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What is the Meaning of Meaningful Use? How to Decode the Opportunities and Risks in Health Information Technology

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To achieve greater efficiencies in health care, enhanced care coordination, better quality, and a reduction of medical errors, many health care entities and professionals are implementing electronic health record ("EHR") systems and other forms of health information technology. The enterprise integration of EHRs and the exchange and use of such health information are incentivized through the Medicare and Medicaid EHR Incentive Programs ("EHR Incentive Programs"), which were enacted as part of the American Recovery and Reinvestment Act of 2009, Health Information Technology for Clinical and Economic Health Act ("HITECH Act").

This article provides an overview of the EHR Incentive Programs, explores the legal framework for health care entities to subsidize EHR technology for health care professionals, and offers practical guidance regarding the legal issues in this area.

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The Medicare and Medicaid EHR Incentive Programs

The EHR Incentive Programs are estimated to pay more than $30 billion in EHR incentive payments to eligible professionals ("EPs"), eligible hospitals, critical access hospitals, and Medicare Advantage organizations that make "meaningful use of certified EHR technology" between 2011 and 2021. EPs who qualify for Medicare incentives receive up to $44,000 per EP over a five-year period,[2] while EPs who meet Medicaid patient-volume requirements and qualify for Medicaid incentives receive up to $63,750 per EP over six years.[3] (EPs who qualify for both EHR Incentive Programs must choose one.) The amount available to hospitals varies based on several factors, including the size of the hospital and Medicare or Medicaid patient volumes, but begins with a $2 million base payment.[4] Since the inception of these programs, over $19.5 billion in Medicare incentive payments[5] and $9 billion in Medicaid incentive payments[6] have been made to hospitals and EPs. Approximately 92% of hospitals and 75% of EPs now participate in these programs.[7]

Although the Medicare EHR Incentive Program has a "carrot" in the form of incentive payments, it also has a "stick" in the form of downward Medicare payment adjustments. Those EPs who were not meaningful EHR users by calendar year ("CY") 2015 received a downward payment adjustment to their Medicare physician fee schedule payments. Hospitals that were not meaningful users by federal fiscal year ("FY") 2015 received a downward adjustment to their annual increase in inpatient prospective payment system payment rate. The amount of these payment adjustments will increase each year until they reach a statutory limit. As discussed in more detail below, beginning in CY 2019, the payment penalty for EPs is incorporated into the Merit-Based Incentive Payment System. In limited situations, such as demonstrated lack of internet access or unforeseen circumstances (e.g., natural disasters), EPs and

hospitals can potentially qualify for a "hardship exception" to these payment adjustments.

Meaningful Use

A central component of the EHR Incentive Programs is the requirement that eligible hospitals and EPs make "meaningful use" of certified EHR technology. The EHR Incentive Programs utilize a phased approach to implementing the meaningful use criteria, whereby meaningful use criteria of increasing complexity are implemented in three stages.

Stage 1

The Stage 1 meaningful use criteria, released on July 28, 2010, require the achievement of 13 "core" objectives and five of nine "menu" objectives for EPs. Eligible hospitals are required to satisfy 11 core objectives and five of 10 menu objectives. According to the Centers for Medicare and Medicaid Services ("CMS"), the goal of the Stage 1 criteria is to set a baseline for electronic data capture and information sharing.

Stage 2

The Stage 2 meaningful use criteria, released on September 4, 2012, build upon the goals of Stage 1 by focusing on "continuous quality improvement at the point of care and the exchange of information in the most structured format possible."[8] In Stage 2, EPs must meet 17 core objectives and three of six menu objectives, while hospitals must meet 16 core objectives and three of six menu objectives. Almost all of the Stage 1 core and menu objectives are incorporated into Stage 2.

Stage 3

CMS released the proposed Stage 3 regulations for comment on March 20, 2015.[9] These proposed regulations consolidate the meaningful use criteria into eight objectives, with a total of one to six measures per objective. CMS proposes that all hospitals and EPs will be required to meet a single standard for the Stage 3 meaningful use requirements in 2018, and participants will no longer be permitted to progress through the stages of meaningful use.

Several of the Stage 3 objectives were present in Stages 1 and 2 (e.g., e-prescribing), but now have higher thresholds for completion. In addition, the proposed Stage 3 regulations continue to focus on patient engagement and expand the requirement to collection of patient-generated data from Fitbits or mobile applications. CMS also seeks to further align the Medicare and Medicaid Incentive Programs with other CMS quality reporting programs that use certified health information technology, such as the hospital inpatient quality reporting and physician quality reporting systems.

