH Act”) established financial incentives under Medicare and Medicaid for eligible health care providers that adopt, implement, and demonstrate use of certified EHR technologies to advance positive health outcomes consistent with identified meaningful uses. Given recent sizeable settlements, heightened regulatory oversight, and ongoing Medicare payment reform efforts relative to EHR meaningful use, health care providers should evaluate their risk exposure, including financial and legal liability, if EHR attestations are deemed inaccurate or unsubstantiated, or if the ongoing utilization of EHR technologies fails to meet program objectives.

DOJ Settlement with eClinicalWorks

On May 31, 2017, the United States Department of Justice (“DOJ”) [announced](#) a \$155 million settlement with eClinicalWorks (“ECW”) to resolve allegations under the False Claims Act alleging that ECW misrepresented the capabilities of its EHR software. According to its website, ECW is a cloud-based EHR vendor with a customer base of more than 125,000 physicians and nurse practitioners, 850,000 users, and 70,000 facilities across all 50 U.S. states and 24 countries.

The government alleged that ECW falsely obtained meaningful use certification for its EHR software when it did not comply with applicable criteria. For example, according to the DOJ, ECW hardcoded a limited set of drug codes required to pass certification testing rather than programming the software to retrieve any drug code from a comprehensive database. ECW’s software also failed to accurately record user actions in an audit log, reliably record diagnostic imaging orders, and satisfy data portability requirements. Because of such deficiencies, the government alleged that ECW caused the submission of false claims for meaningful use incentive payments.



The ECW settlement, the OIG report, and Medicare payment reform efforts, including MACRA, indicate that EHR meaningful use criteria are changing and likely to be the focus of ongoing governmental scrutiny.



OIG Report Scrutinizing EHR Incentive Payments

Within two weeks after the ECW settlement announcement, the OIG released a [report](#) finding that, from May 2011 through June 2014, CMS paid an estimated \$729 million in Medicare EHR incentive payments (approximately 12 percent of all incentive payments paid during such time period) that did not comply with federal requirements.

As conveyed in the OIG report, the OIG determined that the EHR incentive payments program is susceptible to fraud and abuse, in part because CMS conducts minimal audits of self-attestations that health care providers submit when certifying compliance with meaningful use criteria. The OIG recommended, among other things, that CMS review a sample of health care providers’ self-attestations to identify any inappropriate payments that may have been made after the audit period and educate health care providers on documentation requirements. Moreover, as CMS implements the Medicare Access & CHIP Reauthorization Act (“MACRA”), the OIG recommended that any modifications to meaningful use requirements include stronger safeguards for more consistent verification of reporting required measures in furtherance of MACRA’s “advancing care information” goal.

Best Practices for Health Care Providers

The ECW settlement, the OIG report, and Medicare payment reform efforts, including MACRA, indicate that EHR meaningful use criteria are changing and likely to be the focus of ongoing governmental scrutiny. In fact, in response to an earlier draft of the OIG’s report, CMS stated that it has implemented “targeted risk-based audits” to strengthen program integrity and will continue to do so in 2017. In light of this, health care providers should take immediate steps to implement mitigation strategies to reduce regulatory risks with their EHR vendors, as well as be prepared to respond thoroughly and timely to governmental audits of meaningful use attestations. In our view, the following strategies are critical to these efforts:

- Remain fully informed of MACRA implementation efforts, including the requirements of the Advancing Care Information component of the Merit-based Incentive Payment System, as health information technology and EHR tools are key elements of such programs.
- Negotiate specific representations and ongoing covenants in EHR vendor agreements appropriate to ensure the equipment and software purchased comply with basic meaningful use requirements and allow for potential future upgrades, if needed. Further, providers should consider indemnification and other risk-sharing provisions in the event technical aspects of the EHR result in flawed reports underlying meaningful use attestations, or the EHR is decertified by the Office of the National Coordinator for Health Information Technology (“ONC”) after entering into the agreement.
- Perform upfront and ongoing diligence of EHR technology and monitor the ONC website to identify any decertification announcements regarding vendor EHR technology.
- Perform mock audits of meaningful use attestations and maintain complete, readily accessible, supporting documentation.
- Consider engaging legal counsel to assist with developing appropriate policies, practices, and audit preparation strategies to ensure protection by the attorney-client privilege.

THREE KEY TAKEAWAYS

1. Although the ECW settlement may be the first of its kind in the EHR context, the government continues to pursue cases under the False Claims Act against third-party vendors even though such vendors are not the direct recipients of federal funds.
2. CMS is committed to strengthening Medicare and Medicaid program integrity, in part by increasingly engaging in governmental audits, particularly in the area of EHR meaningful use as it changes under MACRA payment reform efforts.
3. Health care providers should develop comprehensive strategies to demonstrate appropriate ongoing EHR meaningful use and to substantiate related attestations so they can reduce the risks of negative audit findings, potential recoupment of EHR incentive payments, and other governmental enforcement actions, including under the False Claims Act.

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