CMS intends for Stage 3 to be the final stage of the meaningful use framework and to incorporate portions of Stage 1 and Stage 2 into its requirements. As a result, Stage 3 will be the single set of objectives and measures for meaningful use and will eliminate Stages 1 and 2. CMS believes this will reduce provider burden and allow for greater focus on improving outcomes, enhancing interoperability, and increasing patient engagement. The comment period for the Stage 3 regulations ended May 29, 2015.

Incorporation of the Medicare EHR Incentive Program into MIPS

On April 16, 2015, Congress signed into law the Medicare Access and CHIP Reauthorization Act,[10] which incorporates Medicare EHR incentive payment penalties and bonuses into a new Merit-Based Incentive Payment System ("MIPS"). Starting in CY 2019, MIPS consolidates three existing quality-incentive programs (the Medicare EHR Incentive Program, the Physician Quality Reporting System, and the Value-Based Payment Modifier) into one program. The Medicare EHR Incentive Program payment adjustments in 2018 will be the last of the penalties under the current program. Importantly, this legislation does not impact the Medicaid EHR Incentive Program.

Under MIPS, EPs earn a bonus, or are subject to a payment penalty, based on a composite score that is generated from EPs' performance in four categories: (1) meaningful use of certified EHR technology, (2) quality, (3) resource use, and (4) clinical practice performance activities. Twentyfive percent (25%) of the composite score is based on meaningful use of certified EHR technology. The potential bonus payment or penalty begins at four percent (4%) of the Medicare physician fee schedule in 2019 and increases to nine percent (9%) for 2022 and subsequent years. Because the MIPS is budget neutral, the MIPS bonuses are funded by the penalties imposed on EPs. Regulations are expected to be promulgated by CMS to implement MIPS and provide additional information regarding its requirements.

Meaningful Use Audits

Given the broad participation in the EHR Incentive Programs and the large amount of federal dollars that have been paid to providers, CMS and the Office of the Inspector General ("OIG") have taken steps to scrutinize the propriety of payments under these programs. In the most recent OIG Work Plan, OIG states that it will "review Medicare incentive payments to eligible health care professionals and hospitals for adopting EHRs and the [CMS] safeguards to prevent erroneous incentive payments."[11] CMS reportedly intends to audit approximately five to ten percent (5-10%) of all participants in the Medicare EHR Incentive Program through Figliozzi & Company, a

contracted auditing firm. OIG meaningful use audits have begun as well.

The stakes in a meaningful use audit are high--failure to pass the audit will result in the recoupment of incentive payments and imposition of the Medicare EHR Incentive Program's Medicare payment adjustment. Failure to pass the audit may also result in allegations that the provider or supplier (or its management personnel) violated the False Claims Act and/or committed Medicare fraud.

Given the consequences of failing to comply with the Medicare and Medicaid EHR Incentive Programs' requirements, eligible hospitals and EPs should consider taking the following steps to document their compliance with the Medicare and Medicaid Incentive Programs' requirements and help prepare for a meaningful use audit:

1. Appoint a specific individual to coordinate the meaningful use attestation process, including the maintenance of supporting documentation. Centralizing the attestation process will ensure that an identifiable person has a holistic view of the process and the data sources and inputs.
2. At the time of attestation, gather all supporting documentation and either print it out and place it in a binder or file it electronically in a single file. This includes the EHR-generated reports to support the numerators and denominators, the documents used to support the yes/no attestation measures (e.g., submission to an immunization registry), a copy of the EHR agreement with the technology vendor, and a copy of the Office of the National Coordinator for Health Information Technology ("ONC") certification. CMS has also provided guidance regarding suggested documentation.12
3. Make sure the documentation includes a security risk analysis dated prior to the end of the reporting period. Many providers and suppliers have failed to follow the technical requirements of this EHR Incentive Program measure. CMS issued specific meaningful use guidance concerning this requirement.13
4. Keep all supporting documentation for the relevant retention period. Documentation regarding Medicare EHR Incentive Program measures and clinical quality measures must be kept for at least six years. Payment calculation data (e.g., cost reports) should follow current documentation retention processes followed by the organization.
5. Conduct mock meaningful use audits to ensure that the information is retrievable and fully supports the attestation.

As noted above, the audit rate for the Medicare EHR Incentive Program is high. The above steps should help to reduce risk and provide a streamlined path to a response in the event that a hospital or EP is audited.14

Subsidizing EHR Technology for Health Care Professionals

Given the potential patient care benefits associated with the adoption of EHR systems, as well as the financial incentives (and penalties), there is significant interest by health care professionals in obtaining EHR systems. Hospitals and other health care entities also stand to benefit from increased EHR adoption rates among health care professionals because wider EHR adoption may translate into improved care coordination. EHR systems, however, can be very expensive, and many physician practices do not have the capital necessary to acquire and maintain new EHR systems.

Some hospitals and health care entities have elected to assist physicians with the purchase of EHR systems and related technology. Because these subsidy programs generally involve the transfer of value from hospitals or other health care entities to referring physicians, both parties must be mindful of health care fraud and abuse laws that regulate the financial relationships between health care entities and health care professionals who refer patients to them. In particular, the federal physician self-referral law (commonly referred to as "Stark") prohibits a physician from referring Medicare beneficiaries for "designated health services" to entities with which the physician has a financial relationship (and prohibits billing for services provided pursuant to such a referral) unless an exception applies.15 The federal Anti-Kickback Statute is a criminal law that prohibits any person from paying any remuneration in exchange for or to induce the referral of any item or service covered by a federal health care program, or in exchange for arranging for or recommending the purchasing, leasing, or ordering any good, facility, service, or item covered by a federal health care program, including Medicare or Medicaid.16 The purpose of Stark and the Anti-Kickback Statute is to prevent impermissible financial relationships from corrupting the judgment of referring physicians, which could lead to overutilization of health care services that are reimbursable under federal health care programs (e.g., Medicare). California has analogues to both of these laws.17

As a preliminary matter, whether a health care entity will be permitted to provide health care technology to health care professionals will depend on the type of technology being donated. Although many providers use the Stark and Anti-Kickback Statute EHR subsidy regulations (discussed below) to subsidize technology for health care professionals, depending on the form of technology, it may be unnecessary to structure the donation to comply with those regulations.

For example, the OIG and CMS have both opined that the provision of certain technology "interfaces" do not implicate Stark and the Anti-Kickback Statute because they are not "remuneration" to the receiving physician. In a December 2012 Advisory Opinion, the OIG approved the provision of an interface and related maintenance services by a hospital to all physicians who requested it. The interface would be used to transmit orders and the results of diagnostic and laboratory services. In its opinion, the OIG states: "Under the Proposed Arrangement, [i]nterface access would be integrally related to the [hospital's] services, such that the free access would have no independent value to the Physicians apart from the services the [hospital] provides. Accordingly, we conclude that the Proposed Arrangement would not, under these particular facts, implicate the anti-kickback statute."18

However, it is important to consider all the facts and circumstances of a particular technology interface donation when analyzing whether Stark and the Anti-Kickback Statute are implicated. In an OIG Advisory Opinion issued on March 18, 2015, OIG declined to

approve an arrangement involving an interface where a laboratory proposed to provide a limited use interface to physician practices, pursuant to an exclusive arrangement between the physician practices and the laboratory company.19 The OIG expressed concern with the exclusive nature of the arrangement (which included the provision of free services to certain patients) and the fact that the donated interface would relieve some physicians of monthly interface maintenance fees charged by EHR vendors. Thus, parties to a technology donation should carefully review the facts and circumstances of a particular technology donation to discern whether the particular exchange could involve remuneration under Stark and the Anti-Kickback Statute.

When a particular technology donation does implicate Stark and the Anti-Kickback Statute, the Stark exception and Anti-Kickback Statute safe harbor for EHR items and services offer a means to subsidize technology (the "EHR Subsidy Regulations"). These regulations were extended at the end of 2013 and will now be in effect until the end of the Medicaid EHR Incentive Program in 2021. The applicable regulations should be consulted for a complete list of the requirements, but the key elements include:

- The donor is not be a laboratory company;
- The donated EHR items and services is used predominately to create, maintain, transmit, or receive EHR;
- The EHR software is interoperable at the time it is provided to the recipient. The software will be deemed interoperable if it is certified by a certifying body authorized by the ONC;
- The donor (or any person acting on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems (including, but not limited to, health information technology, applications, products, or services);
- Before receipt of the items and services, the recipient pays at least fifteen percent (15%) of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services;
- Neither the recipient nor the recipient's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor;
- Neither the eligibility of a recipient for the items or services nor the amount or nature of the items and services is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties;
- A written agreement between the parties sets forth the costs of the items and services and other terms of the arrangement;
- The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items and services equivalent to those provided by the donor;
- For items and services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items and services for any patient;
- The items and services do not include staffing of recipient offices and are not used primarily to conduct personal business unrelated to the recipient's clinical practice or clinical operations; and
- The transfer of the EHR items and services occurs and all conditions of the EHR Subsidy Regulations are satisfied on or before December 31, 2021.20

As evidenced by CMS and OIG's decision to extend the EHR Subsidy Regulations through the end of the Medicaid EHR Incentive Program in 2021, the EHR Subsidy Regulations have proven to be an effective and popular mechanism for health care entities to subsidize the adoption of EHR systems by physicians and other health care professionals.

Conclusion

Legal issues involving health information technology will continue to arise as providers and suppliers seek to acquire and implement health information technology. Given the amount of incentive payments made to hospitals and EPs under the Medicare and Medicaid EHR Incentive Programs and the attendant financial relationships among health care entities and health care professionals, providers and suppliers are well advised to be mindful of potential legal risks when structuring their EHR-related relationships and attesting to meaningful use.

Endnotes

1 Portions of this article were originally published in Foley & Lardner LLP's health care law blog, Foley & Lardner LL P BLOG , http://www.healthcarelawtoday.com/ (last visited May 17, 2015). Back

2 *See* 42 C.F.R. § 495.102(b). The last year for an EP to begin participation in the Medicare EHR Incentive Program was 2014. Back

3 *See* 42 C.F.R. § 495.310(a)(3). The last year for an EP to begin participation in the Medicaid EHR Incentive Program is 2016. Starting in 2019, the incentive payment is incorporated into the Merit-Based Incentive Payment System. Back

4 *See, e.g.*, 42 C.F.R. § 495.104(c). Back

5 The Centers for Medicare & Medicaid Services, U.S. Dep't of Health & Human Services, *Medicare Incentive Payments* (Jan. 2015), available at http://www.cms.gov/Regulations-and- Guidance/Legislation/EHRIncentivePrograms/Downloads/January2015_MedicareEHRIncentivePayments.pdf. Back

6 The Centers for Medicare & Medicaid Services, U.S. Dep't of Health & Human Services, *Medicaid Incentive Payments* (Jan. 2015), at http://www.cms.gov/Regulations-and-Guidance/ Legislation/EHRIncentivePrograms/Downloads/January2015_ MedicaidEHRIncentivePayments.pdf. Back

7 U.S. Dep't of Health & Human Services, Report to Congress, *Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information*, 13 (Oct. 2014). Back

8 77 Fed. Reg. 53968, 53973 (Sept. 4, 2012). Back

9 *See* 80 Fed. Reg. 16732 (Mar. 30, 2015). Back

10 *See* Public Law 114-10, available at https://www.congress.gov/ bill/114th-congress/house-bill/2/text. Back

11 Office of Inspector General, U.S. Dep't of Health & Human Services, Work Plan Fiscal Year 2015, 74, (2015) *available at* http://oig.hhs.gov/reports-and-publications/archives/ workplan/2015/FY15-Work-Plan.pdf. Back

12 *See, e.g.*, Centers for Medicare & Medicaid Services, *EHR Incentive Programs Supporting Documentation for Audits* (Feb. 2013), *available at* http://www.cms.gov/Regulationsand- Guidance/Legislation/EHRIncentivePrograms/Downloads/ EHR_SupportingDocumentation_Audits.pdf. Back

13 *See* Centers for Medicare & Medicaid Services, U.S. Dep't of Health & Human Services, *Security Risk Analysis Tipsheet: Protecting Patients' Health Information* (Dec. 2013), *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/ EHRIncentivePrograms/Downloads/SecurityRiskAssessment_ FactSheet_Updated20131122.pdf. Back

14 Hospitals or EPs that do not pass a meaningful use audit are able to appeal. Information regarding the appeal process is available on the CMS website at CMS.GOV http://www.cms.gov/ Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ Appeals.html (last visited May 17, 2015). Back

15 42 U.S.C. § 1395nn. Back

16 42 U.S.C. § 1320a-7b(b). Back

17 *See, e.g.*, Cal. Bus. & Prof. Code §§ 650, 650.01. Back

18 Office of Inspector General Advisory Opinion 12-20 (Dec. 12, 2012); *see also* CMS-AO-2008-01. Although OIG Advisory Opinions provide useful insight into the OIG's views of particular arrangements, the Advisory Opinions only apply to the requester of the Advisory Opinion. Back

19 Office of Inspector General Advisory Opinion 15-04 (Mar. 18, 2015). Back

20 *See* 42 C.F.R. § 411.357(w), 42 C.F.R. § 1001.952(y). Back

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